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DEVELOPMENT, IMPLEMENTATION, AND EVALUATION OF A WEIGHT-MANAGEMENT PROGRAM BASED ON THE *2005 DIETARY GUIDELINES FOR AMERICANS*

A Dissertation in Nutrition

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ABSTRACT

Our national guidelines for diet and physical activity are the *Dietary Guidelines for Americans*; yet, their effectiveness for weight-management has not been determined. In addition, research indicates that diets consistent with the *Dietary Guidelines* improve chronic disease risk factors and are effective for weight loss; yet, few Americans follow these dietary recommendations. Therefore, the Weight Optimization: Revamping Lifestyles using the *Dietary Guidelines* (WORLD) study evaluated the effects of an intensive, theory-based, nutrition education program for weight management and guided by the *2005 Dietary Guidelines for Americans* on clinical, biochemical, and dietary outcomes. The education program, *Your Healthy World*, was based on the social cognitive theory and delivered using problem-based learning, a format untested in a long-term nutrition education program for consumers. *Your Healthy World* was tailored for the lower end (20% kcal from fat; lower-fat diet) or upper end (35% kcal from fat; moderate-fat diet) of the *Dietary Guidelines* recommended range of fat intake. Pre-menopausal, overweight/obese women (n=101; BMI: 25-39.9 kg/m^2; LDL-cholesterol: 100-189 mg/dL; aged 21-50 years) were randomized to either a lower-fat or moderate-fat diet in a parallel-arm design. The intervention consisted of 28 education sessions and twice weekly supervised aerobic exercise sessions over the course of one year.

Intention-to-treat analyses (n=101) show that after one year weight loss was similar between the lower-fat and moderate-fat treatment groups (-5.0 and -4.3 kg; P's < 0.0001 compared to baseline). Overall, total cholesterol and LDL-cholesterol concentrations decreased (-0.09 and -0.10 mmol/l, respectively; P's < 0.05) and HDL-cholesterol concentration increased (+0.05 mmol/l; P < 0.05). Since energy and nutrient

intakes, specifically total fat intake, did not differ between treatment groups participants were reclassified according to actual fat intake. If average fat intake from months 4 and 12 contributed less than 27.5% of total energy participants were classified as consuming a lower-fat diet; participants consuming a diet in which average fat intake from months 4 and 12 contributed more than 27.5% of total energy were considered moderate-fat consumers. The cutpoint of 27.5% of energy was used since it is the midpoint of the *Dietary Guidelines* recommendation for dietary fat (i.e., 20-35% of energy from fat). After reclassifying participants, total, LDL, and HDL-cholesterol concentrations were lower and triglyceride concentrations higher in participants reporting consumption of a lower-fat diet compared to participants consuming a moderate-fat diet (P's ≤ 0.05). The strongest predictors of weight loss were changes in aerobic capacity, binge-eating behaviors, baseline body weight and changes in *trans* fat intake, which together accounted for 20% of the variance in 12-month weight loss. An increase in aerobic capacity, a decrease in *trans* fat intake, and higher baseline binge-eating behaviors and body weight were associated with greater weight loss.

When evaluating the effects of the intervention on diet-related variables in participants providing data at month 12 (n=60), the Healthy Eating Index-2005 (HEI-2005), a tool to assess adherence to the *Dietary Guidelines*, was used. The HEI-2005 consists of twelve components (i.e., total fruit; whole fruit; total vegetables; dark green and orange vegetables and legumes; total grains; whole grains; milk; and meat and beans; oils; saturated fat; sodium; and calories from solid fats, alcohol, and added sugars). For most components, higher intakes result in higher scores; however, the saturated fat, sodium, and calories from solid fats, alcoholic beverages, and added sugars components, lower intake levels result in higher scores because lower intakes are more desirable. A time effect was seen for increases in total fruit, whole fruit, whole grains, meat and beans, and saturated fat component scores, as well as summary scores, of the HEI-2005 ($P < 0.01$ for all). Total HEI-2005 scores were not different between participants consuming a lower-fat diet or a moderate-fat diet (80.58 ± 1.95 and 74.69 ± 1.33, respectively; $P = 0.13$). Component scores for total vegetables, dark green and orange vegetables and legumes, and whole grains, and total HEI-2005 score increased across tertiles as energy density of the diet decreased ($P < 0.01$ for all). The strongest predictors of energy density were baseline energy density and changes in scores for the total fruit component, the oils component, and total HEI-2005, which together accounted for 56% of the variance in dietary energy density at month 12. The strongest dietary predictors of weight loss were increases in the total vegetables component score, the oils component score, *trans* fat intake, the total grains component score, and baseline body weight, which together accounted for 15% of the variance in weight loss at month 12.

Results of the WORLD study demonstrate that lower-fat and moderate-fat diets consistent with the *Dietary Guidelines* are equally effective for weight management. In particular, study participants were able to maintain weight loss during the maintenance period and did not experience the rebound in body weight often seen in other studies. In support of the *Dietary Guidelines* recommendations for physical activity, aerobic fitness was the main predictor of weight loss in this study. In addition, findings from this study indicate that women can follow the dietary recommendations of the *Dietary Guidelines* for weight loss and maintenance and improve diet quality as assessed by the HEI-2005. Results from this study support using the *Dietary Guidelines* for health promotion and chronic disease risk reduction during weight loss and maintenance of a reduced body weight.

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CHAPTER ONE

INTRODUCTION

Study Rationale

Prevalence of obesity in U.S. adults has doubled in the last three decades with approximately 66% of U.S. adults are either overweight or obese. According to the National Health and Nutrition Examination Survey (NHANES), between 1976-1980 and 2003-2004, the percentage of adults who were overweight or obese increased from 15% to 32%, illustrating the enormity of this public health problem (1). Obesity is associated with an increased risk of various diseases and conditions including cardiovascular disease, type 2 diabetes mellitus, dyslipidemia, hypertension, asthma, obstructive sleep apnea, osteoarthritis, respiratory problems, and various cancers (2). With the increasing prevalence of obesity and its effect on overall health, disease status, and longevity, the steady rise in life expectancy during the past two centuries may not continue in the near future (3). Accordingly, one specific objective of *Healthy People 2010* is to reduce obesity prevalence to prolong and improve the quality of life (4). To help achieve this objective, clinical nutrition studies should assess new interventions that provide guidance about implementing healthy lifestyle strategies.

Research consistently shows that diet and exercise are essential for maintenance of reduced body weight (5, 6) and are more effective together than diet or exercise alone (7-10). Thus, diet and physical activity are key targets of lifestyle interventions for weight reduction and current dietary recommendations are set for life-long adherence. Often, the *Dietary Guidelines for Americans*, evidence-based advice to promote health and reduce chronic disease risk through diet and physical activity (11), are the recommendations for the “standard of care” or control group in nutrition interventions.

The dietary recommendations for treatment groups in clinical trials and for popular weight-loss programs tend to be more extreme (i.e., strict limitation on certain nutrients) in comparison to individuals' usual intake (12, 13) and tend to be difficult to follow long-term (12), leading to high attrition rates (14). In addition, the intensity of the intervention in clinical trials (i.e., number of contacts, inclusion of social support, etc.) is generally greater in the intervention groups than in the control groups (15, 16). Thus, there is a need to evaluate the effectiveness of a well-designed, intensive weight-management program that emphasizes our national dietary and physical activity recommendations included in the *Dietary Guidelines*. Weight-loss and maintenance interventions based on the *Dietary Guidelines* that offer flexibility in diet design may promote long-term dietary adherence leading to decreased chronic disease risk (i.e., improving the lipid profile, decreasing waist circumference, and lowering blood pressure).

Although research indicates that diets consistent with the *Dietary Guidelines*, such as the DASH (Dietary Approaches to Stop Hypertension) diet, improve chronic disease risk factors (17, 18), few Americans follow the recommendations of the *Dietary Guidelines* (19). Since the *2005 Dietary Guidelines* are relatively new and, for many people, represent a dietary pattern that requires multiple changes from current practices, guidance is needed for implementation. One possible reason for lack of adherence to the *Dietary Guidelines* is that consumers struggle to understand the dietary recommendations and find it challenging to change their lifestyle accordingly. For example, consumer research indicates that the general public has difficulty differentiating between types of fats, how they affect health, and how to incorporate fat into a healthy diet (20, 21).

Another potential challenge for Americans may be adjusting their diets to promote weight loss while achieving nutrient adequacy.

MyPyramid was developed by the USDA to help Americans apply the *Dietary Guidelines*; it presents suggested amounts of foods to consume from the basic food groups (i.e., fruits, vegetables, grains, meat and beans, and milk) and oils to meet recommended nutrient intakes. In addition, new recommendations for food subgroups, such as types of vegetables, whole grains, and discretionary calories are included. In addition, MyPyramid requires translation in different ways for various groups, including individuals trying to lose weight. For example, the macronutrient recommendations could be challenging to implement. The recommendation for fat ranges from 20% to 35% of calories; and there are no numerical recommendations (i.e., gram amount or percent of energy) for protein and carbohydrate (11). In light of the increasing prevalence of overweight and obesity (1), the *Dietary Guidelines* suggest decreasing caloric intake and increasing physical activity for gradual weight loss. MyPyramid did not provide guidance about losing weight, regardless of an individual's body mass index, when it debuted and subsequently when this study was proposed. Although MyPyramid has been updated to provide recommendations at reduced-calorie levels for individuals classified as overweight or obese, there remains a pressing need for educational materials that provide clear strategies for successful weight loss as well as maintenance of a healthy weight through implementation of the *Dietary Guidelines.*

In general, consumers desire easy-to-follow strategies for implementing lifestyle changes and for attaining weight loss (20, 22). Thus, innovative education programs and clinical interventions which translate the recommendations of the *Dietary Guidelines* such that they are easy for the general public to incorporate into everyday life – and especially when trying to lose weight – need to be developed, tested, and evaluated. Hence, the Weight Optimization: Revamping Lifestyles using the *Dietary Guidelines* (WORLD) study was designed and the research herein conducted. The WORLD study examined the effects of a year-long, theory-based, free-living, intervention emphasizing diets consistent with the *Dietary Guidelines* and at the extremes of the dietary fat recommendation (i.e., 20% and 35% of energy from fat) during weight loss and maintenance of a healthy body weight. The WORLD study is unique from previous studies because all aspects of the rigorous weight-management intervention are guided by the *Dietary Guidelines*.

Weight-loss diets that are based on the *Dietary Guidelines* and offer flexibility in diet design may promote long-term dietary adherence and achieve desired clinical outcomes, namely improving lipid and lipoprotein concentrations. There is no question about the importance of reducing dietary saturated and *trans* fats, and dietary cholesterol to decrease total cholesterol and low-density-lipoprotein (LDL)-cholesterol concentrations (23-25). To favorably affect other lipid and lipoprotein risk factors, such as triglycerides and high-density-lipoprotein (HDL)-cholesterol, total fat needs to be manipulated. Pertinent to weight loss, is that triglyceride concentration decreases and HDL-cholesterol concentration increases in response to maintenance of a reduced body weight. As discussed herein, a lower-fat diet increases triglycerides and decreases HDL-cholesterol (during weight maintenance). In contrast a moderate-fat diet decreases triglycerides and increases HDL-cholesterol (26, 27).

In addition to the total cholesterol:HDL-cholesterol ratio, C-reactive protein (CRP), is a strong predictor of coronary heart disease risk (28). CRP concentrations are elevated in overweight/obese individuals (29); however, weight loss decreases CRP (30, 31). Studies have shown that the nutrient profile of the diet affects CRP levels. For example, a high glycemic load increases CRP (32) and α-linolenic acid decreases CRP (33). Therefore, a weight-loss diet, a diet rich in complex-carbohydrates, or a diet high in unsaturated fat would be expected to beneficially affect CRP (i.e., lower CRP).

Relative to weight loss, a lower-fat diet may elicit a greater weight loss because of reduced dietary energy density and prevent the adverse effects associated with this diet in weight-stable individuals. On the other hand, adherence may be compromised on this diet because of issues associated with palatability and significant differences in the diet composition compared to "usual" dietary practices (12, 13) thereby resulting in no or minimal weight loss, and possible adverse effects on clinical outcomes. A moderate-fat diet, at the upper end of the recommended fat range, may not be as effective in inducing weight loss because of insufficient calorie reduction, or may even result in caloric excess, which would have an adverse effect on triglyceride, HDL-cholesterol, and CRP concentrations. However, a moderate-fat diet may promote better adherence leading to greater weight loss and more favorable outcomes. Collectively the different diet options, differentiated by percent of energy from fat, for healthy weight loss is not understood by the public. The field of nutrition will make significant strides by identifying which weight-loss diet should be recommended for individuals based on adherence and clinical and biochemical outcomes. Therefore, the WORLD study aimed to assess the effects of each diet, in the context of the *Dietary Guidelines* and during weight-management, on chronic disease risk factors.

Study Aims and Hypotheses

The primary objective of the WORLD study was to conduct and evaluate a year-long, free-living, weight-management intervention using educational materials, based on the *2005 Dietary Guidelines for Americans* and at the extremes of the dietary fat recommendations (i.e., 20% and 35% of calories), in overweight and obese pre-menopausal women. In addition to assessing the effectiveness of the education program, *Your Healthy World*, for weight loss and maintenance of a healthy body weight, this study aimed to determine the impact of the intervention on anthropometric and biochemical measures, energy and nutrient intakes, and adherence to the *Dietary Guidelines* [assess by the Healthy Eating Index (HEI)-2005 (34)].

The first primary hypothesis was that a diet at the extremes of dietary fat recommendations of the *2005 Dietary Guidelines* would be equally effective for weight loss while achieving comparable nutrient adequacy. Another hypothesis was that the moderate-fat diet would have significantly greater beneficial effects on HDL-cholesterol (i.e., maintain or increase) and triglyceride (i.e., maintain or decrease) concentrations than the lower-fat diet; while the lower-fat diet would decrease LDL-cholesterol concentration significantly more than the moderate-fat diet. An additional hypothesis was that weight loss would be greater on a diet lower in energy density, regardless of treatment group (i.e., lower fat or moderate fat), when compared to a diet higher in energy density.

The second primary hypothesis was that the lower-fat and moderate-fat diets would both be nutritionally adequate, based on the HEI-2005. A further hypothesis was that HEI-2005 scores would be directly related to change in body weight.

Within this dissertation, a literature review about dietary recommendations and interventions for weight loss and chronic disease risk reduction are presented in Chapter 2. Chapter 3 details the rationale, design, and methods of the WORLD study. The effects of the WORLD study on clinical and biochemical outcomes and nutrient intakes are presented in Chapter 4. Thus, the first primary hypothesis and the hypothesis regarding lipid levels are addressed in Chapter 4. Chapter 5 summarizes the effects of the WORLD study on the component and total scores of the HEI-2005 and also the impact of the intervention on dietary energy density; therefore addressing the hypotheses regarding dietary intake. Chapter 6 summarizes all the analyses and discusses future research to be done. Chapter 7 is an epilogue and details my perspective of various components of the research project.

The dissertation work as stated in the title entails much more research than is documented in this written dissertation. Future publications will describe in greater detail the development of *Your Healthy World*, the implementation of the program, and process evaluation. This written work primarily focuses on the impact of the intervention.

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CHAPTER TWO

BACKGROUND

Overweight & Obesity – A Major Public Health Concern

According to the National Health and Nutrition Examination Survey (NHANES) 1999-2002, approximately 65% of U.S. adults over the age of 20 are either overweight or obese (1). The magnitude of this major public health problem is illustrated by the marked increase in the prevalence of obesity (i.e., body mass index ≥ 30.0 kg/m^2) in adults; doubling from 15% to 31% between NHANES 1976-1980 and NHANES 2003-2004 (2). Obesity is associated with an increased risk of various diseases/conditions including cardiovascular disease (CVD), type 2 diabetes mellitus, dyslipidemia [elevated total cholesterol, low-density-lipoprotein (LDL)-cholesterol, and triglyceride concentrations and/or decreased high-density-lipoprotein (HDL)-cholesterol concentration], hypertension, asthma, obstructive sleep apnea, osteoarthritis, respiratory problems, and various cancers (i.e., endometrial, breast, and colon) (3). With the increasing prevalence of obesity and the effect of obesity on overall health, disease status, and longevity, an analysis by Olshansky et al. (4) concludes that the steady rise in life expectancy during the past two centuries may not continue in the near future. Accordingly, a specific objective of *Healthy People 2010* is to reduce the prevalence of obesity among adults to less than 15% to prolong and improve the quality of life (5). In order to do this on a population basis, efforts are needed from government agencies at the federal, state, and local levels; the food and restaurant industries; health professionals; and the scientific community.

Initiatives for Preventing and Treating Obesity

With the growing epidemic of obesity, numerous government agencies and health organizations have announced various initiatives and launched programs to provide information to consumers and health professionals for the prevention and treatment of overweight and obesity. Some key federal programs are the Obesity Education Initiative (OEI), Weight-control Information Network (WIN), and HealthierUS. OEI, one of the original government programs was launched by the National Heart, Lung, and Blood Institute of the National Institutes of Health in January 1991 . The overall purpose of the initiative is to reduce the prevalence of overweight and obesity, along with physical inactivity, in order to lower the risk and overall mortality from coronary heart disease (CHD). Another program started in the 1990s was the WIN of the National Institute of Diabetes and Digestive and Kidney Disorders and National Institutes of Health. WIN provides current science-based information on weight control, obesity, physical activity, and related nutritional issues to the general public, health professionals, the media, and Congress (6). A popular initiative of WIN is "Active at any Size" which suggests ways to be active regardless of body weight and emphasizes the health benefits of being physically active. In 2002, the HealthierUS Initiative was issued by the Executive Office of the President and the Department of Health and Human Services to help Americans take steps to improve personal health and fitness by being active every day, eating a nutritious diet, getting preventive screenings, and making healthy lifestyle choices (7). The HealthierUS Initiative was one driving force behind the development of the *2005 Dietary Guidelines for Americans*.

Multiple initiatives specifically targeting children in an effort to reduce the prevalence of overweight and obesity and to promote life-long healthy habits have emerged over the years in an effort to instill the principles of the *Dietary Guidelines for Americans* at a young age. Team Nutrition is an initiative of the United States Department of Agriculture (USDA)'s Food and Nutrition Service (FNS) based on the *Dietary Guidelines for Americans* and the Food Guide Pyramid, the previous USDA-developed education tool for conveying the dietary recommendations in the *Dietary Guidelines* to the public. Team Nutrition supports the Child Nutrition Programs and aims to improve children's lifelong eating and physical activity habits (8). More recently the FNS launched the *"Loving Your Family, Feeding Their Future: Nutrition Education through the Food Stamp Program,"* one of the first comprehensive initiatives based on the *2005 Dietary Guidelines for Americans* and MyPyramid, which aims to help low-income families make healthy food choices and increase their physical activity (9). In addition to initiatives by government agencies, the Clinton Foundation and the American Heart Association started the Creating a Healthier Generation initiative to help children establish healthy eating and exercise habits that will last a lifetime with the long term goal of reducing the public health threat of obesity (10). Also, Shaping America's Youth is an initiative supported by many health organizations, such as the American Diabetes Association and the American Academy of Pediatrics, to consolidate information and efforts to reverse the rapidly increasing prevalence of overweight and inactivity among children and adolescents.

In addition to national initiatives, many states have made great strides in developing and implementing population-wide programs for the prevention and control of obesity . Michigan's Building Healthy Communities Project was designed to improve the built environment; such that residents can incorporate healthy activities more readily into their daily lives. Some accomplishments of this project include enhanced parks and trails, provision of community fitness classes, and construction of school and community gardens. Another success story at the state-level is the Farm-to-Work program in Texas which enables employees to purchase fresh local produce delivered directly to their work sites on a weekly basis. Lastly, the Californian Convergence Partnership is an initiative modeled after the National Convergence Partnership which links existing programs in effort to share information, tools, and resources to build healthy environments where people can thrive . In addition to many initiatives at the national and state level, many cities are starting their own campaigns for improving the health of their residents. One example is Building a Healthier Chicago which aims to make a significant impact on the health of Chicagoans through: 1) increasing physical activity levels, 2) improving healthy eating, and 3) the prevention, detection and control of high blood pressure . According to Katan, a total-environment approach that involves entire neighborhoods and communities, which many of these initiatives do, may be the only effective way to prevent and treat obesity, outside of gastric bypass surgery .

Weight Control Efforts by Americans

Many Americans are trying to lose weight (11). Unfortunately, the poor success rate (12) has caused many individuals to resort to "fad diets" that offer the promise of rapid and easy weight loss. The growth in sales of weight-loss books and products is indicative of Americans' desire to lose weight and parallels the increasing prevalence in obesity. For example, the number of weight-loss books listed on Amazon.com in 2001, 2003, 2005, 2007, and 2009 were 1214; 1802; 2399; 39,163; and 74,346 respectively. In addition, the number of "hits" in a Google search for weight-loss books for 2003, 2005, 2007, and 2009 were 1.3 million, 8.0 million, 15.5, and 43.3 million, respectively. Although the increase in the number of "hits" is partially due to the increase of online use over the past decade, it remains apparent that numerous Americans want to achieve a healthy body weight and are looking for resources to help them do this. One potential challenge for many Americans may be that they lack the knowledge needed to effectively implement a weight-loss program and/or the ability to apply the knowledge such that they permanently maintain weight loss through healthy lifestyle changes.

Diets for Weight-Management and Chronic Disease Risk Reduction

The Macronutrient Evidence

In recent years, great interest in the macronutrient profile of weight-loss diets has led to extensive research with the primary aim of determining what health benefits are observed if the diet profile is "shaped" in different ways (i.e., low-fat, high-protein, low-carbohydrate, or moderate-fat diets). While it is clear that weight loss is due to a reduced-calorie intake relative to energy expenditure, there remains an ongoing scientific debate about what the optimal macronutrient profile is for weight loss and reduction in chronic disease risk. Data from the National Weight Control Registry during the 1990s indicate that a lower-fat, high-carbohydrate diet was preferable for participants sustaining substantial weight loss, along with physical activity, and self monitoring/stimulus control strategies (13). In contrast, a more recent analysis determined that participants of the National Weight Control Registry are following a moderate-fat diet for weight loss and maintenance while continuing the same lifestyle strategies (14). Moreover, there is some evidence that a high-protein, low-carbohydrate weight-loss diet is more efficacious than a standard low-fat, high-carbohydrate weight-loss diet (20-25). Beyond weight loss, determining the effects of these diets on chronic disease risk factors, such as blood lipids and lipoproteins, C-reactive protein (CRP), and fasting glucose and insulin, is essential so that appropriate dietary recommendations can be made. Another important consideration is whether or not a certain diet can be followed long-term. For example, data from the Women's Health Initiative demonstrates that it is difficult to attain and sustain a low-fat diet (15). Thus, ability to adhere to a diet long-term needs to be taken into account when making recommendations for weight loss and reduction in chronic disease.

Currently there are no set definitions for low-fat, moderate-fat, moderate-to-high protein, or low-carbohydrate diets. The Acceptable Macronutrient Distribution Range (AMDR; the range of intake in a nutritionally adequate diet for a particular macronutrient that is associated with reduced risk of chronic disease) for total dietary fat is 20-35% of energy for adults (16). Low-fat diets, which are generally defined as diets for which fat contributes less than 20-30% of calories, are below or at the lower limit of the AMDR. Moderate-fat diets typically are defined as diets for which 30-40% of energy is provided by fat; therefore being at or above the upper end of the AMDR for total dietary fat. Data from NHANES 2005-2006 indicates that U.S. adults consume diets moderate in fat with approximately 34% of energy coming from fat . A wide range of classification for moderate-to-high protein diets and carbohydrate-restricted diets exists. There is no

AMDR for protein; however, the current recommended dietary allowance (RDA; i.e., an intake level set to meet nutrient requirements) for protein for adult males and females are 56 g/d and 46 g/d, respectively (16). For an adult consuming a 2000-calorie diet and meeting the RDA, protein would account for approximately 10% of calories. Consequently, many studies assessing the impact of moderate- or high-protein intakes on weight and chronic disease risk factors test diets which are often 2-3 times the current RDA for protein. Thus, the percent of energy provided by carbohydrates is variable in these research diets and often below the current AMDR for carbohydrate (45-65% of energy for adults) (16). To put these recommendations and treatment diets into context, the percent of energy from carbohydrate and protein in the diets of U.S. adults is approximately 48% and 16%, respectively . Below is a short review of the literature on dietary interventions in which the macronutrient profile is altered and weight-loss and chronic disease risk are assessed.

Health effects of lower-fat diets

Lower-fat diets tend to be inherently hypo-caloric when compared to the typical American diet; therefore, low-fat diets can be effective when trying to lose weight. The Pritikin Program is a lifestyle intervention program that is based on a low-fat (< 10% total calories) diet which also is a high-complex-carbohydrate, high-fiber (35-40g/1000 calories), and low-cholesterol (< 25 mg/d) diet. After 26 days following the Pritikin Program, the combination of diet and exercise, reduced weight by 5% . Another study (30) yielded similar results when assessing the short-term effects of a low-fat, reduced-calorie diet on weight loss and lipids. After 10 weeks, mean body weight declined by

0.62 ± 0.47 kg/wk during the first 5 weeks and 0.43 ± 0.43 kg/wk during the second 5 weeks for a total approximate weight loss of 7%. Low-fat diets, as part of a weight-loss program, can be equally effective long-term. For example, after one year on the Lifestyle Heart Program (10% calories from fat, vegetarian diet, aerobic exercise, stress management, smoking cessation, and group psychological support), participants lost 10.9 kg (12% of initial body weight) and sustained a loss of 5.8 kg (6% of initial body weight) at 5 years (31). After one year, weight loss in the experimental group was associated with significant decreases in total cholesterol and LDL-cholesterol concentrations; while weight loss at five years was associated with significantly less cardiac events in comparison to the control group. Although low-fat, high-carbohydrate diets can achieve desired weight loss and beneficially affect some risk factors of chronic disease [i.e., decrease total cholesterol, LDL-cholesterol, glucose, and insulin concentrations (29-32)], they may also exacerbate other risk factors of chronic disease [i.e., increase triglyceride concentration and decrease HDL-cholesterol concentration (29, 30, 33)]. However, replacing simple carbohydrates with complex carbohydrates and increasing dietary fiber when following a high-carbohydrate, low-fat diet to elicit weight loss can blunt the hypertriglyceridemic response (34, 35) and possibly even decrease triglyceride concentrations (17).

Health effects of moderate-fat diets

Over the years, several studies have shown that moderate-fat, reduced-calorie diets can result in weight loss (36-39) and improve diet adherence (25, 36, 39) and weight maintenance (36, 38) while improving chronic disease risk factors (i.e., LDL-cholesterol, triglycerides, HDL-cholesterol, and insulin concentrations) (25, 32, 37-40). When comparing low-fat, high-carbohydrate weight-loss diets with moderate-fat, weight-loss diets, rich in monounsaturated fats, in controlled clinical settings, Colette et al. (37) and Pelkman et al. (18) reported that similar weight loss can be achieved on both diets. However, both studies showed greater beneficial effects on the lipid profile [i.e., LDL-cholesterol (37), triglycerides (37, 38), and HDL-cholesterol concentrations (18)] when following the moderate-fat diet. Yet another more recent study comparing a moderate-fat diet (35-45% of calories from fat) and low-fat diet (20-30% of calories from fat) showed that both diets were not only equally effective for weight loss but also for improving chronic disease risk (i.e., reduced postprandial glycemia and insulinemia and lowered fasting insulin) after 6 months . Conversely, one randomized, prospective study indicates that a moderate-fat diet results in significantly more weight loss and greater improvements to chronic disease risk factors (i.e., decreased total cholesterol, LDL-cholesterol, and triglycerides concentrations and systolic blood pressure) . In contrast, Gerhard et al. found that a low-fat *ad libitum* diet (20% calories from total fat, 3.9% calories from SFA) similarly affected chronic disease risk factors when compared to a moderate-fat *ad libitum* diet (40% calories from total fat, 6.3% from SFA, 26% from MUFA), and only the low-fat diet significantly decreased weight (1.53 kg, $P < 0.001$). In general, most studies suggest that moderate-fat, weight-loss diets may be more beneficial for reducing chronic disease risk; however, weight-loss appears to be comparable to that achieved when following low-fat weight-loss diets.

Health effects of moderate-to-high-protein and carbohydrate-restricted diets

While some recent studies show some beneficial effects of energy-restricted, moderate-to-high-protein and carbohydrate-restricted diets on both weight loss and chronic disease risk factors (20-22, 25, 40, 42-45) others do not (22, 24). In a recent study, researchers reported that a 6-month very-low-carbohydrate-diet program, similar to the Atkins' Diet (carbohydrate intake <25 g/d), led to a sustained weight loss (10.3%, $P < 0.02$) with improvements in CVD risk factors (i.e., total cholesterol decreased by 5%, LDL-cholesterol by 7% and triglyceride concentration by 43% and HDL-cholesterol increased by 19%, all P's < 0.02) . In another short-term study, Layman et al. (20, 21) found that decreasing the proportion of carbohydrate to protein in the diet [CHO/PRO ratio of 0.4 (125 g protein/d)] had similar effects on weight loss but had a greater beneficial effect on body composition and blood lipids than a diet with a higher carbohydrate to protein ratio [CHO/PRO ratio of 3.5 (68 g protein/d)] at the end of 10 weeks. In a multi-center study, Foster et al. found that 12 weeks of weight-loss therapy utilizing the Atkins' diet resulted in a greater weight loss (4%) in 63 non-diabetic subjects when compared to a conventional weight-loss diet. Brinkworth et al. (24) and Skov et al. (19) and have both shown that high-protein diets (25-30% of calories) are more beneficial for weight loss when compared to diets with a protein content typical of the average American (12-15% of calories) and are associated with improvement in other chronic disease risk factors (i.e., blood lipids, insulin, and body composition). Although these results indicate that higher-protein diets are preferable to diets lower in protein content, the studies were relatively short-term – 3 and 6 months, respectively. Thus, the feasibility and benefit of following a higher-protein diet long-term has yet to be determined.

Lower-fat, moderate-fat, and high-protein diets may be equally effective, at least in the short term, in promoting weight loss due to a reduced-calorie intake (32, 46, 47). The *2005 Dietary Guidelines* recommendation for total fat (20-35% of total energy) allows flexibility in diet planning; however, the important question remains about which diet should be recommended for weight loss, maintenance of a healthy body weight, and the "best" health benefits as assessed by risk factors for chronic disease. Selecting the ideal weight-loss diet for an individual depends, in large part, on their ability to follow a particular diet. Moreover, it is important to determine *a priori* which macronutrient profile is most appropriate for weight loss for different individuals.

Energy Density of the Diet

While the macronutrient profile of a diet can impact risk factors for chronic disease, the energy density of a diet is influential on weight status. Energy density is the energy (calories) in a given weight (g) of food. When consuming a diet lower in energy density, a greater weight of food can be consumed for the same amount of energy than if the diet is higher in energy density. Since numerous research studies indicate that people consume a fairly constant weight of food (48-58), as opposed to calories, manipulating the energy density of the diet can be an effective weight management strategy (20). Observational studies suggest that lower energy density diets are associated with lower body weights (60-62) and suggest that energy density may predict body weight independent of energy intake (61). In weight-loss intervention trials, decreasing dietary energy density promotes greater weight loss (63-65). Accordingly, one strategy for weight reduction recommended in the *2005 Dietary Guidelines* is consuming foods low in energy density in order to decrease energy intake (21).

Low-fat diets tend to be inherently low in energy density (22); however, higher-fat diets (> 30% kcal from fat) rich in fruits and vegetables (> 9 servings/day) are less energy dense than lower-fat diets (≤ 30% kcal from fat) low in fruits and vegetables (<5 servings/day) (23). Thus, individuals in a nationally representative sample meeting recommendations for fruits and vegetables had diets lower in energy density than those not meeting the recommendations and the lowest prevalence of obesity, regardless of dietary fat content (23). Assessing the energy density of a weight management diet, along with the macronutrient profile of the diet, is important. Since diets lower in energy density are associated with higher diet quality than energy-dense diets (24), it is necessary to determine if a diet higher in fat yet consistent with the *Dietary Guidelines* can be followed during weight loss and weight maintenance and be nutritionally adequate.

USDA Dietary Recommendations for Americans

The *2005 Dietary Guidelines for Americans* provide science-based advice for health promotion and chronic disease risk reduction through diet and physical activity (21). Eating patterns for a range of calorie levels have been issued that translate the latest *Dietary Guidelines* into healthy eating patterns. The recommendations are food group based and adapted for twelve calorie levels (i.e., 1000 to 3200, increasing by 200-kcal increments) with a discretionary calorie allowance incorporated into them. In brief, the focus of the *2005 Dietary Guidelines for Americans* is to encourage most Americans to choose a nutritious diet, maintain a healthy weight, and achieve adequate physical activity (21). Since the *2005 Dietary Guidelines* and MyPyramid are relatively new and, for many people, represent a dietary pattern that requires multiple changes , guidance is needed for implementation. MyPyramid was developed by the USDA to teach implementation of the *2005 Dietary Guidelines*. Many changes were made to the Food Guide Pyramid, the previous USDA-developed education tool for conveying the dietary recommendations in the *Dietary Guidelines* to the public. MyPyramid presents suggested amounts of foods to consume from the basic food groups (i.e., fruits, vegetables, grains, lean meat and beans, and milk) and oils to meet recommended nutrient intakes. In addition, new recommendations have been made for specific food subgroups, such as types of vegetables and grains, and discretionary calories. There is a noticeable level of complexity associated with MyPyramid that requires translation in different ways for various groups, including individuals who are decreasing calories to reduce weight. For example, the recommendation for macronutrients could be challenging to implement. To illustrate this point, the recommendation for total fat ranges from 20% to 35% of calories; and although there are no numerical recommendations for protein and carbohydrate (i.e., gram amount or percent of energy), the guidance specified is to choose lean protein sources and fiber-rich foods (21). Regarding fat intake, consumer research indicates that the general public struggles to understand the different kinds of fats, how they affect health, and how to incorporate fat into the diet (25, 26). Therefore, the wide range of the fat recommendation and the lack of numerical recommendations for protein and carbohydrate may be confusing for the general public to implement. Additionally, MyPyramid did not provide guidance about losing weight when it debuted and subsequently when this study was first proposed. The previous guidance provided recommendations at calorie levels for weight maintenance, regardless of an individual's body mass index (BMI). Although MyPyramid has since been updated to provide recommendations at reduced-calorie levels for individuals classified as overweight and obese, there remains a pressing need for an educational program that teaches weight loss and maintenance of a healthy weight through implementation of the *2005 Dietary Guidelines.* Also, determining ways to teach dietary recommendations for weight management that can be individualized based on an individual's health profile and food preferences is important.

To assess compliance to the *2005 Dietary Guidelines*, the Healthy Eating Index (HEI)-2005 was adapted . The HEI-2005 is also used to monitor the nation's diet. The HEI-2005 assesses food and nutrient intakes on a density basis (i.e., amounts per 1000 calories of intake); therefore it determines diet quality while controlling for diet quantity. Twelve components comprise the HEI-2005; five which represent the major food groups in MyPyramid (i.e., total fruit; total vegetables; total grains; milk; and meat and beans) and seven additional components (i.e., whole fruit; dark green and orange vegetables and legumes; whole grains; oils; saturated fat; sodium; and calories from solid fats, alcoholic beverages, and added sugars). Each one is scored from 0 to 5 (i.e., total fruit; whole fruit; total vegetables; dark green and orange vegetables and legumes; total grains; whole grains), 10 (i.e, milk; meat and beans; oils; saturated fat; sodium), or 20 (i.e., calories from solid fats, alcoholic beverages, and added sugars) with a maximum total score of 100 . For most components, higher intakes result in higher scores; however, for the saturated fat, sodium, and calories from solid fats, alcoholic beverages, and added sugars components, lower intake levels result in higher scores because lower intakes are more desirable. For each component, intakes meeting or exceeding the standard are assigned the maximum score for a component; thus, higher scores indicate greater adherence to the dietary recommendations of the *Dietary Guidelines*.

The summary HEI-2005 score for diets meeting the recommendations of the *Dietary Guidelines* and MyPyramid, such as the DASH diet and the American Heart Association's No-Fad diet, are between 98 and 100 . In comparison, studies indicate that Americans are consuming diets with relatively low HEI-2005 scores (67, 70-72). An analysis of the USDA Continuing Survey of Food Intakes by Individuals in 1994-96 and NHANES 2000-2002 shows that American diets score 58 for the summary HEI-2005 score . Data from the Multi-Ethnic Study of Atherosclerosis (MESA), a longitudinal population-based study, indicates that American adults, regardless of ethnicity (white, black, Hispanic, or Chinese) have relatively low HEI-2005 scores, ranging from 54-57 (71). Also, HEI-2005 is inversely related to BMI and waist circumference across ethnicities. Collectively, these data suggest that Americans need to consume more fruits, vegetables, whole grains, and fat-free or low-fat milk and milk products – all "food groups to encourage" according to the *Dietary Guidelines for Americans 2005,* and that doing so would likely improve measures of weight status (67, 71, 72).

Lifestyle Modifications for Weight-Management

Results of Research Studies Targeting Lifestyle Changes

The current recommendations for weight loss, weight maintenance, and chronic disease risk reduction emphasize lifestyle changes that incorporate diet, exercise, and other behavioral changes, such as smoking cessation and stress management. Many health benefits are associated with weight loss achieved through lifestyle modifications. A meta-analysis of 70 studies indicates that weight reduction alone significantly decreases total cholesterol, LDL-cholesterol, VLDL-cholesterol, and triglyceride concentrations ($P \leq 0.001$). Furthermore, for every 1-kg decrease in body weight, a 0.009-mmol/L (0.35 mg/dl) increase ($P \leq 0.01$) in HDL-cholesterol concentration occurs for individuals at a stabilized, reduced weight (27). In clinical trials assessing the combined effectiveness of diet and exercise on chronic disease risk, lifestyle modification not only significantly decreased the blood lipid levels of total cholesterol (74-78), LDL-cholesterol (74-78), and triglycerides (76-79) but it also decreased body weight (74-78), body fat percentage (74, 77-79), and CRP (28). In addition, HDL-cholesterol concentration (74, 77, 79) and various fitness measures (74-79) improved when altering the diet and increasing exercise.

The Diabetes Prevention Program (DPP) and Look AHEAD (Action for Health in Diabetes) trial are two examples of lifestyle interventions with impressive results in terms weight loss and chronic disease risk factors. The DPP was a multi-center, randomized, parallel-arm, free-living study designed to compare the efficacy and safety of three interventions – an intensive lifestyle intervention, metformin therapy (850 mg twice daily) combined with standard lifestyle recommendations, and standard lifestyle recommendations combined with placebo (29). The goals for participants randomized to the intensive lifestyle intervention group were: 1) to achieve and maintain a weight reduction of ≥ 7% of initial body weight by following a low-fat, low-calorie diet (< 25% kcal from fat) and engaging in physical activity and 2) to achieve and maintain ≥ 150 minutes/week of moderate-intensity activity equivalent to ~700 kcal/week (29). The intensive lifestyle intervention group had one-one counseling about diet, exercise, and behavior modification during the first 6 months of the study followed by individual and group sessions reinforcing the behavior change. The standard lifestyle recommendations provided to the other treatment groups included an annual 20-30 minute visit and print materials encouraging a diet consistent with the Food Guide Pyramid and the National Cholesterol Education Program's Step 1 diet, increasing physical activity, and decreasing weight (30). After an average follow-up of 2.8 years, the incidence of diabetes was 58% lower (95% CI: 48% to 66%) in the lifestyle intervention group and 31% lower (95% CI: 17% to 43%) in the metformin group than in the placebo group. The incidence of diabetes was 39% lower (95% CI: 24% to 51%) in the lifestyle intervention group than in the metformin group. The main predictor of the decreased incidence of diabetes in the lifestyle intervention group was attributed to the 7.2% weight loss (82). Although both metformin therapy and lifestyle modifications reduced incidence of diabetes and the development of metabolic syndrome in individuals at high-risk, the lifestyle intervention program was more effective (81, 83).

A more recent study, the Look AHEAD trial, is an ongoing multi-center, randomized, parallel-arm, free-living study with the primary aim of assessing the long-term (up to 11.5 years) effects of an intensive weight-loss program delivered over four years in overweight and obese individuals with type 2 diabetes (31). The trial was designed to compare the effects of two interventions – an intensive lifestyle intervention for achieving and maintaining weight loss and a control condition of diabetes support and education on the combined incidence of cardiovascular events. The goal for participants randomized to the intensive lifestyle intervention group is to achieve and maintain a weight reduction of ≥ 7% of initial body weight through diet modification and increased physical activity. Participants are instructed to follow a moderate-fat, low-calorie diet (≤ 30% kcal from fat, < 10% kcal from saturated fat; 1200-1500 kcal/day for those who weight < 250 lbs, 1500-1800 kcal/day for those > 250 lbs). The physical activity program recommends starting at 50 minutes/week of moderate activity and increasing to 175 minutes/week by the end of the first 6 months. During the first 6 months, participants in the lifestyle intervention group attended 3 group sessions and one individual counseling session per month. During the next six months, participants were provided one individual and two group sessions per month. Participants in the diabetes support and education group were provided three group sessions on diet, exercise, and social support session during the first year of the study (31). After one year, the mean weight loss was 8.6% and 0.7% in participants in the intensive lifestyle and diabetes support groups, respectively ($P < 0.001$) (85). Additionally, improvements in fitness (+20.9 vs. +5.8%), SBP (-5.3% vs. -2.2%), DBP (-4.3% vs. -2.6%), triglycerides (-16.6% vs. -8.1%), and HDL-cholesterol concentration (+7.8% vs. +3.2%) were significantly greater in the intensive lifestyle group compared to the diabetes support group, respectively (P’s < 0.001). While the initial findings of this trial are impressive, several additional years are needed to determine if the initial weight loss can be maintained, whether weight loss will favorably affect chronic disease risk factors long-term, and whether the impact on risk factors will lead to a reduction in CVD events in the lifestyle intervention group compared with the diabetes support group (85).

As with the DPP, the Look AHEAD trial demonstrates that intensive lifestyle interventions successfully promote weight loss and reduce chronic disease risk. Both trials, which included interventions beyond diet and exercise, resulted in at least 5 kg of weight loss long term which is beyond what is expected by dietary/lifestyle interventions (32). These studies demonstrate that the most beneficial interventions for weight loss, weight maintenance, and chronic disease risk reduction include diet, physical activity, *and* additional behavior modifications, such as goal setting, self-monitoring, and social support (87).

Commercial Weight-loss Programs

Outside of the research setting, numerous commercial weight-loss programs are available to the general public through weight-loss centers and internet sources. Although these programs often incorporate behaviors important for weight loss, such as self-monitoring and social support, the attrition rate for them is often high. For example, data from Weight Watchers indicate that 50% of participants drop out in six weeks and 70% in 12 weeks (33). However, in a recent review of major commercial weight-loss programs in the United States, Tsai and Wadden (34) found that Weight Watchers is the most effective, although minimally, in comparison to other commercially available programs, such as eDiets.com, Health Management Resources, Take Off Pounds

Sensibly, and OPTIFAST. In a randomized trial, Dansinger et al. (35) compared four popular diets (i.e. Atkins', the Zone, Weight Watchers, and Ornish) and determined that self-reported dietary adherence ($r = 0.6$, $P < 0.001$), but not diet type ($r = 0.07$, $P = 0.4$), was associated with weight loss. After one year, the attrition rates were approximately 50% for Atkins' and Ornish, the more extreme diets, and 35% for the Zone and Weight Watchers, which take a more moderate approach to decreasing caloric intake.

Theoretical Frameworks to Explain Behavior Change

In addition to determining the best dietary recommendations to include in weight-management interventions and commercial weight-loss programs, ways to get individuals motivated to make healthy lifestyle changes need to be determined. Often many behaviors need to change in order to lose weight and improve overall health. There are many theories to explain behavior change at various levels – individual, interpersonal, and community. Research indicates that theory-based interventions are more effective than non-theory-based interventions (36); thus theories that explain behavior change should be considered when designing lifestyle-modification programs.

The Transtheoretical Model (TTM) developed by Prochaska and DiClemente is one theory which explains behavior at the individual level (37). This framework suggests that behavior change is a process and that a person moves through different stages (i.e., precontemplation, contemplation, preparation, action, and maintenance) while altering a behavior. TTM has been used in various interventions targeting factors that affect health, such as physical activity, sun exposure, smoking, and dietary fat consumption . The

Social Cognitive Theory (SCT) is a theory that accounts for the impact one's environment and relationships can have on behavior, in addition to personal factors, and thus is a model to explicate interpersonal influence on behavior change (38). SCT is one the most frequently used and robust theories regarding health behaviors and has been successful when guiding dietary interventions to increase fruit and vegetable consumption. Community-level models help explain how social systems function. For example, the Diffusion of Innovations theory addresses how ideas, products, and social practices that are perceived as "new" spread throughout different cultures, such as no-smoking sections in public places (39).

When developing weight-loss interventions, incorporating a theoretical framework should be considered. Theories may help to create more effective programs; identify factors influencing the target audience and their behaviors; and guide evaluation of lifestyle interventions. Additionally, using theory as a foundation for intervention development is consistent with the current emphasis on using evidence-based practices to guide overall health care, and specifically dietary counseling. Although more research is needed to determine the impact of theoretical frameworks on weight management interventions, incorporating promising concepts from different models might be prudent at this time .

Problem-Based Learning

In addition to theoretical frameworks for nutrition interventions, another component to consider is the dissemination of health information. Although most interventions utilize individual counseling, group education sessions, or a combination of the two, the internet and telephone are also used for contacting study participants and sharing information (80, 84). One approach that has been successful for distributing information while increasing knowledge is problem-based learning (PBL). In PBL, learners are self-directed and determine the steps for solving a problem as a group while educators serve as facilitators of learning . PBL, as a delivery method for health information, may enhance interventions targeting lifestyle modification since they may increase motivation, retention of information, and critical thinking skills while offering social support – an important component for behavior change (87, 99-101)

PBL has been implemented as part of medical school education for over twenty years but only recently has it become an approach for disseminating nutrition information and increasing nutrition knowledge. Bayard et al demonstrated that PBL was an effective way to assimilate nutrition education into preclinical medical curriculum . More recently, Lohse et al showed that PBL increased critical thinking skills of dietetics students in a undergraduate nutrition course . Additionally, PBL was a successful approach for conveying nutrition information to consumers short-term (i.e., during two education sessions) . In addition to being a useful way to disseminate nutrition information and increase nutrition knowledge, PBL is an educational method that encourages social interaction and support – two behaviors that improve weight loss success (101, 106).

Summary

Overall, interventions consistently show that diet and exercise together are important for maintenance of a reduced body weight (107, 108) and that both are more effective than either diet or exercise alone (109-112). Since current weight-loss programs and popular diets are relatively difficult to follow and have high attrition rates, there is a need to develop programs that are easy-to-follow, and that effectively teach ways to incorporate the *Dietary Guidelines* into every day life. Beyond the recommendations set forth for diet and physical activity in the *Dietary Guidelines*, there is a need to develop a program that teaches weight loss, as well as maintenance of weight loss, through dietary changes that assure nutrient adequacy and incorporate multiple lifestyle changes. Thus, individuals should be taught the requisite skills for adhering to a healthy lifestyle program that can be maintained long-term for overall chronic disease risk reduction.

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CHAPTER THREE

Weight Optimization: Revamping Lifestyles Using the *Dietary Guidelines* (WORLD) Study – Rationale, Design, and Methods

Abstract

The Weight Optimization: Revamping Lifestyles using the *Dietary Guidelines* (WORLD) Study is a randomized clinical trial evaluating the effects of an intensive, theory-based education program for weight management guided by the *2005 Dietary Guidelines for Americans*. The education program, *Your Healthy World*, is based on the social cognitive theory and delivered using problem-based learning, a format untested in a long-term nutrition education program for consumers. *Your Healthy World* is tailored for the lower end (20% kcal from fat; lower-fat diet) or upper end (35% kcal from fat; moderate-fat diet) of the *2005 Dietary Guidelines* recommended range of fat intake. The WORLD study is a year-long, free-living weight management intervention in pre-menopausal, overweight/obese women (n=101; BMI: 25-39.9 kg/m^2; LDL-cholesterol: 100-189 mg/dL; aged 21-50 years). The primary goals are to promote weight loss, through dietary changes and increased physical activity followed by weight maintenance and to evaluate lower-fat and moderate-fat diets. Effectiveness of the intervention will be assessed by clinical measures (BMI, waist circumference, blood pressure, body composition, and fitness), biomarkers (lipids and lipoproteins, glucose, insulin, and C-reactive protein), dietary intake, diet satisfaction, appetite, and cognitive-behavioral parameters (eating behavior, eating competence, and quality of life).

Introduction

Approximately 66% of U.S. adults are overweight or obese and the magnitude of this major public health problem is illustrated by obesity prevalence in adults doubling (i.e., from 15% to 32%) between NHANES 1976-1980 and NHANES 2003-2004 (1). With the increasing prevalence of obesity and its effect on overall health, disease status, and longevity, the steady rise in life expectancy during the past two centuries may cease in the near future (2). Accordingly, one objective of *Healthy People 2010* is to reduce obesity prevalence to prolong and improve the quality of life (3). To achieve this objective, innovative education programs about healthy lifestyle strategies are needed.

The *2005 Dietary Guidelines for Americans* provide evidence-based advice to promote health and reduce chronic disease risk through diet and physical activity (4). Since the *Dietary Guidelines* are relatively new and, for many people, represent a dietary pattern that requires multiple changes from current practices, guidance is needed for implementation. MyPyramid.gov was developed to help implement the *Dietary Guidelines*; it presents suggested amounts of foods to consume from the basic food groups (i.e., fruits, vegetables, grains, lean meat and beans, and milk) and oils to meet recommended nutrient intakes. In addition, new recommendations for food subgroups, such as types of vegetables, are included. The Pyramid requires translation in different ways for various groups, including individuals trying to lose weight. For example, the macronutrient recommendations could be challenging to implement. The recommendation for fat ranges from 20% to 35% of calories; and there are no numerical recommendations (i.e., gram amount or percent of energy) for protein and carbohydrate

(4). Regarding dietary fat, consumer research indicates that the general public struggles to understand different types of fats, how they affect health, and how to incorporate fat into a healthy diet (5, 6). The Pyramid did not provide guidance about losing weight, regardless of an individual's body mass index (BMI), when it debuted and subsequently when this study was proposed. Although MyPyramid.gov has been updated to provide recommendations at reduced-calorie levels for individuals classified as overweight/obese, there remains a pressing need for an educational program that provides clear strategies for successful weight loss as well as maintenance of a healthy weight through implementation of the *Dietary Guidelines.*

Research consistently shows that diet and exercise are important for maintenance of a reduced body weight (7, 8) and are more effective together than diet or exercise alone (9-12). Current weight-loss programs and popular diets are relatively difficult to follow and have high attrition rates (13), warranting new easy-to-follow programs that assure nutrient adequacy while integrating multiple lifestyle changes. Weight-management interventions based on the *Dietary Guidelines* that offer flexible diets may promote long-term adherence and desired health outcomes. Therefore, the primary objective of the WORLD (Weight Optimization: Revamping Lifestyles using the *Dietary Guidelines*) study is to conduct a theory-based, free-living, weight-management intervention using educational materials tailored for the extremes of the *Dietary Guidelines* recommendation for dietary fat. The purpose of this paper is to describe the rationale, design, and methods of the WORLD study.

Methods

Study Design

The WORLD study is a year-long randomized controlled trial in free-living overweight/obese pre-menopausal women. Participants were randomly assigned to follow either a lower-fat diet (LF, 20% kcal from fat) or a moderate-fat diet (MF, 35% kcal from fat) for weight management in a parallel-arm design. The two phases of the study are a weight-loss phase (phase 1) and a weight-maintenance phase (phase 2) (Figure 3-1). During phase 1, months 1 through 4, participants consume a hypo-caloric diet consistent with the *Dietary Guidelines*. During phase 2, months 5 through 12, participants shift into weight maintenance and are instructed to consume a eucaloric diet consistent with the *Dietary Guidelines*.

The WORLD study was approved by the Pennsylvania State University's Institutional Review Board. All participants provided written informed consent.

Participant Selection and Screening

Six hundred sixteen pre-menopausal women were recruited for this year-long weight management intervention; 101 women were enrolled. Recruitment methods included newspaper advertisements and emails to the Penn State University listserv for faculty and staff from October 2006 to May 2007. Eligible women were between the ages of 21 and 50 with low-density-lipoprotein cholesterol (LDL-C) between 100 and 189.9 mg/dl, and a BMI classification of overweight or obese (BMI: 25-39.9 kg/m^2). The upper limit of BMI was 40 kg/m^2 so that serious co-morbidities associated with morbid obesity were minimized; also, morbidly obese individuals may have special exercise needs (14). Subjects completed a telephone-screening interview to review medical history information. If the subject was eligible after the telephone interview, they were scheduled for a screening appointment at Penn State's General Clinical Research Center (GCRC) in University Park, PA. At this appointment, informed consent was obtained and participants completed questionnaires to assess medical history, eating attitudes (15), depression (16), binge eating severity (17), and physical activity readiness (18). Height, weight, and blood pressure were measured and a fasting blood sample was obtained. A complete list of eligibility criteria is listed in Table 3-1.

Intervention

The intervention consists of group nutrition education sessions and supervised physical activity.

Nutrition education program

The educational program, titled "Your Healthy World," focuses on healthy eating during weight loss *and* weight maintenance along with behaviors conducive to a healthy lifestyle (i.e., goal setting, reading food labels, and planning meals). *Your Healthy World* is available in two curriculums – one tailored for a lower-fat diet and one for a moderate-fat diet.

Your Healthy World is based on social cognitive theory (SCT), which is the most frequently employed paradigm in weight management interventions (19, 20) . The constructs of SCT target key components of health behavior change, specifically environment, situation, behavioral capability, expectations, expectancies, self-efficacy, self control, and reciprocal determinism (21), and are the basis for the content of the educational materials. The wording, format, presentation of information, and self-directed activities presented in the educational materials followed the principles of the SCT. For example, self-monitoring checklists, integral to the self control construct of SCT, were included in a variety of lessons. Table 3-2 includes a sample theoretical development guide for one lesson (i.e., fruits and vegetables) of *Your Healthy World*.

Some lessons of *Your Healthy World* were information -based addressed topics such as the food groups (i.e., fruits and vegetables, lean meats and beans, and grains) and certain nutrients (i.e., fat, fiber, sodium, potassium, and calcium) emphasized in the *Dietary Guidelines*. Other lessons were behavior-based and presented information about behaviors which influence one's lifestyle and health, such as goal setting, portion estimation, and snacking.

The educational materials of *Your Healthy World* were color-printed on 11" x 17" sheets of paper which were folded in half to create a 4-page leaflet. Each page of the leaflet was 8" x 11". The Flesch-Kincaid reading levels for all leaflets were between 6.0 and 8.4.

Formative evaluation of *Your Healthy World* consisted of expert review, cognitive interviewing, and a pilot test. To establish content validity, nutrition educators and registered dietitians reviewed the educational materials. Cognitive interviews with six women representative of the target audience established face validity. Feedback indicated that the content and design of the materials were appropriate for the target audience (22). Following the interviews, minor changes were made to graphics and text to address participant responses. A pilot test was completed to assess the delivery method of the education program, problem-based learning (PBL) (23). Consistent with PBL, the sessions were learner-driven through small group activities with nutrition educators serving as facilitators of learning. Therefore, the education program was designed to increase motivation, retention of information, and critical thinking skills. The outline of session topics is shown in Table 3-3. Overall, the educational materials and intervention were well-received during the interviews and pilot study.

Participants attend 28 education sessions throughout the 12-month intervention (Figure 3-1). One-hour education sessions are held weekly during phase 1. During phase 2a (months 5-8), participants attend one-hour sessions every other week. During phase 2b (months 9-12), participants attend monthly education sessions. At the first education session, participants receive instructions for following a diet consistent with the *Dietary Guidelines* and in a target calorie range to meet recommendations for each food group. The calorie range is calculated by the Harris-Benedict Equation (24) and individualized to induce weight loss of one to two pound(s) per week, as recommended by the National Institutes of Health & National Heart, Lung, and Blood Institute Evidence Report (25). Subsequent sessions include vignettes such that information from print materials of the education program is applied and/or includes interactive activities on specific topics.

Exercise

The exercise component consists of daily stretching and five aerobic and two strength-training sessions per week. Each week participants are required to attend two supervised aerobic sessions and complete three aerobic sessions on their own. Aerobic exercise sessions initially are 20 minutes and increase gradually to 60-90 minutes, consistent with the *Dietary Guidelines* recommendation for sustained weight loss during adulthood (4). Exercise is performed at heart rates equal to 65-85% of the maximal heart rate obtained during the participants' initial test of maximal aerobic capacity. Treadmills, elliptical machines, a stair climber, and upright and recombinant bicycles are available for supervised aerobic sessions. Participants complete a variety of activities of their choice, such as jogging, swimming, rowing, and aerobic classes/videos, for unsupervised aerobic sessions. The strength-training routine consists of basic strength-training exercises, such as bicep curls, tricep extensions, lunges, and squats, presented in the educational program and reviewed by trainers in the research training room. Participants complete the strength-training routine, which consists of two sets of each exercise, two times per week on their own using dumb bells.

Data Collection

Demographic, anthropometric, biochemical, and cognitive-behavioral data were collected. The primary outcome variables are weight loss and chronic disease risk factors. The data collection timeline is in Table 3-4; while the specific details of all outcome measures are as follows.

Clinical measures

Weight is measured using the same calibrated digital scale with the participant dressed in light indoor clothing without shoes. Height is measured once at screening using a calibrated wall-mounted stadiometer. Waist circumference is measured using an anthropometric measuring tape at the uppermost lateral border of the right iliac crest, according to the NHANES III protocol (26). After a 5-minute rest period in the seated position with legs uncrossed, blood pressure is measured using a calibrated mercury manometer and stethoscope according to the JNC 7 guidelines (27). Three blood pressure measurements are taken at 1-minute intervals and averaged.

<u>Biochemical measures</u>

Following an overnight fast, venous blood samples are drawn by antecubital venipuncture with the subject in the recumbent position and collected in EDTA-containing vials. Plasma samples are recovered by low-speed centrifugation at 1500 x g for 30 minutes at 4°C. Samples are stored at -70°C until the end of the study when all samples will be analyzed.

Total cholesterol and triglycerides are quantified using enzymatic assays (Olympus Diagnostica GmbH, Irish branch) conducted at Quest Diagnostics Incorporated (Baltimore, MD). High-density-lipoprotein cholesterol is estimated according to the modified heparin-manganese precipitation procedure of Warnick and Albers (28). LDL-C is calculated by the Friedewald equation (29).

C-reactive protein is measured by high sensitivity enzyme-linked immunosorbent assays (Dade Behring Marburg GmbH) conducted at Quest Diagnostics Incorporated (Baltimore, MD). Fasting insulin is measured by radioimmunoassay and glucose is determined through spectrophometry using glucose oxidase at the GCRC Core Laboratory of the Penn State Hershey Medical Center.

Body composition

Body composition is determined by dual energy x-ray absorptometry and completed by the GCRC nursing staff. Three components are measured: fat mass, bone mineral content, and mineral-free lean mass for the whole body and five regions of the body (arms, legs, and trunk).

Physical fitness

Physical fitness is assessed by maximal aerobic capacity, measured by VO_2max. The measurement takes place during a progressive exercise test on a motor-driven treadmill. Participants walk or run until exhaustion using a modified Balke protocol (30).

Dietary intake

Trained interviewers at Penn State's Diet Assessment Center Diet collect 24-hour dietary recalls by telephone from each participant on unannounced, random, nonconsecutive days (two weekdays and one weekend day) using a multiple-pass technique (31, 32). Food portion posters (2-D Food Portion Visual, Nutrition Consulting Enterprises, Framingham, Mass) are used to estimate portion sizes (31). Dietary recalls are collected and analyzed using the Nutrient Data System for Research (NDS-R) software version 5.0 (Nutrition Coordinating Center, University of Minnesota, Minneapolis, MN). Three-day average intakes are calculated to estimate intake at each time-point. Macro- and micronutrient intakes will be determined, in addition to the energy density of participant diets and Healthy Eating Index-2005 scores (33).

Cognitive-behavioral measures

Validated self-report instruments were used to asses perceived quality of life (34-36), eating competence (37-40), eating behavior (41, 42), appetite (43-46), diet satisfaction (46, 47), nutrition knowledge (46), and self-reported physical activity (48, 49). Table 3-5 describes these instruments in detail.

Sample Size Calculations

All calculations used to estimate required sample size were made with the following assumptions: power of 0.95 and alpha of 0.05. Two-tailed tests were used. Based on these calculations, a sample size of 100 subjects (balanced across groups) was determined sufficient to test the proposed hypotheses and allow for a 50% drop-out rate. Typical drop-out rates for long-term weight-loss studies range from 30-40%, although a drop-out rate of 46% has been reported previously (50).

The sample size calculation for detecting a difference in body weight from baseline was based on a study by McManus et al. (51) comparing the effects of hypocaloric low-fat and moderate-fat diets over 18 months (n=101). The mean weight change in the low-fat diet group was 5.0 kg (± 7.3 kg) at 12 months. According to these findings, a sample size of 30 participants would be necessary to detect a 5.6% weight loss for those following a low-fat diet. McManus et al. also reported a mean weight loss of 4.8 kg (± 5.2 kg) at 12 months among participants following a moderate-fat diet. Based on these findings, a sample of 17 participants would be necessary to detect a 5.2% weight loss when following a moderate-fat diet.

Statistical Analysis

Analysis is planned under the intention-to-treat principle. All statistical analyses will be performed by using SAS (version 9.1; Statistical Analyses System, Cary, NC). The mixed-models procedure (PROC MIXED) in SAS will test the effects of diet on each outcome variable (i.e., body weight, dietary intake, body composition, physical fitness, lipids and lipoproteins, CRP, glucose, insulin, quality of life, eating competence, eating behavior, appetite, diet satisfaction, nutrition knowledge, and physical activity). Tukey-Kramer–adjusted *P* values will determine whether the differences in the outcome variables are significant (52, 53). Change scores and percentage change will be calculated from baseline for each outcome variable. Pearson correlation coefficients will estimate interrelationships between the variables. Multivariate regression analysis will be performed to determine predictors of weight loss, including type of diet and program adherence, and predictors of biomarkers, such as weight loss and dietary adherence.

Discussion

The WORLD study is, to the best of our knowledge, the first randomized controlled trial evaluating the effects of a nutrition education program promoting weight loss as well as maintenance of a healthy body weight through diet and exercise modification governed by the *Dietary Guidelines*. The WORLD study is unique from previous studies because the *Dietary Guidelines* are the driving force for a rigorous, weight-management intervention. Often the *Dietary Guidelines* and the Food Guide Pyramid, the previous USDA-developed education tool for conveying the dietary recommendations in the *Dietary Guidelines* to the public, serve as the dietary recommendations for a "standard of care" or control group in nutrition interventions. The dietary recommendations for treatment groups tend to be more extreme (i.e., strict limitation on certain nutrients) in comparison to participants' usual intake (54, 55) and often can be hard to follow long-term (54). In addition, the intensity of the intervention (i.e., number of contacts, inclusion of social support, etc.) is greater in the treatment groups than in the control groups (56, 57). Thus, there is a need to evaluate the effectiveness of a well-designed, intensive weight-management program emphasizing our national dietary and physical activity recommendations of the *Dietary Guidelines*, to the same extent that previous studies have done with other diets.

As stated above, the treatment diets used for weight-loss and weight-management interventions frequently are "fad" diets or diets with more extreme macronutrient profiles (i.e., very-low-fat, low-fat, very-low-carbohydrate, high-protein, etc.) than the average American's diets and current dietary recommendations (4). Although these diets may be more challenging to follow for some people (51, 54, 55), they are effective for weight-loss and maintenance in some individuals. One nutrient of interest in many clinical nutrition studies, such as this one, is dietary fat. Although weight-loss is due to caloric reduction, some people are more successful in terms of weight-loss when consuming a diet lower in dietary fat, in comparison to moderate- or high-fat diets, since caloric reduction may be easier to achieve simply by decreasing fat intake. Data from the National Weight Control Registry indicate that a low-fat, high-carbohydrate diet is preferable for substantial and sustained weight loss, along with physical activity, and self monitoring/stimulus control strategies (58). However, some individuals find a LF diet to be more difficult to follow long-term (54). Determining defining characteristics of individuals (i.e., a profile) that might predict weight loss and long-term maintenance of weight loss in response to diets differing in fat content is important for diet counseling. Thus, results from the WORLD study will contribute to the growing database of studies not only comparing LF and MF weight-loss diets but also will help identify characteristics (i.e., profiles) of individuals successful in reducing chronic disease risk reduction when following each diet.

A distinctive characteristic of the WORLD study is the target population – middle-class women of child-bearing age across a wide range of BMI and LDL-C classifications. Women of child-bearing age were chosen because of their potential to beneficially affect the food choices and overall risk for chronic disease of the family unit. Research indicates that mothers are more concerned about family health and feel more responsible for the health of their children than fathers (59). Maternal education level, nutritional knowledge, food preferences, intake, and/or attitudes related to healthy eating and disease prevention are predictors of children's food preferences (60), fruit and vegetable consumption (61), and other food choices (62-65). Also, mothers often are responsible for menu-planning, shopping, and cooking (66), all of which greatly affect foods available in the home and potentially the food choices of other family members.

In addition to a mother's potential to impact the dietary intake of family members, associations exist between a mother's profile of chronic disease risk factors (i.e., BMI) and a child's (65, 67-71). Therefore, the inclusion criterion for BMI and LDL-C represents the majority of U.S. women. Fifty-five percent of adult U.S. women have a BMI between 25.0 and 39.9 kg/m^2 (1); while the inclusion criteria for LDL-C represents women above the optimal level for LDL-C (i.e., 100 mg/dl) and between the 25th and 95th percentile for adult women in the United States (72).

The WORLD study is the first study, to our knowledge, that uses PBL long-term (i.e., on multiple occasions over the course of a year) in a consumer population. While PBL has been an approach for medical school education for over twenty years (73), only recently has it become an approach for disseminating nutrition information and increasing nutrition knowledge. Bayard et al demonstrated that PBL was an effective way to integrate nutrition education into preclinical medical curriculum (74). More recently, Lohse et al showed that PBL increased critical thinking skills of dietetics students in a life-span nutrition class (75) and was a successful approach for conveying nutrition information to consumers short-term (i.e., during two education sessions) (76). In addition to being a useful way to disseminate nutrition information and increase nutrition knowledge, PBL is an educational method that encourages social interaction and support – two behaviors that improve weight loss success (77, 78).

The results of the WORLD study will be able to guide future research, diet counseling, and educational programs targeting weight management and reduction of chronic disease risk. Future studies will be able to focus on certain sub-populations as a result of this study's findings. Statistical analysis of the data collected will identify predictors of weight loss and diet responsiveness in the study population. Identification of these variables may aid dietary counseling and recommendations. Also, the outcomes of this study may help to identify certain sub-populations that benefit most from: 1) a LF or MF diet and 2) the combination of a diet consistent with the *Dietary Guidelines*, either LF or MF, and an exercise program consisting of stretching, aerobic exercise, and strength training in terms of weight management and/or changes to the lipid profile. In addition, the outcomes of this study will help clarify the use of emerging risk factors, such as CRP, for predicting diet responsiveness. We believe that the findings from the study can be used to develop a web-based approach for teaching healthy weight-management diets based on the *Dietary Guidelines* using a spectrum of dietary fat levels.

Overall, the WORLD study aims to identify which diet is most effective in terms of current fat recommendations for adherence rates and CVD risk, in addition to the influence of total diet energy density on weight loss and weight maintenance. This study will significantly contribute to the growing body of literature comparing LF and MF diets. The extensive data collected (i.e., clinical, biochemical, dietary, and psychosocial) will allow for many sub-analyses to comprehensively determine predictors of weight loss, weight maintenance, and dietary adherence. Lastly, this study forms the basis for outreach activities and has the potential to reach other populations (.i.e., low-income) and, consequently, have large-scale impact.

FIGURE 3-1

Study design and intervention activities

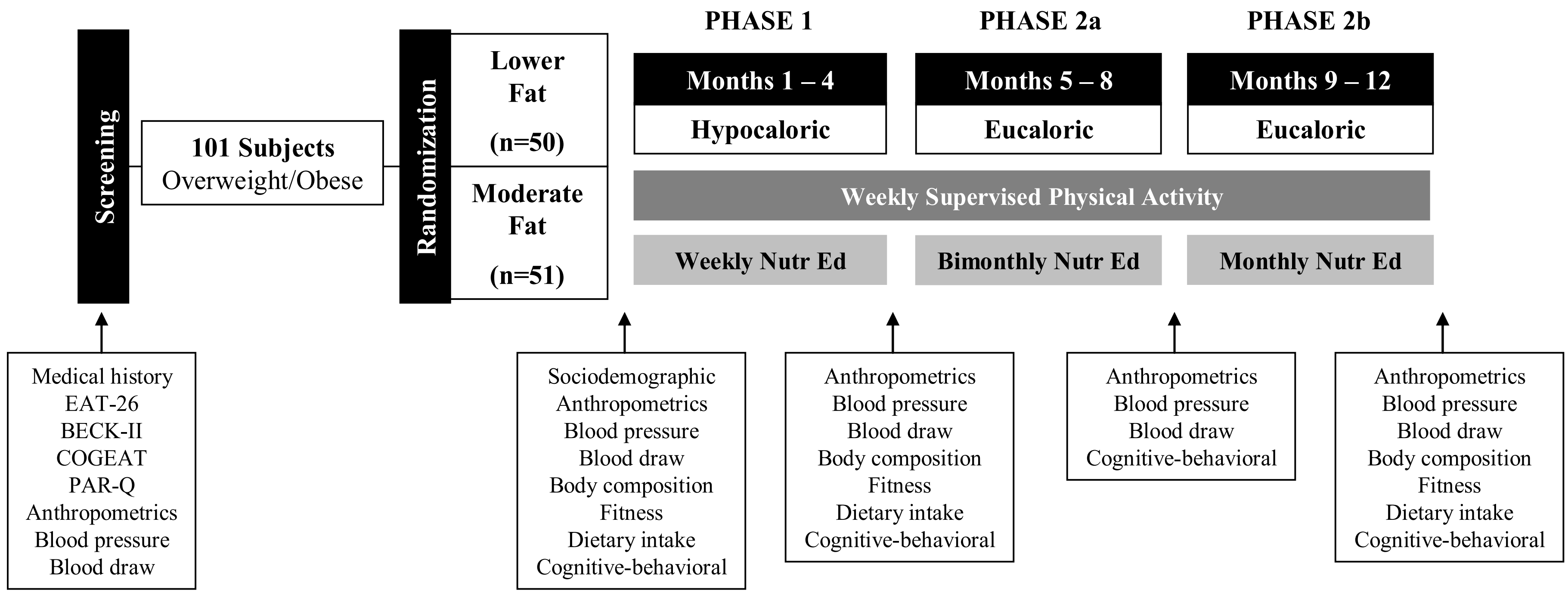

TABLE 3-1

Eligibility criteria

Inclusion criteria

- 21-50 years
- BMI: 25-39.9 kg/m^2
- LDL-C: 100-189.9 mg/dL

Exclusion criteria

- Triglycerides > 350 mg/dL
- History of myocardial infarction, stroke, diabetes mellitus, liver disease, kidney disease, and thyroid disease
- High alcohol consumption (>14 drinks/week)
- Use of medication or supplements for lowering blood lipid levels (i.e., statin, fibrates, psyllium, fish oil capsules, soy lecithin, phytoestrogens)
- Lactating, pregnant, or wanting to become pregnant during the study time period
- Weight loss or gain ≥ 10% body weight in the previous 6 months
- Eating Attitudes Test-26 score > 20[1]
- Beck Depression Inventory-II score ≥ 29[2]
- Gormally Cognitive Factors Related to Binge Eating Scale score > 30[3]
- Physical Activity Readiness Questionnaire score > 2[4]

[1] A score > 20 does not necessarily indicate presence of an eating disorder, but it does indicate concerns regarding body weight, body shape, and eating and a participant is referred to their physician (15).
[2] A score of ≥ 29 is associated with severe depression and the participant is referred to their physician (16).

[3] A score > 30 is considered severe for bingeing behavior and the participant is referred to their physician (17).
[4] A score > 2 indicates that a person may have multiple health problems that could prevent them from participating in physical activity (18).

TABLE 3-2

Theoretical development guide for the fruit and vegetable lesson

SCT[1] construct	Definition	Application to the handout
Situation	Person's perception of the environment	• Addressed misconceptions about canned and frozen fruits and vegetables
Behavioral capability	Knowledge and skill to perform a given behavior	• Discussed nutrients provided by fruits and vegetables • Included tips for increasing fruits and vegetables intakes
Expectations	Anticipatory outcomes of behavior	• Listed health conditions for which daily consumption of 5 servings of fruits and vegetables lowers risk
Self-efficacy	Person's confidence in performing a behavior and in overcoming barriers to that behavior	• Phrased title and text to increase confidence in ability to consume more fruits and vegetables (i.e., "fruits and vegetables can easily be added to your diet to improve your health.")
Self-control	Personal regulation of goal-directed behavior or performance	• Included checklist to enable self-reflection related to current fruits and vegetables consumption • Fostered self-reflection through questions related to fruits and vegetables

intake and knowledge

[1] SCT = social cognitive theory

TABLE 3-3

Outline of education sessions

Month	Lesson	Lesson topic	Includes a vignette	Interactive	Applies material from previous lesson
1	1	Energy Balance & Weight Loss: What to Eat and Do			
	2	Setting goals and Monitoring Progress	X		
	3	Physical Activity: Where to Start?	X		X
	4	Managing Food Portions In and Out of Your Home		X	X
2	5	Fats: What you Should and Can Eat	X	X	
	6	Understanding and Using Food Labels	X		
	7	Exercise Variety	X		
	8	Fats and Food Labels		X	X
3	9	Dietary Fiber & Grains	X		
	10	Personal Assessment		X	X
	11	Fruits and Vegetables	X	X	

	12	Meal Planning	X		X
4	13	Fiber and Grains		X	X
	14	Tips For Food Shopping	X		
	15	Powerful Protein: Choosing Lean Meats and Beans	X		X
	16	Healthy Snacking			X
5	17	Food Shopping at the Grocery Store		X	X
	18	Sugars & Sweets	X		X
6	19	Eating Away From Home		X	X
	20	Lean Meats and Beans		X	X
7	21	Sodium & Potassium	X	X	X
	22	Calcium & Iron	X	X	X
8	23	Sugars and Sweets		X	X
	24	Healthy Lifestyle Strategies			X
9	25	Beverages: Their Place in a Healthy Diet	X		X
10	26	Recipe Adaptation for the Dietary Guidelines		X	X

11	27	Planning Menus	X		X
12	28	Lifelong Habits for a Healthy Life		X	X

TABLE 3-4

Outcome variables and time of data collection*

Measure	Screening	Baseline	Month 4	Month 8	Month 12
Eligibility data	X				
Medical history	X				
Eating Attitudes Test-26	X				
Beck Depression Inventory-II	X				
Gormally Cognitive Factors Related to Binge Eating Scale	X				
Physical Activity Readiness Questionnaire	X				
Medications	X				
Height	X				
Weight	X	X	X	X	X
Blood pressure	X	X	X	X	X
Waist circumference		X	X	X	X
Lipids/lipoproteins	X	XX	XX	XX	XX
Glucose	X	X	X	X	X
Insulin		X	X	X	X
C-reactive protein		X	X	X	X
Body composition via DEXA		X	X		X

Fitness via VO_2max	X	X		X
24-hour dietary recalls	XXX	XXX		XXX
Sociodemographic data	X			
Appetite for the day	XXX	XXX	XXX	XXX
Diet satisfaction	X	X	X	X
Perceived quality of life questionnaire	X	X		X
ecSatter Inventory	X	X		X
Three-factor eating questionnaire-R18	X	X		X
Nutrition knowledge	X	X		X
Current and past physical activity survey	X	X		X

* X = one day

TABLE 3-5

Description of psychosocial measures

Instrument	Constructs/variables measured	Items	Scoring procedure and interpretation
Perceived Quality of Life (PQoL) (34-36)	General health satisfaction: • physical • social • cognitive	• 19, 11-point Likert-type scale • 1 global item on happiness for comparison	• Overall score is a mean of 19 scaled items • < 7.5 dissatisfied • ≥ 7.5 satisfied • For convergent validity, the PQoL score is correlated with the global happiness rating
ecSatter Inventory (37-40)	• eating attitudes • food acceptance • internal regulation of eating • contextual skills related to eating	16-item survey with 5 possible responses each	• Range 0-48 • < 32 non-eating competent • ≥ 32 eating competent

Three Factor Eating Questionnaire-R21 (TFEQ-R21) (41, 42)	• cognitive restraint • uncontrolled eating • emotional eating.	• 20, 4-point Likert-type scale • 1, 8-point Likert-type scale	• Raw-scale score is transformed to a 0-100 scale • Higher scores indicate more uncontrolled, restrained, and emotional eating
Appetite for a day, adapted from Womble et al (43-46)	• hunger • fullness • cravings • thoughts about food	5, visual analog scale	• Higher scores indicate greater fullness, hunger, cravings, or more thoughts about food
Diet satisfaction (D-SAT) (46, 47)	• family dynamics • cost • preparation • convenience • healthy lifestyle • negative aspects	45, 5-point Likert-type scale	• Higher scores indicate greater diet satisfaction

	• preoccupation with food		
Nutrition knowledge (46)	Current nutrition knowledge, specifically related to dietary fat	13, multiple-choice	• Range: 0 -13 • Higher scores indicate greater nutrition knowledge
Current and past physical activity survey (48, 49)	Frequency and duration of a wide-range of activities, such as walking, cycling, dancing, weight training, and yard work.	• 1, multiple-choice • 14, yes/no • 36, fill-in-the-blank	• Higher scores indicate greater levels of activity

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CHAPTER FOUR

Weight Optimization: Revamping Lifestyles Using the *Dietary Guidelines* (WORLD) Study Improves Clinical, Biochemical, and Dietary Outcomes at One Year

Abstract

Background: Our national guidelines for diet and physical activity are the *Dietary Guidelines for Americans*; yet, their effectiveness for weight-management has not been determined.

Objective: The Weight Optimization: Revamping Lifestyles using the *Dietary Guidelines* (WORLD) study evaluated the effects of a theory-based, nutrition education program promoting weight loss, as well as maintenance of a healthy body weight, on clinical, biochemical, and dietary outcomes.

Design: Participants were randomized to either a lower-fat (20% kcal from fat) or moderate-fat diet (35% kcal from fat) in a parallel-arm design. Participants attended 28 education sessions and twice weekly supervised aerobic exercise sessions for one year.

Results: After one year, weight loss was similar between the lower-fat and moderate-fat treatment groups (-5.0 and -4.3 kg; P's < 0.0001 compared to baseline). Total cholesterol and LDL-cholesterol concentrations decreased (-0.09 and -0.10 mmol/l, respectively; P's < 0.05) and HDL-cholesterol concentration increased (+0.05 mmol/l; $P < 0.05$). Participants were reclassified according to actual fat intake because energy and nutrient intakes did not differ between treatment groups. Total, LDL, and HDL-cholesterol concentrations were lower and triglyceride concentrations higher in participants reporting consumption of a lower-fat diet compared to participants consuming a moderate-fat diet (P's ≤ 0.05). The strongest predictors of weight loss were changes in aerobic capacity, binge-eating behaviors, baseline body weight and changes in *trans* fat intake, which together accounted for 20% of the variance in 12-month weight loss. An increase in

aerobic capacity, a decrease in *trans* fat intake, and higher baseline binge-eating behaviors and body weight were associated with greater weight loss.

Conclusions: Results demonstrate that lower-fat and moderate-fat diets consistent with the *Dietary Guidelines* are equally effective for weight management. In support of the *Dietary Guidelines* recommendations for physical activity, aerobic fitness was the main predictor of weight loss.

Introduction

Approximately 66% of U.S. adults are either overweight or obese; and the doubling of obesity prevalence in U.S. adults (i.e., from 15% to 32%) between NHANES 1976-1980 and NHANES 2003-2004 illustrates the enormity of this public health problem (1). Obesity is associated with an increased risk of various diseases/conditions including cardiovascular disease, type 2 diabetes mellitus, dyslipidemia, hypertension, asthma, obstructive sleep apnea, osteoarthritis, respiratory problems, and various cancers (2). In light of the increasing prevalence of obesity and its effect on overall health, disease status, and longevity, an analysis by Olshansky et al. (3) concludes that the steady rise in life expectancy during the past two centuries may not continue in the near future. Accordingly, a specific objective of *Healthy People 2010* is to reduce the prevalence of obesity among the U.S. adult population to less than 15% not only to increase life expectancy but to improve the quality of life (4). To achieve this objective, clinical nutrition studies should assess new interventions, such as innovative nutrition education programs, that provide guidance about implementing healthy lifestyle strategies.

Research consistently shows that diet and exercise are essential for maintenance of a reduced body weight (5, 6) and are more effective together than diet or exercise alone (7-10). The *Dietary Guidelines for Americans*, evidence-based advice to promote health and reduce chronic disease risk through diet and physical activity (11), are commonly the recommendations for the "standard of care" or control group in nutrition interventions. The dietary recommendations for intervention groups in clinical trials and for popular weight-loss programs tend to be more extreme (i.e., strict limitation on certain nutrients) in comparison to individuals' usual intake (12, 13) and often can be hard to follow long-term (12), leading to high attrition rates (14). In addition, the intensity of the intervention in clinical trials (i.e., number of contacts, inclusion of social support, etc.) is generally greater in the treatment groups than in the control groups (15, 16). Thus, there is a need to evaluate the effectiveness of a well-designed, intensive weight-management program that emphasizes our national dietary and physical activity recommendations included in the *Dietary Guidelines*. Interventions based on the *Dietary Guidelines* that target weight loss and maintenance and offer flexibility in diet design may promote long-term dietary adherence leading to decreased chronic disease risk by improving the lipid profile, decreasing waist circumference, and lowering blood pressure. Therefore, the Weight Optimization: Revamping Lifestyles using the *Dietary Guidelines* (WORLD) study, a randomized controlled trial, evaluated the effects of a theory-based, nutrition education program promoting weight loss, as well as maintenance of a healthy body weight, through diet and exercise modification governed by the *Dietary Guidelines*. The WORLD study is unique from previous studies because the *Dietary Guidelines* are the basis for a rigorous, weight-management intervention.

Subjects and Methods

Subjects and Experimental Design

Overweight and obese women who were premenopausal and residing in State College, PA and the surrounding areas were recruited through advertisements in the local paper and emails to the university's faculty and staff listserv. After undergoing an initial telephone screening interview, interested and eligible women completed additional medical, clinical, and psychosocial screening at the General Clinical Research Center (GCRC) at the Pennsylvania State University. Inclusion criteria were: 1) BMI: 25–39.9 kg/m^2, 2) age: 21–50 y, and 3) LDL-cholesterol: 2.60-4.91 mmol/l. Exclusion criteria included: 1) the inability to comply with the study protocol, 2) triglycerides > 3.94 mmol/l, 3) the use of lipid-lowering agents (medications, psyllium, fish oil, soy lecithin, and phytoestrogens), 4) lactating, being pregnant, or wishing to become pregnant during the study, 5) having a weight loss ≥10% body weight within the 6 mo before the study, 6) following vegetarian or weight-loss diets at screening, 7) having any of the following conditions: stroke, diabetes, liver disease, kidney disease, or autoimmune diseases, 8) Eating Attitudes Test-26 score > 20 (17), 9) Beck Depression Inventory-II score ≥ 29 (18), 10) Gormally Cognitive Factors Related to Binge Eating Scale score > 30 (19), and 11) Physical Activity Readiness Questionnaire score > 2 (20).

Of the 616 women recruited for the study, 101 participants fulfilled the inclusion criteria and were randomized to follow either a lower-fat diet (20% kcal from fat) or a moderate-fat diet (35% kcal from fat) for weight management in a parallel-arm design. The two phases of the study were a weight-loss phase (phase 1) and a weight-maintenance phase (phase 2). During phase 1, months 1 through 4, participants consumed a hypo-caloric diet consistent with the *Dietary Guidelines*. During phase 2, months 5 through 12, participants shifted into weight maintenance and were instructed to consume a eucaloric diet consistent with the *Dietary Guidelines*.

The Institutional Review Board at the Pennsylvania State University approved the experimental protocol and all subjects provided written informed consent.

Intervention

The intervention consisted of group nutrition education sessions and supervised exercise. The educational program was based on the social cognitive theory (SCT) (21) and delivered with a problem-based learning approach (22), such that specific SCT constructs which target behaviors important for health were emphasized and subjects actively participated in the learning process. The educational materials were based on the *Dietary Guidelines* and tailored for the two extremes of the dietary fat recommendations (20% and 35% of calories). A calorie range was calculated by the Harris-Benedict Equation (23) to induce weight loss of one to two pound(s)/week, as recommended by the NIH/NHLBI Evidence Report (24). Participants were instructed to follow a diet consistent with the *Dietary Guidelines* within their individualized target calorie range to meet recommendations for each food group. Participants attended 28 one-hour education sessions throughout the 12-month intervention. Sessions were held weekly for the first four months, bi-monthly for the next four months, and monthly for the last four months of the study.

The exercise component consisted of daily stretching and five aerobic sessions, two supervised and three on-their-own, and two unsupervised strength-training sessions per week. The aerobic exercise sessions initially lasted twenty minutes and increased gradually to 60-90 minutes, consistent with the *Dietary Guidelines*' recommendation for sustained weight loss during adulthood (11). Aerobic exercise was performed at 65-85% of the maximal heart rate obtained during the participants' initial test of maximal aerobic capacity.

Data Collection

Anthropometric, biochemical, and other health-related data were collected at baseline and months 4, 8, and 12. The primary outcome variables were weight loss and chronic disease risk factors.

Weight was measured using the same calibrated digital scale with the participant dressed in light indoor clothing without shoes. Height was measured once at screening using a calibrated wall-mounted stadiometer. Waist circumference was measured using an anthropometric measuring tape at the uppermost lateral border of the right iliac crest, according to the NHANES III protocol (25). After a 5-minute rest period in the seated position with legs uncrossed, blood pressure was measured using a calibrated mercury manometer and stethoscope according to the JNC 7 guidelines (26). Three blood pressure measurements were taken at 1-minute intervals and averaged.

Body composition was determined by dual energy x-ray absorptometry and measured by the GCRC nursing staff. Physical fitness was assessed by maximal aerobic capacity, measured by VO_2max. The measurement took place during a progressive exercise test on a motor-driven treadmill. Participants walked or ran until exhaustion using a modified Balke protocol (27).

Following an overnight fast, venous blood samples were drawn by antecubital venipuncture with the subject in the recumbent position and collected in EDTA-containing vials. Plasma samples were recovered by low-speed centrifugation at 1500 x g for 30 minutes at 4°C. Samples were stored at -70°C until the end of the study when all samples were analyzed. Total cholesterol and triglycerides were quantified using enzymatic assays (Olympus Diagnostica GmbH, Irish branch) conducted at Quest

Diagnostics Incorporated (Baltimore, MD). High-density-lipoprotein cholesterol was estimated according to the modified heparin-manganese precipitation procedure of Warnick and Albers (28). LDL-C was calculated by the Friedewald equation (29). C-reactive protein was measured by high sensitivity enzyme-linked immunosorbent assays (Dade Behring Marburg GmbH).

Trained interviewers at Penn State's Diet Assessment Center Diet collected 24-hour dietary recalls by telephone from each participant on unannounced, random, nonconsecutive days (two weekdays and one weekend day) using a multiple-pass technique (30, 31). Food portion posters (2-D Food Portion Visual, Nutrition Consulting Enterprises, Framingham, Mass) were used to estimate portion sizes (30). Dietary recalls were collected and analyzed using the Nutrient Data System for Research (NDSR) software version 5.0 (Nutrition Coordinating Center, University of Minnesota, Minneapolis, MN). Three-day average intakes were calculated to estimate intake at each time-point.

The experimental design, intervention activities, and data collection are described in detail elsewhere (Psota et al, in review).

Statistical Analysis

All statistical analyses were performed by using SAS (version 9.1; Statistical Analyses System, Cary, NC). The study was powered to detect a 5% weight loss over a one-year period, assuming a withdrawal rate of 50%. The results are reported as least-squares means ± standard error of the means. To appropriately analyze the initial treatment intent, analyses were conducted under the intention-to-treat principle. The intention-to-treat analysis for long-term weight loss consisted of imputing weight regain at a rate of 0.3 kg per month and a rate of 0.3 cm per month of regained waist circumference after withdrawal. All other outcome variables also were analyzed according to the intention-to-treat principle, with zero change from baseline imputed for missing data. The dietary data are presented for participants who provided recalls at each time-point (13, 32, 33).

The mixed-models procedure (PROC MIXED) in SAS was used to test the effects of diet on each outcome variable (i.e., body weight, dietary intake, body composition, physical fitness, lipids and lipoproteins, CRP). Categorical variables were analyzed by chi-square tests. Tukey-Kramer–adjusted *P* values were used to determine whether the differences in the outcome variables were significant. Change scores and percentage change was calculated from baseline for each outcome variable. Interrelationships between the variables were estimated by Pearson correlation coefficients. Regression analyses were performed to determine predictors of weight loss, including baseline body weight, changes in macronutrient and fiber intakes, change in aerobic capacity, baseline cognitive-behavioral measures, and attendance at education session.

Since participants did not necessarily follow the recommendation for dietary fat intake of their treatment group and percentage of energy from fat did not differ between treatment groups, analyses were performed again after reclassifying participants by actual dietary fat intake. Participants were classified as consuming a lower-fat diet if average fat intake from months 4 and 12 contributed less than 27.5% of total energy; participants consuming a diet in which average fat intake from months 4 and 12 contributed more than 27.5% of total energy were considered moderate-fat consumers. The cutpoint of

27.5% of energy was used since it is the midpoint of the *Dietary Guidelines* recommendation for dietary fat (i.e., 20-35% of energy from fat).

Results

Subject Characteristics

Of the 616 women who screened for the study, 101 (17%) were randomly assigned to follow either a lower-fat or moderate fat diet, and 60 (59% of those assigned) completed the study (i.e., provided anthropometric, biochemical, and dietary data at month 12). Baseline characteristics, except for binge eating scale scores, were similar among participants assigned to the two diets (Table 4-1). All baseline characteristics were similar between those who completed the study and those who did not (Table 4-1) and participants who consumed a lower-fat diet and those who consumed a moderate-fat diet (data not shown).

Of the 50 participants randomized to the lower-fat treatment group 14 participants consumed a lower-fat diet (< 27.5% of energy from fat) at baseline; while 39 of the 51 participants randomized to the moderate-fat diet consumed a moderate-fat diet (> 27.5% of energy from fat) at baseline. When assessing the 60 participants who provided dietary recalls at each time-point, 10 participants randomized to the lower-fat diet consumed a lower-fat diet and 22 consumed a moderate-fat diet; while 9 participants randomized to the moderate-fat diet consumed a lower-fat diet and 19 consumed a moderate-fat diet. No differences were detected between treatment groups for categorization based on actual dietary fat consumption.

Clinical Parameters

The amount of weight loss after one year (Table 4-2) was similar in participants assigned to the lower-fat diet and moderate-fat diet (-5.0 and -4.3 kg, respectively; P's < 0.0001 compared to baseline). The majority of weight loss occurred during the first four months (-4.5 and -3.9 kg, respectively; P's < 0.0001) with a non-significant loss from month 4 to month 12 (-0.5 and -0.2 kg, respectively) (Figure 4-1). Thus, a significant decrease in BMI (Table 4-2) was attained by month 4 in both treatment groups and maintained at month 12 (-1.9 and -1.5 units, respectively; time effect, P < 0.0001). For participants who completed the study, 22% had lost 5 to 9.9% of their initial body weight; 32% lost 10 to 19.9% of their initial body weight; and 14% had lost more than 20% of their initial body weight. Accordingly, 31 participants (52%) shifted down in BMI classification by the end of the study; 10 (17%) from obese to overweight, 20 (33%) from overweight to normal, and one (2%) from obese to normal. All other participants remained in their original BMI category. Waist circumference (Table 4-2) was significantly lower at month 4 (-4.1 cm; P < 0.0001 compared to baseline); however this change was not maintained through month 12 (-2.2 cm; P = 0.06 compared to baseline). Weight loss over time and changes in BMI classification and waist circumference did not differ significantly between treatment groups.

Body composition (Figure 4-2) shifted in a favorable direction, with percent lean mass increasing and percent body fat decreasing (Table 4-2; P < 0.0001 for both). A similar shift was seen in both treatment groups and when participants were categorized by actual dietary fat intake (data not shown). In addition, aerobic capacity, assessed by

VO_2max, increased overall ($P < 0.0001$); however this increase was significant in the moderate-fat treatment group only (Table 4-2).

The improvements in measures of weight status, body composition, and aerobic capacity were significantly greater when only analyzing participants who provided data at month 12 ($P < 0.001$ for all), which reflects the effect of imputing the missing values for participants who dropped out of the study. The amount of change in clinical parameters did not differ between participants assigned to the lower-fat diet who completed the study and those assigned to the moderate-fat diet that completed the study (data not shown). In addition, the measures of weight status, body composition, and aerobic capacity were not different between groups when categorizing participants by actual dietary fat intake (data not shown).

Risk Factors for Cardiovascular Disease

When analyzing all participants together, total cholesterol and LDL-cholesterol concentrations (Table 4-3) were significantly lower than baseline values (-0.09 and -0.10 mmol/l, respectively; P's < 0.05) and HDL-cholesterol concentration (Table 4-3) significantly increased over time (+0.05 mmol/l, $P < 0.0001$). Triglyceride concentrations (Table 4-3) tended to be lower at month 12 than at baseline (-0.05 mmol/l; $P = 0.07$). Accordingly, the ratios of total cholesterol/HDL-cholesterol, LDL-cholesterol/HDL-cholesterol, and triglycerides/HDL-cholesterol significantly improved over time ($P < 0.001$ for all; data not shown).

Total and LDL-cholesterol concentrations at month 4 were similar in participants assigned to the lower-fat diet and moderate-fat diet (-0.21 and -0.15 mmol/l and -0.21 and

-0.18 mmol/l, respectively; P's < 0.01 compared to baseline); however, only LDL-cholesterol in participants in the moderate-fat treatment group remained significantly lower than baseline at month 12 (-0.13 mmol/l; P = 0.02 compared to baseline). HDL-cholesterol concentration increased significantly in participants assigned to the moderate-fat diet by month 8 and was maintained through month 12 (+0.06 mmol/l; P = 0.0007). HDL-cholesterol concentration was unchanged in participants assigned to the lower-fat diet (+0.03 mmol/l; P = 0.12).

CRP concentrations were similar for participants assigned to each diet (Table 4-3, P = 0.47). At months 4 and 8, CRP concentration was significantly lower than baseline (-0.65 and -0.85 mg/l, respectively; P's < 0.05); however, this change was not maintained through month 12 (-0.52 mg/l compared to baseline; P = 0.44).

Systolic blood pressure and diastolic blood pressure (Table 4-2) at month 4 were significantly lower in participants assigned to the moderate-fat diet (-3.1 and -2.8 mm Hg, respectively; P's < 0.05 compared to baseline); however, these improvements did not remain at month 12 (-1.7 and -1.8 mm Hg, respectively). When analyzing all participants together, systolic blood pressure and diastolic blood pressure significantly improved over time (P's < 0.001) and were not different between treatment groups.

The changes in lipid concentrations and SBP were significantly greater in participants who provided data at month 12 and significantly improved compared to baseline values (P < 0.05 for all), which reflects the effect of imputing the missing values. When stratifying participants based on actual dietary fat intake, total and LDL-cholesterol concentrations were significantly lower in participants consuming a lower-fat diet (P < 0.05 for both; data not shown). HDL-cholesterol and triglyceride concentrations significantly improved by month 12 only in participants consuming a moderate-fat diet ($P \leq 0.01$ for both; data not shown). Blood pressure and CRP concentration did not differ between participants eating a lower-fat diet and those eating a moderate-fat diet.

Dietary Intake

Participants significantly decreased total energy intake and percent energy from fat, saturated fat, and *trans* fat and significantly increased percent energy from protein and dietary fiber intake by month 4 (Table 4-4, $P \leq 0.05$ for all). Only the changes in energy and fiber intake were sustained through month 12 (-157 kcal and +2.1g/d, respectively; $P < 0.01$ for both). A trend was seen for saturated fat contributing less to energy intake at month 12 compared to baseline (-0.9%, $P = 0.08$).

Since energy and nutrient intakes did not differ between treatment groups, the dietary data are presented with participants categorized by actual dietary fat consumption. Although participants consuming a moderate-fat diet reported higher energy intakes than those consuming a lower-fat diet at each time-point ($P = 0.007$ for group effect), participants in consuming a moderate-fat diet significantly decreased energy intake (-228 kcal; $P < 0.0001$) throughout the study while participants consuming a lower-fat diet did not (-87 kcal; $P = 0.83$). Percent of energy from carbohydrate and protein was significantly higher (6% and 2%, respectively; $P \leq 0.051$ for both) in the lower-fat group than in the moderate-fat group throughout the study. Overall, participants consuming a lower-fat diet reported higher fiber intakes than those consuming a moderate-fat diet ($P = 0.01$ for group effect). As expected, fat contributed a greater percent of energy in the moderate-fat group than in the lower-fat group (7%; $P < 0.0001$). Accordingly, percent of energy from saturated fat, monounsaturated fat, polyunsaturated fat, and *trans* fat also were higher in the moderate-fat group (3%, 3%, 1%, and 0.4%, respectively; $P < 0.01$ for all).

Predictors of Weight Loss

Regression analyses were performed to determine predictors of weight loss. Simple linear regression indicates that attendance at the group education sessions predicts weight loss at 12 months (Figure 4-3, 0.3 kg for every session attended). Stepwise regression analyses were performed for two models – an initial model that included terms for macronutrient and fiber intakes, cognitive-behavioral measures, and fitness and a second model which also included baseline body weight (Table 4-5). When baseline body weight was excluded from the model, the strongest predictors of weight loss were changes in aerobic capacity (12%), binge-eating behaviors (4%), and changes in *trans* fat intake (2%), which together accounted for 18% of the variance in the 12-month body weight change. When included in the model, baseline body weight had a small but significant influence on body weight at 12 months, accounting for 2.3% of the variance in weight loss. This was preceded by changes in aerobic capacity and binge-eating behaviors which together accounted for 16% of the variability.

Discussion

The WORLD study is, to the best of our knowledge, the first randomized controlled trial evaluating the effects of an intensive weight-management program emphasizing the dietary and physical activity recommendations of the *2005 Dietary Guidelines for Americans*. The primary finding of the study is that diets across the recommended range of fat intake (i.e., 20-35% kcal from fat) were equally effective for weight loss and weight maintenance. Anthropometric measures (i.e., body weight, BMI, and waist circumference), body composition (i.e., percent body fat and percent lean mass), risk factors for cardiovascular disease (i.e., lipids and blood pressure), and nutrient and energy intake were similar between treatment groups. Changes to clinical, biochemical, and dietary measures were beneficial and in the direction that would be expected with weight-loss and maintenance of a reduced body weight. Thus, the results of this study support our national guidelines for health promotion and chronic disease risk reduction.

Strengths of our study include a relatively large sample, assessment of many variables related to health, and a focus on a diet more comparable to participants' usually dietary intake and less extreme than other weight-loss diets. A limitation of our study is a lack of generalizability since it only included mostly Caucasian women; however, the results can be applied to most U.S. adult women because their BMI and LDL-cholesterol concentration were similar to national prevalence data (1, 34). Although our retention rate (60%) was not ideal, it is consistent with other long-term weight-management interventions (35). Since our study was powered to account for 50% attrition, we still can make many conclusions based on this intervention.

Study participants were unable to reach the target levels of dietary fat intake. Consistent with the Women's Health Initiative (36), participants had difficulty attaining a lower-fat diet; the diet of only one participant (i.e., 21% energy from fat) in the lower-fat treatment group approached the target level for dietary fat (i.e., 20% of energy from fat). Also, only 7 participants in the moderate-fat treatment group were within 2% of the target fat level for the treatment group (i.e., 35% energy from fat). During the intervention, the majority of participants (57%) consumed a diet that matched their reported intake of dietary fat at baseline regardless of treatment group. These data support previous findings which indicate that people find it difficult to significantly change the macronutrient profile of their diet (13). However, individuals were able to alter intake such that they lost weight and consumed a diet associated with chronic disease risk reduction. For example, data from this study and others (13, 37-39) indicate that participants can decrease energy intake and percent of energy from saturated fat and *trans* fat while increasing dietary fiber. Also, consistent with prior studies is the apparent under-reporting of energy intake by research participants (40-42). The participants who provided data at month 12 had a mean weight loss of 6.3 kg, which corresponds to a net reduction of approximately 133 kcal/d from increased energy expenditure and decreased caloric intake. However, participants reported consuming -157 kcal/d at month 12 in comparison to baseline values from diet alone.

One possible explanation for the difference between reported fat intakes and target intakes of the treatment groups is that participants have a preference for either a lower-fat or moderate-fat diet and thus do not alter the macronutrient profile of their diets. Another possible explanation is that the main difference between the education programs for the treatment groups was in the recipes provided within them; the recipes differed in ingredients which provide fat. Thus, if participants did not follow the recipes, the nutrient profile of their diets during the intervention might not differ from their baseline dietary intake. During the course of the study, participants were exposed to some of the recipes included in the educational materials at their group sessions. Several participants stated that they did incorporate the recipes into their meal plans while others mentioned they did not. Thus, to explore this potential relationship further, future studies would need to collect data regarding the use of the recipes consistent with the *Dietary Guidelines* and tailored for the target fat levels of the treatment groups. In addition, future interventions should determine reasons why people struggle to attain lower dietary fat levels which would have significant implications for future *Dietary Guidelines*.

Although there were no overall treatment effects on blood lipid concentrations, this was not surprising since dietary intake did not differ across treatment groups. Nonetheless, HDL-cholesterol concentration was higher at month 12 compared to baseline in the moderate-fat treatment group but not the lower-fat treatment group. Since the nutrient intakes did not differ between treatment groups, one explanation for the difference in HDL-cholesterol concentration is that the majority of participants actually consumed a moderate-fat diet and therefore likely accounted for this difference. Also, data indicate that increases in aerobic exercise raise HDL-cholesterol concentration; however, aerobic capacity did not differ between treatment groups in the present study so this is unlikely.

To explore the lack of blood lipid differences between the treatment groups, participants were reclassified according to reported dietary fat intake. When doing so, the expected differences in nutrient intakes and blood lipid concentrations between these groups were observed. Total fat, saturated fat, monounsaturated fat, polyunsaturated fat, and *trans* fat contributed less energy to the diets of participants consuming a lower-fat diet in comparison to those participants consuming a moderate-fat diet. Consistent with previous findings (43, 44), total cholesterol and LDL-cholesterol concentrations were lower in participants consuming a lower-fat diet; while triglyceride concentrations were lower and HDL-cholesterol concentrations were higher in participants consuming a moderate-fat diet.

Results from this study confirm many previous findings, specifically the relationships between attendance at the education/support sessions, eating behavior, and fitness with weight loss. The association between attendance at the education sessions and weight loss reaffirms the importance of face time with research participants and social support for individuals trying to lose weight (45-48). Also, eating behaviors and specifically binge-eating behaviors have been shown to influence weight status (49-51); yet this is the first study, to our knowledge, which indicates that these behaviors predict weight loss more than changes in nutrient and energy intakes. Data from this study also supports the impact of aerobic fitness on body weight (52).

In conclusion, the WORLD study demonstrates that individuals can successfully lose and maintain weight loss while following diets consistent with the dietary fat recommendations of the *Dietary Guidelines*. Since most participants consumed a diet similar in total fat to their baseline diet, regardless of treatment group, this study emphasizes the importance of considering an individual's usual dietary intake when making dietary recommendations for weight management and chronic disease risk reduction. Data from this study confirms previous findings regarding dietary intake and the effects on blood lipids. Thus, this study adds to the strong evidence-base in support of the *Dietary Guidelines* for health promotion and chronic disease risk reduction even during weight loss and maintenance of a reduced body weight.

TABLE 4-1

Baseline characteristics of subjects (n = 101)[1]

Characteristic	Lower-fat Diet (n = 50)	Moderate-fat Diet (n = 51)	All Participants (n = 101)	Subjects Who Completed the Study (n = 60)
Age (yr)	38.8 ± 0.8	39.0 ± 0.9	38.9 ± 0.6	39.9 ± 0.8
BMI (kg/m^2)				
25.0-29.9	25 (50)	27 (53)	52 (51)	31 (52)
≥ 30.0	25 (50)	24 (47)	49 (49)	29 (48)
Race				
White	46 (92)	48 (94)	94 (93)	59 (98)
Black	0 (0)	2 (4)	2 (2)	1 (2)
Other	2 (4)	1 (2)	3 (3)	0 (0)
Education level (%)[2]				

High school	4 (8)	6 (12)	10 (10)	8 (13)
Some college	5 (10)	8 (16)	13 (13)	4 (7)
Business/technical degree	1 (2)	9 (17)	10 (10)	6 (10)
College graduate	26 (52)	16 (31)	42 (41)	25 (42)
Graduate degree	12 (24)	12 (24)	24 (24)	17 (28)
Cognitive-behavioral state				
EAT-26	5.8 ± 0.7	6.7 ± 0.8	6.2 ± 0.5	5.9 ± 0.6
BECK-II	4.8 ± 0.6	5.9 ± 0.6	5.4 ± 0.4	5.3 ± 0.6
COGEAT	10.4 ± 0.9	13.5 ± 0.9	12.0 ± 0.6	11.7 ± 0.9
PAR-Q	0.14 ± 0.06	0.14 ± 0.06	0.14 ± 0.04	0.18 ± 0.05

[1]Baseline values after participants have been randomized to a treatment diet. Values are expressed as mean ± standard error or numbers (percentages). BMI = Body Mass Index. EAT-26 = Eating Attitudes Test-26 (17). BECK-II = Beck Depression Inventory-II (18). COGEAT = Gormally Cognitive Factors Related to Binge Eating Scale (19). PAR-Q = Physical Activity Readiness Questionnaire (20).

[2]Two participants, randomized to the lower-fat diet that did not complete the study, did not report education level or race at baseline.

TABLE 4-2

Effects of treatment diets on clinical measures, based on intention-to-treat analyses (n = 101)[1,2]

Variable	Baseline	Month 4	Month 8	Month 12
Weight (kg)	82.9 ± 1.3	78.7 ± 1.3[a]	78.2 ± 1.3[a]	78.3 ± 1.4[a]
Lower-fat	84.2 ± 1.9	79.7 ± 1.9[a]	79.2 ± 1.9[a]	79.2 ± 1.9[a]
Moderate-fat	81.6 ± 1.9	77.7 ± 1.9[a]	77.3 ± 1.9[a]	77.5 ± 1.9[a]
Body mass index (kg/m^2)	30.8 ± 0.4	29.2 ± 0.4[a]	29.0 ± 0.4[a]	29.1 ± 0.4[a]
Lower-fat	31.0 ± 0.6	29.3 ± 0.6[a]	29.1 ± 0.6[a]	29.1 ± 0.6[a]
Moderate-fat	30.6 ± 0.6	29.2 ± 0.6[a]	29.0 ± 0.6[a]	29.1 ± 0.6[a]
Waist circumference (cm)	99.6 ± 1.3	95.5 ± 1.3[a]	95.3 ± 1.3[a]	97.4 ± 1.3[b]
Lower-fat	99.4 ± 1.8	94.5 ± 1.8[a]	94.9 ± 1.8[a]	97.6 ± 1.8
Moderate-fat	99.7 ± 1.8	96.5 ± 1.8	95.8 ± 1.8[b]	97.1 ± 1.8
Systolic blood pressure (mm Hg)	114.8 ± 1.0	111.2 ± 1.0[a]	112.0 ± 1.0[a]	112.7 ± 1.0[a]
Lower-fat	114.4 ± 1.5	112.2 ± 1.5	111.5 ± 1.5	112.0 ± 1.5
Moderate-fat	115.2 ± 1.4	112.1 ± 1.4[a]	112.4 ± 1.4	113.5 ± 1.4

Diastolic blood pressure (mm Hg)	77.4 ± 0.8	75.1 ± 0.8[a]	75.6 ± 0.8[a]	76.3 ± 0.8
Lower-fat	76.8 ± 1.1	74.9 ± 1.2	75.6 ± 1.1	76.4 ± 1.1
Moderate-fat	78.0 ± 1.1	75.2 ± 1.1[a]	75.6 ± 1.1[b]	76.2 ± 1.1
Percent lean mass	57.0 ± 0.5	59.1 ± 0.5[a]	-	58.9 ± 0.5[a]
Lower-fat	57.3 ± 0.7	59.5 ± 0.7[a]	-	59.2 ± 0.7[a]
Moderate-fat	56.8 ± 0.7	58.7 ± 0.7[a]	-	58.6 ± 0.7[a]
Percent body fat	37.9 ± 0.5	36.2 ± 0.5[a]	-	36.1 ± 0.5[a]
Lower-fat	37.7 ± 0.7	35.9 ± 0.7[a]	-	35.7 ± 0.7[a]
Moderate-fat	38.1 ± 0.7	36.4 ± 0.7[b]	-	36.5 ± 0.7[a]
VO_2max ($ml * kg^{-1} * min^{-1}$)	27.7 ± 0.8	30.4 ± 0.7[a]	-	31.0 ± 0.7[a]
Lower-fat	27.8 ± 1.1	30.7 ± 1.1[c]	-	30.4 ± 1.1
Moderate-fat	27.5 ± 1.1	30.1 ± 1.1	-	31.7 ± 1.1[a]

[1]Values are expressed as mean ± standard error. Data were analyzed under the intention-to-treat principle with repeated-measures ANOVA using the MIXED procedure (SAS, Version 9.1, Cary, NC). A significant time effect was observed for all outcomes (P's < 0.01). No significant differences were observed between treatments.

[2]Significant differences within a row are denoted by: [a] $P \leq 0.05$, compared to baseline; [b] $P \leq 0.10$, compared to baseline.

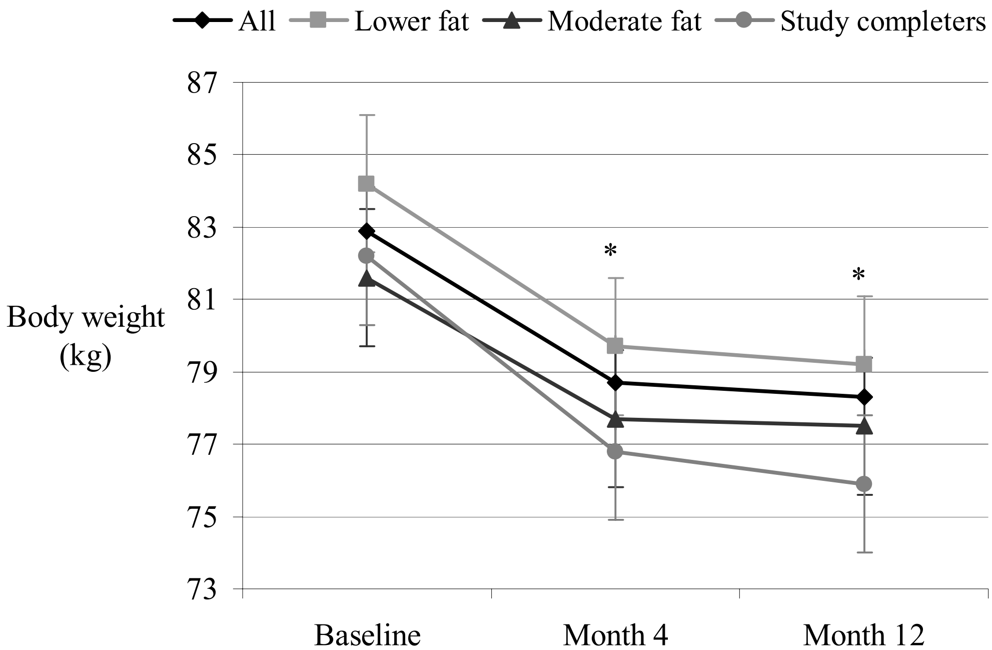

FIGURE 4-1. Body weight over time (± SEMs) based on intention-to-treat analyses (n = 101) with repeated-measures ANOVA using the MIXED procedure (SAS, Version 9.1, Cary, NC). A significant time effect was observed for all participants, both treatments, and the study completers (P's < 0.0001). *Significantly different from baseline ($P \leq 0.05$ for all). No significant differences were observed between treatments.

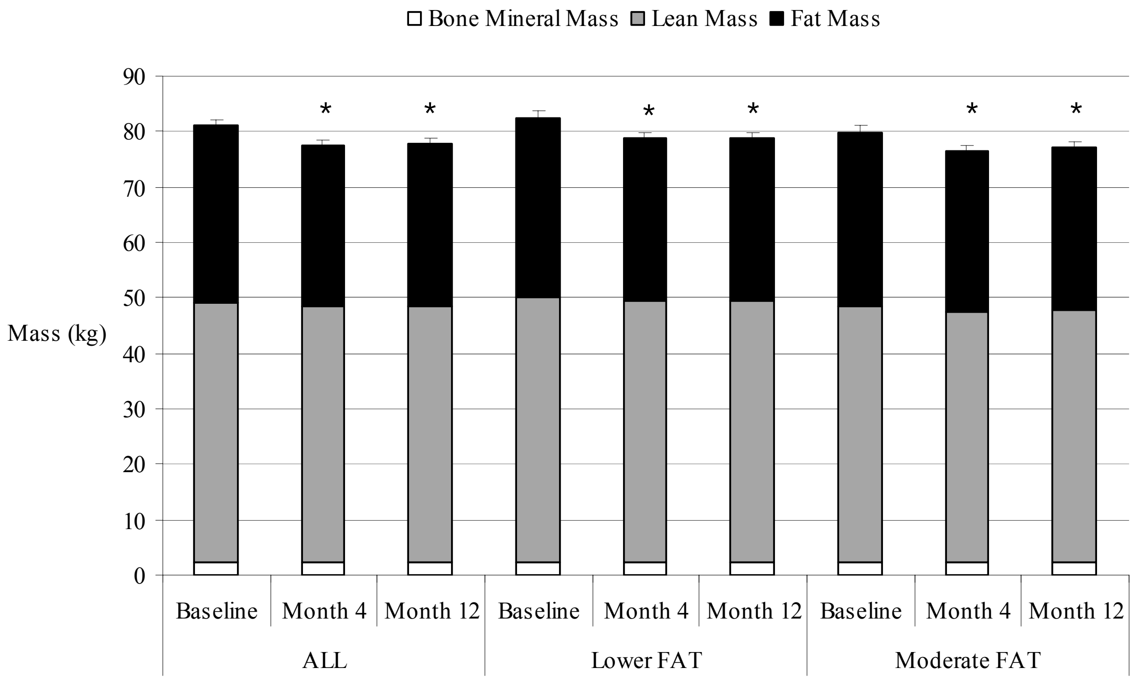

FIGURE 4-2. Body composition (± SEMs) based on intention-to-treat analyses (n = 101) with repeated-measures ANOVA using the MIXED procedure (SAS, Version 9.1, Cary, NC). A significant time effect was observed for total mass, lean mass, and fat mass (P's < 0.0001). *Significantly different from baseline (P ≤ 0.05 for all). No significant differences were observed between treatments.

TABLE 4-3

Effects of treatment diets on biomarkers, based on intention-to-treat analyses (n = 101)[1,2]

Variable	Baseline	Month 4	Month 8	Month 12	P-value
Total cholesterol (mmol/l)	4.68 ± 0.1	4.47 ± 0.1[a]	4.56 ± 0.1[a,b]	4.59 ± 0.1[a,b]	<0.0001
Lower-fat	4.58 ± 0.1	4.37 ± 0.1[a]	4.47 ± 0.1	4.49 ± 0.1[d]	0.14
Moderate-fat	4.78 ± 0.1	4.57 ± 0.1[a]	4.66 ± 0.1[c]	4.69 ± 0.1	
LDL-cholesterol (mmol/l)	2.90 ± 0.1	2.74 ± 0.1[a]	2.78 ± 0.1[a]	2.80 ± 0.1[a]	<0.0001
Lower-fat	2.84 ± 0.1	2.69 ± 0.1[a]	2.73 ± 0.1[c]	2.76 ± 0.1	0.36
Moderate-fat	2.97 ± 0.1	2.79 ± 0.1[a]	2.82 ± 0.1[a]	2.84 ± 0.1[a]	
HDL-cholesterol (mmol/l)	1.23 ± 0.02	1.22 ± 0.02	1.27 ± 0.02[a,b]	1.28 ± 0.02[a,b]	<0.0001
Lower-fat	1.20 ± 0.04	1.19 ± 0.04	1.23 ± 0.04[d]	1.23 ± 0.04[b]	0.13
Moderate-fat	1.26 ± 0.03	1.25 ± 0.03	1.30 ± 0.03[a]	1.32 ± 0.03[a,b]	
Triglycerides (mmol/l)	1.17 ± 0.05	1.08 ± 0.05[a]	1.13 ± 0.05	1.12 ± 0.05[c]	0.001
Lower-fat	1.16 ± 0.06	1.07 ± 0.06	1.11 ± 0.06	1.08 ± 0.06	0.69
Moderate-fat	1.18 ± 0.08	1.09 ± 0.06[c]	1.15 ± 0.06	1.15 ± 0.06	

C-reactive protein (mg/l)	3.78 ± 0.4	3.13 ± 0.4[a]	2.93 ± 0.4[a]	3.26 ± 0.4	0.04
Lower-fat	3.89 ± 0.5	3.37 ± 0.5	3.42 ± 0.5	3.32 ± 0.5	0.47
Moderate-fat	3.48 ± 0.5	2.91 ± 0.5	2.45 ± 0.5[a]	3.20 ± 0.5[e]	

[1]Values are expressed as mean ± standard error. Data were analyzed under the intention-to-treat principle with repeated-measures ANOVA using the MIXED procedure (SAS, Version 9.1, Cary, NC). A significant time effect was observed for all outcomes (P's < 0.05). No significant differences were observed between treatments.

[2]Significant differences within a row are denoted by: [a] $P \leq 0.05$, compared to baseline; [b] $P \leq 0.05$, compared to month 4; [c] $P \leq 0.10$, compared to baseline; [d] $P \leq 0.10$, compared to month 4; [e] $P \leq 0.10$, compared to month 8.

TABLE 4-4

Dietary intake over time when categorizing participants by dietary fat intake (n = 60)[1,2]

Variable	Baseline	Month 4	Month 12
Energy (kcal)	1522.8 ± 48.3	1336.8 ± 48.3[a]	1365.7 ± 48.6[a]
Lower-fat	1369.4 ± 79.8	1225.0 ± 79.8	1282.9 ± 80.5
Moderate-fat	1676.2 ± 54.4	1448.6 ± 54.4[a]	1448.4 ± 54.5[a]
Percent energy from CHO	52.7 ± 0.9	53.7 ± 0.9	53.9 ± 0.9
Lower-fat	55.5 ± 1.5	56.7 ± 1.5	57.5 ± 1.5
Moderate-fat	49.8 ± 1.0	50.6 ± 1.0	50.4 ± 1.0
Percent energy from PRO	18.0 ± 0.5	19.9 ± 0.5[a]	18.9 ± 0.5[d]
Lower-fat	18.7 ± 0.8	20.9 ± 0.8[c]	20.1 ± 0.8
Moderate-fat	17.4 ± 0.5	19.0 ± 0.5	17.7 ± 0.5
Percent energy from fat	30.8 ± 0.7	28.7 ± 0.7[a]	29.4 ± 0.7
Lower-fat	27.7 ± 1.2	25.1 ± 1.2	24.9 ± 1.2
Moderate-fat	33.8 ± 0.8	32.2 ± 0.8	33.9 ± 0.8
Percent energy from SFA	10.2 ± 0.3	8.9 ± 0.3[a]	9.3 ± 0.3[c]
Lower-fat	8.5 ± 0.6	7.3 ± 0.6	7.8 ± 0.6
Moderate-fat	11.9 ± 0.4	10.5 ± 0.4[a]	10.9 ± 0.4
Percent energy from MUFA	11.3 ± 0.3	10.8 ± 0.3	10.9 ± 0.3
Lower-fat	10.4 ± 0.6	9.5 ± 0.6	9.3 ± 0.6
Moderate-fat	12.2 ± 0.4	12.0 ± 0.4	12.6 ± 0.4
Percent energy from PUFA	6.8 ± 0.2	6.5 ± 0.3	6.7 ± 0.3
Lower-fat	6.6 ± 0.4	5.9 ± 0.4	5.6 ± 0.4

Moderate-fat	7.0 ± 0.3	7.1 ± 0.3	7.7 ± 0.3
Percent energy from TFA	1.6 ± 0.1	1.2 ± 0.1[a]	1.4 ± 0.1[d]
Lower-fat	1.5 ± 0.2	1.0 ± 0.2[c]	1.2 ± 0.2
Moderate-fat	1.8 ± 0.1	1.4 ± 0.1[a]	1.6 ± 0.1
Fiber (g/d)	17.1 ± 0.7	19.6 ± 0.7[a]	19.3 ± 0.7[a]
Lower-fat	19.1 ± 1.2	20.3 ± 1.2	21.2 ± 1.2
Moderate-fat	15.1 ± 0.8	18.9 ± 0.8[a]	17.4 ± 0.8[a]
Cholesterol (mg/d)	194.5 ± 11.5	164.9 ± 11.5[c]	167.6 ± 11.6
Lower-fat	189.6 ± 19.0	155.0 ± 19.0	137.8 ± 19.3
Moderate-fat	199.3 ± 12.9	174.9 ± 12.9	197.3 ± 13.0

[1]Values are expressed as mean ± standard error. All outcomes were analyzed with repeated-measures ANOVA using the MIXED procedure (SAS, Version 9.1, Cary, NC). CHO = carbohydrate, PRO = protein, SFA = saturated fatty acids, PUFA = polyunsaturated fatty acids, MUFA = monounsaturated fatty acids, and TFA = *trans* fatty acids. A significant time effect was observed for total energy, percent of energy from CHO, PRO, SFA, PUFA, MUFA, and TFA, and fiber (P's ≤ 0.01). A trend for a time effect was observed for the percent of energy from fat and cholesterol (P's ≤ 0.07). A significant group effect was observed for total energy, percent of energy from CHO, PRO, fat, SFA, PUFA, MUFA, and TFA, and fiber (P's ≤ 0.01). A trend for a group effect was observed for cholesterol (P = 0.07).

[2]Significant differences within a row are denoted by: [a] P ≤ 0.05, compared to baseline; [b] P ≤ 0.05, compared to month 4; [c] P ≤ 0.10, compared to baseline; [d] P ≤ 0.10, compared to month 4.

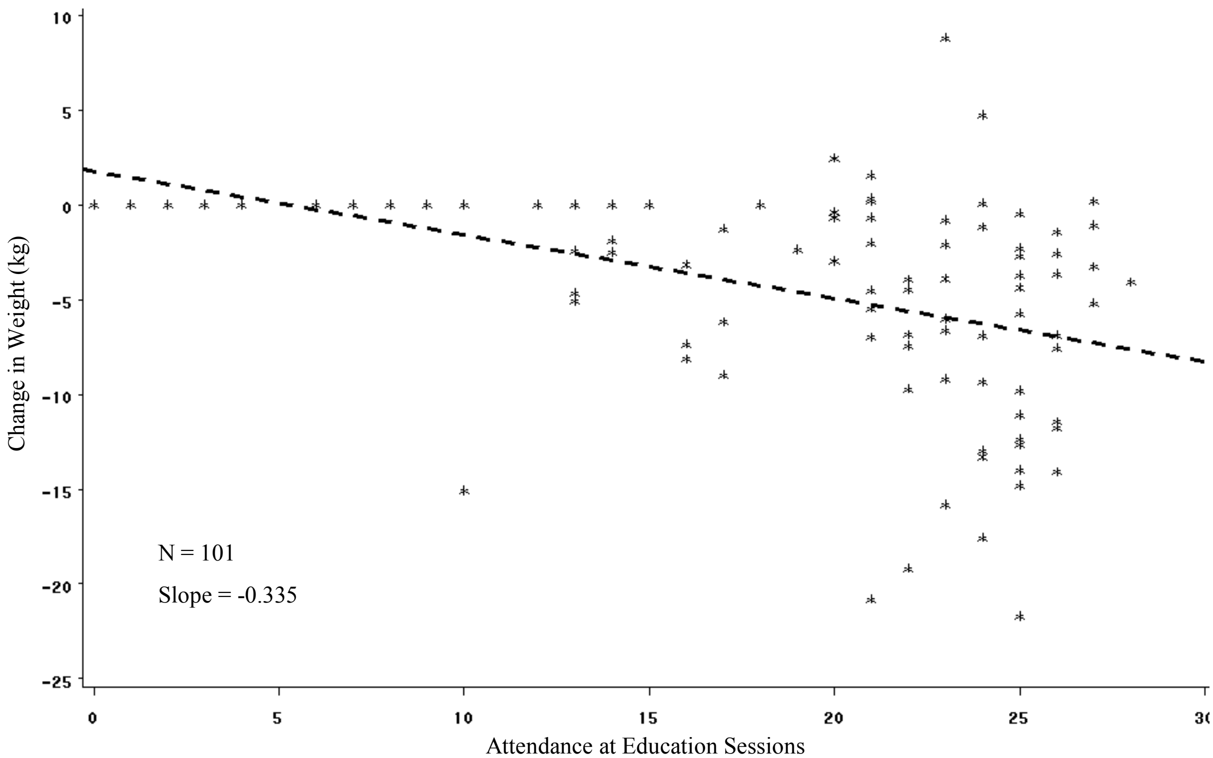

FIGURE 4-3. Change in body weight from baseline to 12 months according to attendance at the education sessions. Data were analyzed under the intention-to-treat principle using the REG procedure (SAS, Version 9.1, Cary, NC).

TABLE 4-5

Stepwise regression models predicting change in body weight among WORLD study participants (n = 101)[1,2]

Model and predictive variables	**β Coefficient (SE)**	**Partial R^2**	**Model R^2**	**P**
Model 1[2]				
Change in aerobic capacity	-0.32 (0.05)	0.1195	0.1195	<0.0001
COGEAT score	0.14 (0.04)	0.0388	0.1584	<0.0001
Change in TFA (g)	0.33 (0.10)	0.0195	0.1779	0.0026
Change in MUFA (g)	-0.10 (0.03)	0.0150	0.1929	0.0077
Change in SFA (g)	0.07 (0.03)	0.0136	0.2065	0.0106
EAT-26 score	0.13 (0.05)	0.0109	0.2173	0.0213
Model 2[3]				
Change in aerobic capacity	-0.33 (0.05)	0.1195	0.1195	<0.0001
COGEAT score	0.15 (0.04)	0.0388	0.1584	<0.0001
Change in TFA (g)	0.06 (0.02)	0.0231	0.1814	0.0010
Baseline body weight	0.31 (0.10)	0.0157	0.1971	0.0063
Change in MUFA (g)	-0.11 (0.03)	0.0164	0.2135	0.0047
Change in SFA (g)	0.07 (0.03)	0.0140	0.2275	0.0087
EAT-26 score	0.13 (0.05)	0.0110	0.2385	0.0188

[1]Models 1 and 2, predicting body weight change. Regression analysis with the forward selection technique was used in which variables were allowed to enter and to stay in the

model at P = 0.05 (SAS, Version 9.1, Cary, NC). Aerobic capacity assessed by VO_2max (ml * kg^{-1} * min^{-1}), COGEAT = Gormally Cognitive Factors Related to Binge Eating Scale (19), EAT-26 = Eating Attitudes Test-26 (17), SFA = saturated fatty acids, MUFA = monounsaturated fatty acids, and TFA = *trans* fatty acids.

[2]Includes changes in macronutrient and fiber intakes, change in aerobic capacity, baseline cognitive-behavioral measures, and attendance at education session.

[3]Includes baseline body weight, changes in macronutrient and fiber intakes, change in aerobic capacity, baseline cognitive-behavioral measures, and attendance at education session.

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CHAPTER FIVE

Impact of the Weight Optimization: Revamping Lifestyles Using the *Dietary Guidelines* (WORLD) Study on Healthy Eating Index-2005 Scores and Energy Density

Abstract

Background: Research indicates that diets consistent with the *Dietary Guidelines* improve chronic disease risk factors and are effective for weight loss; yet, few Americans follow these dietary recommendations.

Objective: The Weight Optimization: Revamping Lifestyles using the *Dietary Guidelines* (WORLD) study evaluated the effects of *Your Healthy World*, a theory-based, education program for weight management, on dietary energy density and Healthy Eating Index-2005 component and summary scores.

Design: Participants (n=101) were randomized to participate in 28 education sessions utilizing *Your Healthy World*, tailored for either a lower-fat (20% kcal from fat) or moderate-fat (35% kcal from fat) diet, in a parallel-arm design over one year. The analyses presented here are based on the women who provided dietary and anthropometric data at baseline and months 4 and 12 (n=60).

Results: Body weight decreased significantly in participants assigned to the lower-fat diet and to the moderate-fat diet (-6.6 and -6.1 kg, respectively; P's < 0.0001 compared to baseline). Participants were reclassified according to actual fat intake because energy and nutrient intakes did not differ between treatment groups. A time effect was seen for increases in total fruit, whole fruit, whole grains, meat and beans, and saturated fat component scores, as well as summary scores, of the HEI-2005 (P < 0.01 for all). Total HEI-2005 scores were not different between participants consuming a lower-fat diet or a moderate-fat diet (80.58 ± 1.95 and 74.69 ± 1.33, respectively; P = 0.13). Component scores for total vegetables, dark green and orange vegetables and legumes, and whole

grains, and total HEI-2005 score increased across tertiles as energy density of the diet decreased ($P < 0.01$ for all). The strongest predictors of energy density were baseline energy density and changes in scores for the total fruit component, the oils component, and total HEI-2005, which together accounted for 56% of the variance in dietary energy density at month 12. The strongest predictors of weight loss were increases in the total vegetables component score, the oils component score, *trans* fat intake, the total grains component score, and baseline body weight, which together accounted for 15% of the variance in weight loss at month 12.

Conclusions: Women can follow the dietary recommendations of the *Dietary Guidelines* for weight loss and maintenance and improve diet quality as assessed by the HEI-2005.

Introduction

The *2005 Dietary Guidelines for Americans* provide evidence-based advice to promote health and reduce chronic disease risk through diet and physical activity (1). Although research indicates that diets consistent with the *Dietary Guidelines*, such as the Dietary Approaches to Stop Hypertension (DASH) diet which is low in energy density (2), improve chronic disease risk factors (3, 4) and are effective for weight loss (5), few Americans follow the recommendations of the *Dietary Guidelines* (6).

One possible reason for lack of adherence to the *Dietary Guidelines* is that consumers struggle to understand the dietary recommendations and consequently find it challenging to change their lifestyle accordingly. For example, consumer research indicates that the general public has difficulty differentiating between types of fats, how they affect health, and how to incorporate fat into a healthy diet (7, 8). Another potential challenge for Americans is identifying a diet that promotes weight loss while remaining nutritionally adequate. As a result of the increasing prevalence of overweight and obesity (9), the *Dietary Guidelines* suggest decreasing caloric intake and increasing physical activity for gradual weight loss. One strategy recommended for weight reduction is consuming foods low in energy density to decrease overall energy intake (1). Studies indicate that various methods of reducing dietary energy density (i.e., increasing fruit and vegetable intake, decreasing fat intake, and consuming low energy-dense soups in place of high energy-dense snacks) both are successful ways to decrease overall energy intake and thus body weight (10, 11). In general, consumers desire easy-to-follow strategies for implementing lifestyle changes and for attaining weight loss (7, 12). Thus, innovative education programs and clinical interventions which translate the recommendations of the *Dietary Guidelines* such that they are easy for the general public to incorporate into everyday life – and especially when trying to lose weight – need to be developed and tested.

The WORLD (Weight Optimization: Revamping Lifestyles using the *Dietary Guidelines*) study examined the effects of a year-long intervention emphasizing diets consistent with the *Dietary Guidelines* and at the extremes of the dietary fat recommendation (i.e., 20% and 35% of energy from fat) during weight loss and maintenance of a healthy body weight. Adherence to the dietary recommendations of the *Dietary Guidelines* was determined by the Healthy Eating Index (HEI)-2005, a tool designed to assess overall diet quality and measure adherence to the *2005 Dietary Guidelines* (13). Since the recommended dietary changes would likely alter the energy density of participants' diets, dietary energy density and its influence on weight loss also was assessed.

Subjects and Methods

Details of the WORLD study design and interventions were published elsewhere (Psota et al, in review), as were the clinical and biochemical effects of the intervention (Psota et al, in review). In brief, this study evaluated the effects of two diets, a lower-fat diet and a moderate-fat diet, as well as physical activity in a weight-management intervention based on the *2005 Dietary Guidelines for Americans*.

The Institutional Review Board at the Pennsylvania State University approved the study protocol and all participants provided written informed consent.

Subjects and Experimental Design

The target population consisted of generally healthy, overweight and obese women who were premenopausal and residing in State College, PA and the surrounding areas. Eligible women were classified as overweight or obese, with a BMI between 25 and 39.9 kg/m^2, and aged 21–50 years with LDL-cholesterol concentrations between 2.60 and 4.91 mmol/l. Exclusion criteria included: 1) the inability to comply with the study protocol, 2) triglycerides > 3.94 mmol/l, 3) the use of lipid-lowering agents (medications, psyllium, fish oil, soy lecithin, and phytoestrogens), 4) lactating, being pregnant, or wishing to become pregnant during the study, 5) having a weight loss ≥10% body weight within the 6 mo before the study, 6) following vegetarian or weight-loss diets at screening, 7) having any of the following conditions: stroke, diabetes, liver disease, kidney disease, or autoimmune diseases, 8) Eating Attitudes Test-26 score > 20 (14), 9) Beck Depression Inventory-II score ≥ 29 (15), 10) Gormally Cognitive Factors Related to Binge Eating Scale score > 30 (16), and 11) Physical Activity Readiness Questionnaire score > 2 (17).

A total of 101 participants were enrolled in the study and randomized to follow either a lower-fat diet (20% kcal from fat) or a moderate-fat diet (35% kcal from fat) for weight management in a parallel-arm design. The two phases of the study were a weight-loss phase (phase 1) and a weight-maintenance phase (phase 2). During phase 1, months 1 through 4, participants consumed a hypo-caloric diet consistent with the *Dietary*

Guidelines. During phase 2, months 5 through 12, participants shifted into weight maintenance and were instructed to consume a eucaloric diet consistent with the *Dietary Guidelines*. The analyses presented here are based on the women who provided dietary and anthropometric data at baseline and months 4 and 12 (n = 60).

Intervention

The intervention consisted of group nutrition education sessions and supervised exercise. The educational program was based on social cognitive theory (SCT) (18) and delivered by problem-based learning (19), such that specific SCT constructs which target behaviors important for health were emphasized and subjects actively participated in the learning process. The educational materials were based on the *Dietary Guidelines* and tailored for the two extremes of the dietary fat recommendations (20% and 35% of calories). Participants were instructed to consume a diet consistent with the *Dietary Guidelines* to meet recommendations for each food group while staying within a calorie range calculated by the Harris-Benedict Equation (20) to induce weight loss of one to two pound(s)/week, as recommended by the NIH/NHLBI Evidence Report (21). Participants attended 28, one-hour group education sessions throughout the 12-month intervention. The exercise component consisted of daily stretching and five aerobic sessions, two supervised and three on-their-own, and two unsupervised strength-training sessions per week. The aerobic exercise sessions initially lasted twenty minutes and increased gradually to 60-90 minutes, consistent with the *Dietary Guidelines*' recommendation for sustained weight loss during adulthood (1). Aerobic exercise was performed 65-85% of the maximal heart rate obtained during the participants' initial test of maximal aerobic capacity.

Data Collection

All measurements were obtained at baseline and 4 and 12 months after randomization by staff members who were unaware of randomization assignment. Trained interviewers at Penn State's Diet Assessment Center Diet collected 24-hour dietary recalls by telephone from each participant on unannounced, random, nonconsecutive days (two weekdays and one weekend day) using a multiple-pass technique (22, 23). Food portion posters (2-D Food Portion Visual, Nutrition Consulting Enterprises, Framingham, Mass) were used to estimate portion sizes (22). Dietary recalls were collected and analyzed using the Nutrient Data System for Research (NDS-R) software version 5.0 (Nutrition Coordinating Center, University of Minnesota, Minneapolis, MN). Three-day average intakes were calculated to estimate intake of energy, nutrients, and food groups at each time-point.

Prior research indicated that including beverages in dietary energy density calculations may weaken associations with outcome variables because of increased within-person variance (24). Thus, energy density values were calculated only on the basis of food intake, excluding all beverages (24), in accordance with other analyses (2).

Twelve components compromise the HEI-2005; five of which represent the major food groups found in MyPyramid (i.e., total fruit; total vegetables; total grains; milk; and meat and beans). The remaining seven components reflect key recommendations emphasized in the *2005 Dietary Guidelines*, such as eating more whole grains, a variety of different vegetables, and specific types of fats. These components include whole fruit; dark green and orange vegetables and legumes; whole grains; oils; saturated fat; sodium; and calories from solid fats, alcohol, and added sugars. The HEI-2005 assesses food and nutrient intakes on a density basis (i.e., amounts per 1000 calories of intake); therefore it determines diet quality while controlling for diet quantity) (13).

The Nutrition Data System for Research (NDSR) output files for nutrients, foods, food components/ingredients, and food groups were used to generate the USDA's HEI-2005 and the 12 component scores using the methodology described in the USDA's technical report (13). NDSR food subgroup files for fruit, vegetables, grains, milk, and meat were summed to contain cup or ounce equivalents for the food-group-based component scores. For fruits and vegetables, NDS-R serving data were converted to cup equivalents based on the MyPyramid Equivalent's Database (25). The NDSR nutrient totals file was used for the sodium, saturated fat, and calories from alcohol and added sugar calculations. To calculate oils and calories from solid fat the ingredients from the NDSR component file were coded based on the type of fat present in meats, meat alternatives, grain products, and oil and solid fat additions to foods or ingredients in commercially prepared foods. Additional details about calculating HEI-2005 from NDSR are described elsewhere (26). Once the components are derived, each one is scored from 0 to 5 (i.e., total fruit; whole fruit; total vegetables; dark green and orange vegetables and legumes; total grains; whole grains), 10 (i.e, milk; meat and beans; oils; saturated fat; sodium), or 20 (i.e., calories from solid fats, alcoholic beverages, and added sugars) with a maximum summary score of 100 (13). For most components, higher intakes result in higher scores; however, the saturated fat, sodium, and calories from solid fats, alcoholic beverages, and added sugars components, lower intake levels result in higher scores because lower intakes are more desirable. For each component, intakes meeting or exceeding the standard are assigned the maximum score for a component; thus, higher scores intake greater adherence to the dietary recommendations of the *Dietary Guidelines*.

Weight was measured using the same calibrated digital scale with the participant dressed in light indoor clothing without shoes. Height was measured once at screening using a calibrated wall-mounted stadiometer. Waist circumference was measured using an anthropometric measuring tape at the uppermost lateral border of the right iliac crest, according to the NHANES III protocol (27).

Statistical Analysis

All statistical analyses were performed by using SAS (version 9.1; Statistical Analyses System, Cary, NC). Analyses were conducted to compare treatment groups. Comparisons also were made between participants whose diet increased in energy density versus those whose diet decreased in energy density from baseline to month 12. Participants were further classified according to tertile cutpoints for energy density. Since percentage of energy from fat did not differ between treatment groups, data also were analyzed by reclassifying participants according to actual reported dietary fat intake. Participants were categorized as consuming a lower-fat diet if average fat intake from months 4 and 12 contributed less than 27.5% of total energy; participants consuming a diet in which average fat intake from months 4 and 12 contributed more than 27.5% of total energy were considered moderate-fat consumers. The cutpoint of 27.5% of energy was chosen because it is the midpoint of the *Dietary Guidelines* recommended range for fat consumption (i.e., 20-35% of energy from fat).

Results are reported as least-squares means ± SEMs. We performed repeated-measures analysis of variance (ANOVA) for continuous variables and chi-square tests for categorical variables. Tukey-Kramer–adjusted *P* values were used to determine whether the differences in the outcome variables were significant. Multivariate regression analysis was performed to determine predictors of weight loss and change in energy density.

Results

Subject Characteristics

Baseline demographic and cognitive-behavioral characteristics were similar among participants assigned to the two diets (Psota et al, under review). Additionally, participants who dropped out of the study did not differ from participants who completed the intervention. The women who completed the study (n = 60), and thus the sample for these analyses, were aged 39.9 ± 0.8 y and had a mean BMI of 30.7 ± 0.5 at baseline. In accordance with the demographic composition of State College, PA, the majority of women were white (98%) with a college or graduate degree (70%).

Of the 32 participants randomized to the lower-fat treatment group, 10 participants reported consuming a lower-fat diet (< 27.5% of energy from fat) during the course of the study. Of the 28 participants assigned to the moderate-fat treatment group, 19 reported consuming a diet moderate in fat (> 27.5% of energy from fat). Thus, when participants were classified according to actual dietary fat intake, 19 participants consumed a lower-fat diet and 41 participants consumed a moderate-fat diet during the weight-management intervention.

Weight Loss

Body weight decreased significantly in participants assigned to the lower-fat diet and to the moderate-fat diet (-6.6 and -6.1 kg, respectively; P's < 0.0001 compared to baseline; Table 5-1). The majority of weight loss occurred during the first four months (-5.2 and -5.6 kg, respectively; P's < 0.0001) with a non-significant loss from month 4 to month 12 (-1.4 and -0.5 kg, respectively). Thus, a significant decrease in BMI was attained by month 4 in both treatment groups and maintained through month 12 (-2.5 and -2.2 units, respectively; time effect, P < 0.0001). Waist circumference was significantly lower at month 4 in the lower-fat treatment group only (-6.1 cm; P < 0.0001 compared to baseline); however, this change was not maintained through month 12 (-2.7 cm compared to baseline; P = 0.12). Reported energy intakes declined for both treatment groups (-179.2 kcal/d; P < 0.0001) and were similar across groups (P = 0.83). Thus, although body weight and BMI were different between treatment groups (P's < 0.05), the amount of weight loss and change in BMI and waist circumference did not differ between the treatment groups. In addition, there were no group effects when participants were reclassified according to actual dietary fat intake or by change in dietary energy density (i.e., increase versus decrease and across tertiles of energy density).

Energy and Nutrient Intakes

Energy and nutrient intakes did not differ between treatment groups ($P > 0.05$ for all). There was a significant group effect for energy, fiber, and percent of energy from carbohydrate, protein, total fat, saturated fat, monounsaturated fat, polyunsaturated fat, and *trans* fat between participants consuming a lower-fat diet and those consuming a moderate-fat diet [$P \leq 0.01$ for all, detailed elsewhere (Psota et al, in preparation)]. Participants consuming a moderate-fat diet had higher energy intakes and percent of energy from total fat, saturated fat, monounsaturated fat, polyunsaturated fat, and *trans* fat; while participants consuming a lower-fat diet had higher intakes of fiber and percent of energy from carbohydrate and protein.

Healthy Eating Index-2005

A time effect was seen for increases in total fruit, whole fruit, whole grains, meat and beans, and saturated fat component scores, as well as summary scores, of the HEI-2005 ($P < 0.01$ for all). Although the scores for whole fruit, total vegetables, whole grains, meat and beans, and saturated fat components were significantly higher at month 4 in comparison to baseline ($P < 0.05$ for all), scores tended to remain higher at month 12 in comparison to baseline values only for the whole grains and saturated fat components ($P \leq 0.10$ for both). Total HEI-2005 summary scores were significantly higher at month 4 and 12 compared to baseline (+6.84 and +4.13, respectively; $P \leq 0.02$ for both).

Only the component scores for milk and sodium differed between participants assigned to the lower-fat and moderate-fat treatment groups. The change in the milk component score was significantly different between participants in the lower-fat treatment group and participants in the moderate-fat treatment group (+0.51 and -1.68, respectively; $P = 0.003$). Scores for the sodium component decreased for participants in the lower-fat treatment group and increased for participants in the moderate-fat treatment group (-0.93 and +1.39, respectively; $P = 0.006$).

When participants were classified according to actual dietary fat intake, a group effect was seen for component scores of total fruit, whole fruit, dark green and orange vegetables and legumes, total vegetables, saturated fat, and total score ($P \leq 0.10$ for all; Table 5-2). Although scores for participants consuming a lower-fat diet were higher for each component, total HEI-2005 scores were not significantly different (80.58 ± 1.95 and 74.69 ± 1.33, respectively; $P = 0.13$) and both groups displayed similar increases in all of the individual component scores ($P \geq 0.10$ for all).

Dietary Energy Density

Baseline dietary energy density values were 1.53 ± 0.06 and 1.44 ± 0.06 kcal/g for the lower-fat and moderate-fat treatment groups, respectively, and did not change over time or differ between treatment groups at any point in time (Table 5-1, $P = 0.70$). Twenty-three participants assigned to the lower-fat treatment group (72%) and 14 participants assigned to the moderate-fat treatment group (50%) consumed a diet lower in energy density in comparison to their baseline diets; while 9 participants in the lower-fat treatment group (28%) and 14 participants in the moderate-fat treatment group (50%) increased the energy density of their diets.

Overall 37 participants (62%) decreased the energy density of their diets from 1.58 ± 0.05 to 1.29 ± 0.05 kcal/g ($P < 0.0001$); while 23 participants (38%) increased the energy density of their diets from 1.36 ± 0.06 to 1.67 ± 0.06 kcal/g ($P < 0.0001$). When participants were classified according to actual dietary fat intake, energy density values were significantly different at baseline, month 4, and month 12 ($P < 0.0001$ for group effect) (Table 5-2). Diets of participants consuming a lower-fat diet were lower in energy density in comparison to diets of participants consuming a moderate-fat diet at each point in time.

To examine the relationship between changes in dietary energy density values and changes in anthropometric measures and diet-related variables, participants were classified into tertiles on the basis of 12-month energy density changes. When tertile cutoffs were applied, participants with an increase in the energy density of their diet were categorized together in tertile 1. Participants with a modest decrease in the energy density of their diet (0.01-0.25 kcal/g) were classified as tertile 2. The remaining participants, those in tertile 3, had the largest decreases in energy density (≥0.26 kcal/g).

Baseline characteristics by tertile of energy density did not differ. Although participants in tertile 3 reported a significant decrease in energy intake (-358 kcal/d; $P < 0.0001$), there was no difference between tertiles for anthropometric measures – weight, BMI, and waist circumference (data not shown). Even though participants in tertile 3 had a substantial decrease in energy intake, the mean weight of food they reported consuming at month 12 was similar to baseline values (Table 5-3).

Patterns of food intake and HEI component and total scores differed among the 3 tertiles of energy density change (Table 5-3). Component scores for total vegetables, dark green and orange vegetables and legumes, and whole grains, and total HEI-2005 score increased across tertiles as energy density of the diet decreased ($P < 0.01$ for all). A similar trend was seen for the component scores for total fruit and whole fruits ($P \leq 0.10$ for both). These differences in scores based on reported food intakes were accompanied by changes in nutrient intake profiles. Decreases in total fat, saturated fat, and monounsaturated fat intakes were greatest in participants with the largest decrease in dietary energy density (tertile 3) (data not shown, $P < 0.05$ for all).

Predictors of Energy Density and Weight Loss

Stepwise regression analyses were performed to determine which dietary changes were most predictive of changes in energy density and weight loss. We analyzed an initial model that included terms for macronutrient intakes and HEI-2005 component scores and total score; a second model also included baseline energy density values (Table 5-4). When baseline energy density values were excluded from the model, the strongest predictors of energy density were changes in the whole fruit component score (25%), monounsaturated fat intake (7%), the total vegetables component score (4%), the oils component score (4%), and total HEI-2005 score (4%), which together accounted for 44% of the variance in energy density change at month 12. When included in the model, baseline energy density had a strong influence on energy density values at 12 months, accounting for 39% of the variance in energy density change. This was followed by changes in the total fruit component score, the oils component score, and total HEI-2005 score which together accounted for 17% of the variability.

A similar analysis was performed to determine which diet-related variables were most predictive of weight loss (Table 5-4). In addition to changes in macronutrient intakes and Healthy Eating Index component scores and total score, the initial model included terms for changes in energy density, energy intake, and food weight; a second model also included baseline body weight. Regardless of whether baseline body weight was included in the model, the strongest predictors of weight loss were changes in the total vegetables component score (4%), the oils component score (4%), *trans* fat intake (2%), and the total grains component score (2%), which together accounted for 13% of the variance in weight loss at month 12. When included in the model, baseline body weight had a small but significant influence on body weight at 12 months, accounting for 1.5% of the variance in weight loss. This was followed by changes in the calories from solid fats, alcohol, and added sugar and the meat and beans component scores which each accounted for 1% of the variability. Thus, changes in dietary changes and baseline body weight together accounted for 17% of the variance in weight loss at month 12.

Discussion

The WORLD study is, to the best of our knowledge, the first randomized controlled trial evaluating the effects of an intensive education program emphasizing the dietary recommendations of the *2005 Dietary Guidelines for Americans* for weight-management. The primary finding of this analysis is that individuals not only can follow the dietary recommendations of the *Dietary Guidelines* for weight management but also can improve adherence to the *Dietary Guidelines* during weight loss and maintenance of a reduced body weight. Participants significantly decreased body weight by 7.7% while significantly increasing HEI-2005 scores. At study entry, the dietary pattern of the study participants was fairly healthy, according to the HEI-2005 with a mean summary score of

74, compared to other samples of American adults [HEI-2005 = 54-58; (6, 28)]. In spite of this, we still demonstrate significant improvements in the component scores for total fruit, whole fruit, whole grains, mean and beans, and saturated fat, along with total HEI-2005 score.

There were no differences between treatment groups for most HEI component scores and HEI total score. This is not surprising considering the intervention and education program, *Your Healthy World*, were similar for both treatment groups. The information about fruits, vegetables, whole grains, and mean and beans (i.e., the foods whose component scores increased) provided to each treatment group were almost identical; while the education program was different for treatment groups in regard to dietary fat. The information about the latter differed such that ingredients contributing fat were used in lesser amounts in the recipes provided in the education program tailored for the lower-fat treatment group. These same recipes were provided in the education program tailored for the moderate-fat treatment group; however, the ingredients contributing to dietary fat were used in slightly greater amounts while ingredients contributing carbohydrate were used in slightly smaller amounts. The striking similarities between the nutrient intakes and dietary patterns of the treatment groups likely is due to the lack of extensive differences in the education programs tailored for the treatment groups. Data from this study suggest that to achieve greater differentiation between nutrient intakes of the treatment groups the education program would need to be altered more substantially. However, since participants in both groups attained and maintained significant weight loss while improving dietary intake, as assessed by the HEI-2005, we do not feel that this is necessary for this purpose. For populations with specific dietary requirements where restrictions in dietary fat are important, such as individuals with hypertriglyceridemia, the education program would need to be revised.

When participants were reclassified according to actual reported dietary fat intake, instead of treatment assignment, total fruit, whole fruit, dark green and orange vegetables and legumes, total vegetables, and saturated fat component scores and total HEI-2005 scores were higher over the course of the study in participants consuming a lower-fat diet. However, participants consuming a moderate-fat diet had a significantly greater change in the HEI-2005 summary score and thus total HEI-2005 scores did not differ between groups at month 12. These differences suggest that participants consuming a diet higher in fat consumed less nutritious food options at baseline and as a result had more opportunity for improving their dietary pattern. Overall, data from this study show that the education program, *Your Healthy World*, was effective for improving dietary patterns.

Although most participants consumed a moderate-fat diet (68%) regardless of treatment group, dietary energy density still decreased for most participants (62%). A significant group effect was observed across tertiles of dietary energy density with the component scores of total vegetables, dark green and orange vegetables and legumes, and whole grains and total HEI score increasing as energy density decreased. These results are in the anticipated direction since dietary energy density is mainly influenced by intakes of fruit, vegetables, and fat, and, to a lesser extent, by dietary fiber (29).

Although change in dietary energy density predicted weight loss in previous studies (2, 10, 11), it did not predict change in body weight at months 4 or 12 in this sample. Potential reasons for conflicting results include a smaller sample size in this study compared to others (i.e., 60 versus 71, 200, and 658). Also, the studies (10, 11) with a sample size [n = 71 (10) and 200 (11)] similar to this study assessed the relationship between changes in weight and energy density over a much shorter time frame – 2 months versus 4 and 12 months in this study. Thus changes in dietary energy density might predict initial weight loss as opposed to long-term weight loss and maintenance. Another possible reason for the differing results is that the change in energy density of the diets in this study ranged from -0.91 to 0.94 kcal/g; whereas in other studies the range of change was much larger [i.e., -2.35 to 1.09 kcal/g; (2)]. If the difference between baseline dietary energy density and the energy density of the diet at months 4 and 12 was as substantial, there might have been an effect on change in body weight. Lastly, dietary energy density was a secondary objective of this intervention while it was a primary target of previous studies (10, 11).

Taken together, the changes in diet-related outcomes attained by WORLD study participants demonstrate that *Your Healthy World* is effective for increasing adherence to the dietary recommendations of the *Dietary Guidelines*. Shifting towards a healthier dietary pattern predicted weight loss and maintenance of a reduced body weight. In addition, these data promote making moderate changes in diet, and thus lifestyle, which can result in significant health improvements long term. Findings from the WORLD study have significant implications for future *Dietary Guidelines* and also identify opportunities for future studies, such as testing the education program in other populations.

TABLE 5-1

Effects of treatment diets on anthropometric measures and diet-related variables[1,2]

Variable	Baseline	Month 4	Month 8	Month 12
Body weight (kg)	82.2 ± 1.6	76.8 ± 1.6[a]	75.9 ± 1.6[a]	75.9 ± 1.6[a]
Lower-fat	86.0 ± 2.1	80.8 ± 2.1[a]	79.8 ± 2.1[a]	79.5 ± 2.1[a]
Moderate-fat	78.4 ± 2.3	72.7 ± 2.3[a]	72.0 ± 2.3[a]	72.3 ± 2.3[a]
Body mass index (kg/m^2)	30.5 ± 0.5	28.5 ± 0.5[a]	28.2 ± 0.5[a]	28.2 ± 0.5[a]
Lower-fat	31.6 ± 0.7	29.7 ± 0.7[a]	29.3 ± 0.7[a]	29.1 ± 0.7[a]
Moderate-fat	29.4 ± 0.8	27.3 ± 0.8[a]	27.1 ± 0.8[a]	27.2 ± 0.8[a]
Waist circumference (cm)	99.1 ± 1.7	93.5 ± 1.7[a]	92.9 ± 1.7[a]	95.8 ± 1.7
Lower-fat	100.3 ± 2.3	94.1 ± 2.3[b]	94.1 ± 2.3[a]	97.8 ± 2.3
Moderate-fat	98.0 ± 2.5	92.9 ± 2.5	91.6 ± 2.5[d]	93.9 ± 2.5
Energy density (kcal/g food)	1.49 ± 0.04	1.40 ± 0.04	-	1.45 ± 0.04
Lower-fat	1.53 ± 0.06	1.36 ± 0.06[a]	-	1.40 ± 0.06

Moderate-fat	1.44 ± 0.07	1.44 ± 0.06	-	1.50 ± 0.06
Total energy (kcal)	1576.7 ± 47.2	1377.1 ± 47.2[a]	-	1397.5 ± 47.4[a]
Lower-fat	1612.5 ± 64.5	1387.3 ± 64.5[a]	-	1378.5 ± 64.5[a]
Moderate-fat	1540.9 ± 68.9	1366.9 ± 68.9[a]	-	1416.5 ± 69.5
Food weight (g)	1818.1 ± 63.1	1686.1 ± 63.1[a]	-	1740.4 ± 63.3
Lower-fat	1889.4 ± 86.2	1806.0 ± 86.2	-	1824.2 ± 86.2
Moderate-fat	1746.7 ± 92.1	1566.3 ± 92.1[a]	-	1656.6 ± 92.7

[1]Values are expressed as mean ± standard error. All outcomes were analyzed with repeated-measures ANOVA using the MIXED procedure (SAS, Version 9.1, Cary, NC). A significant time effect was observed for body weight, body mass index, waist circumference, energy, and food weight (P's < 0.01). A significant treatment effect was observed for body weight and body mass index (P's <0.01).

[2]Significant differences within a row are denoted by: [a] $P \leq 0.05$, compared to baseline; [b] $P \leq 0.10$, compared to baseline.

TABLE 5-2

HEI-2005 total and component scores when categorizing participants by dietary fat intake[1,2]

Component	**Baseline**	**Month 4**	**Month 12**
Energy density (kcal/g food)	1.43 ± 0.04	1.34 ± 0.04	1.38 ± 0.04
Lower-fat	1.28 ± 0.07	1.17± 0.07	1.20 ± 0.07
Moderate-fat	1.58 ± 0.05	1.50 ± 0.05	1.56 ± 0.05
Total energy (kcal)	1522.8 ± 48.3	1336.8 ± 48.3[a]	1365.7 ± 48.6[a]
Lower-fat	1369.4 ± 79.8	1225.0 ± 79.8	1282.9 ± 80.5
Moderate-fat	1676.2 ± 54.4	1448.6 ± 54.4[a]	1448.4 ± 54.5[a]
Food weight (g)	1809.4 ± 68.8	1681.0 ± 68.8[a]	1747.7 ± 69.1
Lower-fat	1772.8 ± 113.8	1645.1 ± 113.8	1751.3 ± 114.4
Moderate-fat	1846.0 ± 77.4	1716.8 ± 77.4	1744.1 ± 77.5
Total fruit	2.8 ± 0.2	3.8 ± 0.2[a]	3.2 ± 0.2[d]
Lower-fat	3.5 ± 0.4	4.4 ± 0.4	3.9 ± 0.4
Moderate-fat	2.2 ± 0.2	3.1 ± 0.2[a]	2.4 ± 0.3

Whole fruit (not juice)	3.4 ± 0.2	4.4 ± 0.2[a]	3.8 ± 0.3
Lower-fat	4.0 ± 0.4	4.9 ± 0.4	4.6 ± 0.4
Moderate-fat	2.8 ± 0.3	4.0 ± 0.3[a]	3.1 ± 0.3
Total vegetables	4.0 ± 0.2	4.4 ± 0.2	4.1 ± 0.2
Lower-fat	4.4 ± 0.3	4.6 ± 0.3	4.2 ± 0.3
Moderate-fat	3.7 ± 0.2	4.2 ± 0.2	4.1 ± 0.2
Dark green and orange vegetables and legumes	3.3 ± 0.3	3.7 ± 0.3	3.7 ± 0.3
Lower-fat	4.0 ± 0.4	4.2 ± 0.4	4.0 ± 0.4
Moderate-fat	2.7 ± 0.3	3.2 ± 0.3	3.3 ± 0.3
Total grains	4.9 ± 0.05	4.9 ± 0.05	4.9 ± 0.05
Lower-fat	4.8 ± 0.1	5.0 ± 0.1	4.9 ± 0.1
Moderate-fat	4.9 ± 0.1	4.8 ± 0.1	5.0 ± 0.1
Whole grains	3.8 ± 0.2	4.4 ± 0.2[a]	4.3 ± 0.2
Lower-fat	4.2 ± 0.3	4.3 ± 0.3	4.5 ± 0.3

Moderate-fat	3.5 ± 0.2	4.5 ± 0.2[a]	4.0 ± 0.2
Milk	7.5 ± 0.4	7.8 ± 0.4	7.5 ± 0.4
Lower-fat	7.0 ± 0.6	8.0 ± 0.6	7.3 ± 0.6
Moderate-fat	8.0 ± 0.4	7.8 ± 0.4	7.7 ± 0.4
Meat and beans	8.1 ± 0.3	9.1 ± 0.3[c]	8.6 ± 0.3
Lower-fat	8.5 ± 0.6	8.9 ± 0.6	8.7 ± 0.6
Moderate-fat	7.6 ± 0.4	9.2 ± 0.4[a]	8.6 ± 0.4
Oils	8.1 ± 0.3	8.6 ± 0.3	8.3 ± 0.3
Lower-fat	8.6 ± 0.5	8.6 ± 0.5	7.8 ± 0.5
Moderate-fat	7.7 ± 0.4	8.7 ± 0.4[c]	8.7 ± 0.4
Saturated fat	6.2 ± 0.4	7.4 ± 0.4[a]	6.9 ± 0.4
Lower-fat	7.9 ± 0.6	8.8 ± 0.6	8.3 ± 0.6
Moderate-fat	4.6 ± 0.4	6.0 ± 0.4[c]	5.6 ± 0.4
Sodium	2.8 ± 0.3	3.0 ± 0.4	2.8 ± 0.3
Lower-fat	2.5 ± 0.6	2.5 ± 0.6	2.9 ± 0.6

Moderate-fat	3.2 ± 0.4	3.4 ± 0.4	2.6 ± 0.4
SoFAAS	19.3 ± 0.3	19.0 ± 0.3	19.6 ± 0.3
Lower-fat	19.3 ± 0.5	18.8 ± 0.5	19.4 ± 0.5
Moderate-fat	19.3 ± 0.4	19.3 ± 0.4	19.7 ± 0.4
Total HEI	74.3 ± 1.2	80.5 ± 1.2[c]	77.6 ± 1.2[a]
Lower-fat	78.6 ± 1.0	82.6 ± 2.0	80.6 ± 2.0
Moderate-fat	70.1 ± 1.3	78.3 ± 1.3[a]	74.7 ± 1.3[c]

[1]Values are expressed as mean ± standard error. All outcomes were analyzed with repeated-measures ANOVA using the MIXED procedure (SAS, Version 9.1, Cary, NC). A significant time effect was observed for total energy, food weight, and total fruit, whole fruit, whole grains, and total HEI scores (P's < 0.05). A trend for a time effect was observed for the component scores for meat and beans and saturated fat (P's = 0.07). A significant group effect was observed for energy density, total energy, and total fruit, whole fruit, dark green and orange vegetables and legumes, saturated fat, and total HEI scores (P's < 0.01). A trend for a group effect was observed for the component score for total vegetables (P = 0.08).

[2]Significant differences within a row are denoted by: [a] P ≤ 0.05, compared to baseline; [b] P ≤ 0.05, compared to month 4; [c] P ≤ 0.10, compared to baseline; [d] P ≤ 0.10, compared to month 4.

TABLE 5-3

Change in diet-related variables and HEI-2005 total and component scores when categorizing participants by tertile of 12-month change in dietary energy density value[1]

	12-month change in dietary energy density		
	Tertile 1 (increase) (n = 23)	**Tertile 2 (moderate decrease) (n = 19)**	**Tertile 1 (greatest decrease) (n = 18)**
Energy density (kcal/g food)			
Baseline	1.32 ± 0.06[a]	1.41 ± 0.07[a,b]	1.78 ± 0.07[c]
Change	0.33 ± 0.05[a]	-0.11 ± 0.05[b]	-0.45 ± 0.06[c]
Total energy (kcal)			
Baseline	1464.3 ± 75.8[a]	1551.2 ± 83.4[a]	1755.0 ± 85.7[a]
Change	-54.9 ± 95.4[a]	-179.4 ± 104.9[a]	-358.0 ± 107.8[a]
Food weight (g)			
Baseline	1923.9 ± 103.9[a]	1813.2 ± 114.3[a]	1703.8 ± 117.4[a]

Change	-199.4 ± 96.0[a]	-57.4 ± 105.6[a]	35.1 ± 108.5[a]
Total fruit			
Baseline	2.9 ± 0.3[a]	2.7 ± 0.4[a]	2.0 ± 0.4[a]
Change	-0.4 ± 0.2[a]	0.6 ± 0.5[a]	1.0 ± 0.5[a]
Whole fruit (not juice)			
Baseline	3.3 ± 0.4[a]	3.6 ± 0.4[a]	2.5 ± 0.4[a]
Change	-0.3 ± 0.5[a]	0.4 ± 0.5[a]	1.2 ± 0.5[a]
Total vegetables			
Baseline	4.0 ± 0.2[a]	4.3 ± 0.3[a]	3.3 ± 0.3[a]
Change	-0.5 ± 0.3[a]	0.2 ± 0.3[a,b]	1.2 ± 0.3[b]
Dark green and orange vegetables and legumes			
Baseline	3.6 ± 0.4[a]	3.3 ± 0.4[a]	4.9 ± 0.1[a]
Change	-1.0 ± 0.4[a]	0.9 ± 0.5[a,b]	1.8 ± 0.5[b]
Total grains			
Baseline	4.8 ± 0.1[a]	4.9 ± 0.1[a]	3.1 ± 0.3[a]

Change	0.2 ± 0.1^{a}	-0.1 ± 0.1^{a}	0.1 ± 0.1^{a}
Whole grains			
Baseline	3.5 ± 0.3^{a}	4.5 ± 0.3^{a}	3.1 ± 0.3^{a}
Change	0.4 ± 0.3^{a}	-0.1 ± 0.3^{a}	1.1 ± 0.4^{a}
Milk			
Baseline	7.6 ± 0.6^{a}	7.4 ± 0.6^{a}	8.0 ± 0.6^{a}
Change	-0.4 ± 0.6^{a}	0.7 ± 0.6^{a}	-0.7 ± 0.6^{a}
Meat and beans			
Baseline	8.1 ± 0.5^{a}	8.4 ± 0.6^{a}	7.2 ± 0.6^{a}
Change	0.5 ± 0.7^{a}	0.2 ± 0.7^{a}	1.9 ± 0.8^{a}
Oils			
Baseline	7.7 ± 0.5^{a}	8.0 ± 0.5^{a}	8.3 ± 0.5^{a}
Change	0.5 ± 0.7^{a}	0.1 ± 0.7^{a}	0.7 ± 0.8^{a}
Saturated fat			
Baseline	6.1 ± 0.6^{a}	6.1 ± 0.7^{a}	4.5 ± 0.7^{a}

Change	-0.3 ± 0.7[a]	0.4 ± 0.8[a]	2.4 ± 0.8[a]
Sodium			
Baseline	3.6 ± 0.5[a]	2.2 ± 0.6[a]	3.0 ± 0.6[a]
Change	-0.8 ± 0.7[a]	0.8 ± 0.8[a]	-0.7 ± 0.8[a]
SoFAAS			
Baseline	19.0 ± 0.5[a]	19.6 ± 0.5[a]	19.5 ± 0.5[a]
Change	0.4 ± 0.6[a]	0.0 ± 0.6[a]	0.5 ± 0.6[a]
Total HEI			
Baseline	74.3 ± 1.8[a]	75.0 ± 2.0[a]	68.5 ± 2.1[a]
Change	-1.5 ± 2.3[a]	3.7 ± 2.5[a,b]	10.5 ± 2.6[b]

[1]Values are expressed as mean ± standard error. All outcomes were analyzed with repeated-measures ANOVA using the MIXED procedure (SAS, Version 9.1, Cary, NC). Values in the same row with different superscript letters are significantly different, P < 0.05. The changes in energy density were 0 to 0.94 kcal/g (increase), -0.01 to -0.25 kcal/g (moderate decrease), and -0.26 to -0.91 kcal/g (largest decrease), respectively. A significant time effect was observed for total fruit, whole fruit, and total HEI scores (P's < 0.05). A trend for a time effect was observed for the component scores for total grains and meat and beans (P ≤ 0.10 for both). A significant group effect was observed for energy density, and total vegetables, dark green and orange vegetables and legumes, whole grains, and

total HEI scores ($P < 0.01$ for all). A trend for a group effect was observed for total energy and the component scores for total fruit and whole fruit ($P \leq 0.10$ for all).

TABLE 5-4

Stepwise regression models predicting change in energy density and body weight among WORLD study participants (n = 60)[1,2]

Model and predictive variables	β Coefficient (SE)	Partial R^2	Model R^2	P
Model 1a[2]				
Change in whole fruits	-0.02 (0.01)	0.2538	0.2538	<0.0001
Change in MUFA (g)	0.01 (0.001)	0.0695	0.3233	<0.0001
Change in total vegetables	-0.03 (0.02)	0.0401	0.3634	<0.0001
Change in oils	0.04 (0.01)	0.0359	0.3993	<0.0001
Change in HEI-2005	-0.01 (0.002)	0.0416	0.4409	<0.0001
Change in whole grains	-0.04 (0.01)	0.0151	0.4560	0.0052
Change in total grains	0.10 (0.03)	0.0184	0.4744	0.0017
Model 1b[3]				
Baseline energy density	-0.46 (0.05)	0.3947	0.3947	<0.0001

Change in total fruit	-0.03 (0.01)	0.1173	0.5119	<0.0001
Change in oils	0.04 (0.01)	0.0323	0.5442	<0.0001
Change in HEI-2005	-0.01 (0.002)	0.0154	0.5596	0.0017
Change in MUFA (g)	0.004 (0.001)	0.0094	0.5690	0.0130
Change in total grains	0.09 (0.03)	0.0093	0.5783	0.0128
Change in sodium	0.001 (0.005)	0.0093	0.5876	0.0116
Model 2a[4]				
Change in total vegetables	0.90 (0.21)	0.0400	0.0400	0.0001
Change in oils	-0.38 (0.08)	0.0454	0.0854	<0.0001
Change in trans fatty acids (g)	0.26 (0.09)	0.0240	0.1094	0.0023
Change in total grains	-1.45 (0.48)	0.0223	0.1317	0.0029
Model 2b[5]				
Change in total vegetables	1.08 (0.21)	0.0400	0.0400	0.0001
Change in oils	-0.36 (0.09)	0.0454	0.0854	<0.0001
Change in trans fatty acids (g)	0.20 (0.09)	0.0240	0.1094	0.0023

Change in total grains	-2.04 (0.51)	0.0223	0.1317	0.0029
Change in baseline weight (kg)	-0.06 (0.02)	0.0146	0.1463	0.0151
Change in SoFAAS	0.25 (0.09)	0.0120	0.1583	0.0263
Change in meat and beans	-0.19 (0.09)	0.0103	0.1687	0.0387

[1]Model 1 (a and b), predicting energy density change; Model 2 (a and b), predicting body weight change. Regression analysis with the forward selection technique was used in which variables were allowed to enter and to stay in the model at P = 0.05 (SAS, Version 9.1, Cary, NC).

[2]Includes changes in macronutrient intakes and Healthy Eating Index component scores and total score.

[3]Includes baseline energy density and changes in macronutrient intakes and Healthy Eating Index component scores and total score.

[4]Includes changes in macronutrient intakes, Healthy Eating Index component scores and total score, food weight, and energy density.

[5]Includes baseline body weight and changes in macronutrient intakes, Healthy Eating Index component scores and total score, food weight, and energy density.

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CHAPTER SIX

CONCLUSION

The WORLD study is the first randomized controlled trial evaluating the effects of an intensive weight-management program emphasizing the dietary and physical activity recommendations of the *2005 Dietary Guidelines for Americans*. The primary finding of the study is that diets across the recommended range of fat intake (i.e., 20-35% kcal from fat) were equally effective for weight loss and weight maintenance. In particular, participants were able to maintain weight loss during the maintenance period and did not experience the rebound in body weight often seen in other studies. In addition, clinical (i.e., BMI, waist circumference, body composition, blood pressure, and aerobic capacity), biochemical (i.e., lipids and CRP), and diet-related factors (i.e., nutrient intakes, HEI-2005 scores, and energy density) were similar between treatment groups. Another key finding of this study was that individuals not only can follow the dietary recommendations of the *Dietary Guidelines* for weight management but also can improve adherence to the *Dietary Guidelines* during weight loss and maintenance of a reduced body weight.

The WORLD study addressed the proposed objectives and hypotheses of this dissertation. Since energy and nutrient intakes did not differ between treatment groups, reclassification of the participants according to actual fat intake answered the proposed questions. Specifically, the findings demonstrate that a diet at the extremes of the dietary fat recommendations of the *2005 Dietary Guidelines* is equally effective for weight loss while achieving comparable nutrient adequacy. As hypothesized, HDL-cholesterol concentration significantly increased and triglyceride concentration significantly decreased in participants consuming a moderate-fat diet but remained unchanged in comparison to baseline values in participants consuming a lower-fat diet. Also hypothesized and demonstrated was that consuming a lower-fat diet was associated with lower total and LDL-cholesterol concentrations.

In regard to the second primary hypothesis, the results indicate that both lower-fat and moderate-fat diets can be nutritionally adequate, based on the HEI-2005 summary score. Although the participants consuming a lower-fat diet had higher component scores for fruit, vegetables, and saturated fat, these component scores and the summary score of the HEI-2005 were all substantially higher in participants consuming a moderate-fat diet in comparison to data from other samples (1-4). One hypothesis was that HEI-2005 scores would be directly related to change in body weight. Although this relationship was not evident, a possible explanation would be limitations in the tool itself. Since dietary indices such as the HEI-2005 are more effective in evaluating relationships between diet and health outcomes if scores vary considerably in a population (5), the limited range of scores in this sample could explain the lack of an association between HEI-2005 summary score and weight loss. Another potential reason is that individuals improved HEI-2005 scores regardless of amount of weight loss. This may also explain why energy density did not predict weight loss even though most participants lost weight and HEI-2005 component scores increased over time for fruits, vegetables and whole grains – foods that influence dietary energy density (6). Together these findings demonstrate that *Your Healthy World* is effective for increasing adherence to the *Dietary Guidelines* and consumption of healthy foods, across a range of weight loss and during weight maintenance.

The WORLD study contributes to the evidence base regarding dietary interventions for weight loss, weight maintenance, and chronic disease risk reduction.

These data confirm that diets with differing macronutrient profiles can be equally effective for weight loss (7-11). Also, this study demonstrates that people struggle to follow a lower-fat diet (12-14) and diets that are significantly different than their usual intakes (12, 14); that people under-report energy and nutrient intakes (15-17); and that physical activity is an important component of weight management (18). Additionally, cognitive-behavioral state impacts weight loss (19-21) and attendance at information and support sessions improves weight loss (22-25).

The strengths of the WORLD study are numerous. First, the education program, *Your Healthy World*, is theory-based and underwent extensive formative evaluation (26). The evaluation process included expert review to establish content validity and cognitive interviews with the target population to ascertain face validity. In addition, the feasibility of delivering the education program via problem-based learning (PBL) was determined in a pilot study. The relatively large sample size of the study and use of intention-to-treat analyses strengthen the conclusions of the WORLD study. The study was designed to determine the effectiveness of implementing the *Dietary Guidelines* for weight management and chronic disease risk reduction; therefore, the conservative approach for statistical analyses involving weight loss and biomarkers was appropriate. Although the generalizability of the results may be disputed since the sample included primarily Caucasian women, the profile of these women based on BMI and LDL-cholesterol concentration is similar to the majority of women in the United States (27, 28). In addition, the target population has the potential to greatly influence food choices and dietary intake of the family (29-35) – and specifically children who are the focus of many obesity prevention programs (36-39).

The limitations of the WORLD study are seen in a few different aspects of the study. Measuring a biomarker to verify dietary intake, such as serum carotenoids for fruit and vegetable intakes, would have contributed greatly to the results of this study. As mentioned above, the demographics of the study sample limits the generalizability of the study results. Lastly, it would have been prudent for additional components of the intervention to be theory-based, opposed to utilizing the theoretical framework primarily for developing the education program. Additionally, gathering more data regarding the aspects of the theoretical framework that worked or did not work would have also enhanced the results of the WORLD study.

The distinguishing characteristics of the WORLD study lend to its ability to contribute to a growing evidence-base regarding interventions for weight management and chronic disease risk reduction. Typically the *Dietary Guidelines* are the dietary recommendations for a "standard of care" or control group in nutrition interventions (40, 41). However, they are our national guidelines and there was a need to test them as rigorously as other diets utilized for weight loss have been tested (40, 41) – not only to validate our national recommendations but also to determine the effectiveness of them and to provide insight for future *Dietary Guidelines* Advisory Committees.

Although problem based learning (PBL) has been incorporated into medical school education (42) and more recently has been used to disseminate nutrition information (43-45), it has not be used over the long-term in a consumer population. Therefore, delivering the information contained in *Your Healthy World* through PBL to consumers over a one year period was another unique characteristic of the study. Additionally, the use of PBL is a potential strength of the intervention since it encourages social interaction and support – two behaviors that improve weight loss success (25, 46). The impact of PBL in this intervention is one component of the study that will be addressed in future analyses.

Other analyses to be conducted on the large dataset of the WORLD study include assessing cognitive-behavioral and physical activity outcomes. The effects of the intervention on perceived quality of life (47-49), eating competence (50-53), eating behavior (54, 55), diet satisfaction (56, 57), nutrition knowledge (57), and self-reported physical activity (58, 59) will be determined. Lastly, the educational components of the study, such as participant inquiries during sessions and group ratings of the session topics and activities, have yet to be analyzed.

Potential areas that future studies could explore are the obstacles to changing dietary fat intake, and more specifically barriers for consuming a lower-fat diet. Also, a weight management intervention which assesses the usual diet of participants prior to randomization and then assigns participants to a treatment group that matches their usual diet profile would greatly add to the literature. Although this study design would not be consistent with random assignment, it would help determine if individualized treatments improve weight-loss and maintenance, long-term adherence to lifestyle strategies, and risk factors for chronic disease. If this approach were effective, it should be tested in a variety of populations and assessed in the clinical setting. Also, *Your Healthy World* should be tailored and evaluated in other population groups (i.e., children, older adults, and men). Lastly, the education materials and thus future interventions should incorporate more information about the strategies recommended for weight management in the *Dietary Guidelines*, such as decreasing energy density.

In conclusion, the WORLD study demonstrates that individuals can successfully lose and maintain weight while following diets consistent with the dietary recommendations of the *Dietary Guidelines*, as assessed by the HEI-2005, and across a range of dietary fat intake. The improvements in the dietary pattern of participants show that *Your Healthy World* is effective for increasing adherence to the dietary recommendations of the *Dietary Guidelines* during weight loss and maintenance. Data from this study also confirm previous findings regarding dietary intake and the effects on blood lipids. Overall, these data promote making moderate lifestyle changes which can result in significant health improvements and increase dietary adherence long term. The study findings also emphasize the importance of considering an individual's usual dietary intake when making dietary recommendations for weight management and chronic disease risk reduction, which has important implications for future research studies, clinical practice, and future *Dietary Guidelines for Americans*. Findings from this study support using the *Dietary Guidelines* for health promotion and chronic disease risk reduction during weight loss and maintenance of a reduced body weight.

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CHAPTER SEVEN

EPILOGUE

During this research project, many lessons were learned regarding the research process. From conception of the study through data analysis, it was important to be flexible and "troubleshoot" continuously. Prior to submitting the grant which funded this research, we had to revise a few project objectives and activities such that it was more inline with the aims of the funding agency [i.e., National Research Initiative of the United States Department of Agriculture (USDA) Cooperative State Research, Education and Extension Service (CSREES)]. For example, we incorporated an outreach component into the project which is a primary aim of the USDA CSREES. By doing so, we not only improved our chances for receiving funding but more importantly we greatly enhanced the research such that the education program that was developed and tested will now be adapted for another population group (i.e., economically disadvantaged individuals).

Once the project was funded, I became more aware of the importance of receiving feedback from the target audience regarding the education program. Therefore, I conducted cognitive interviews with women representative of the target audience. The feedback I obtained about the content, graphics, and format of the education materials was invaluable. Participant comments addressed font type, preferring "less formal" font (i.e., Comic Sans MS) over "more formal" font (i.e., Times New Roman), and layout, favoring a booklet over four individual sheets of paper. Other suggestions were to list websites to which one could refer for additional information and to include photographs of the meals in the recipes. Another aspect of the project that was not originally planned was a pilot test of the education materials and delivery method of the education program. Although very time-consuming, the pilot test helped determine the feasibility of planned activities for the education sessions and also the likability of the program and delivery method. Following the pilot study, the number of case study problems in the education program was reduced while the number of hands-on activities (e.g., estimating portion sizes and cooking healthy snacks) was increased based on participant feedback and preferences.

During the implementation of the intervention, many important new aspects of study design and execution became apparent. Although we anticipated that parking on campus would be challenging and tried to plan accordingly [i.e., scheduling appointments at the General Clinical Research Center (GCRC), hours at the training room, and class times around other studies and college courses], it was more difficult than anticipated. Therefore, we made additional parking arrangements with an on-campus parking garage and set-up a monthly reimbursement program for study participants. Since prior research studies from our group did not include a supervised exercise portion, we learned a lot about including such activities in a clinical intervention. Scheduling was a main consideration for training and education class times. Therefore, we planned around work hours by having early morning, lunchtime, and evening hours available for training sessions. Education classes were held over the lunch-hour or in the evening hours. Childcare heavily influenced scheduling as well and was more challenging during the summer months than during the rest of the year. We tried to provide participants with various childcare options by providing a contact list of college students available for watching children and also a list of other study participants who were interested in group childcare. In the future, I would plan to have a pre-study questionnaire or a post-pilot study questionnaire to assess potential obstacles, such as these, that would be specific to the target audience. If the study was designed to assess efficacy, I would try to minimize as many obstacles as possible. If the study was designed to assess real-world effectiveness, I would consider this when addressing barriers to implementing the intervention.

The primary lesson learned regarding the institutional aspects of the study pertained to reporting problems and adverse effects to the Institutional Review Board (IRB). Since the intervention included supervised activity in a previously sedentary population, various problems (e.g., shin splits versus chronic back pain) arose that required very different measures in terms of medical attention and reporting to the IRB. Although the majority of the problems were minor and only needed to be reported to the IRB annually, it was more than I experienced when conducting other research studies due to the larger sample size and research activities (e.g., physical activity) of this intervention. To address such problems, I developed a protocol to be followed by research staff that included forms provided by the IRB, additional documentation for our study files, and a notification procedure for the study staff, the GCRC staff, and the IRB office.

Detailed records were kept for all aspects of the study. Throughout the intervention, different ways of documenting were determined to be more beneficial than others. For example, when a participant did not show up for an appointment at the GCRC I found it best to note the absence and reason for it in the online calendar. Therefore, it was easy to keep track of what data had been collected from each participant at each point in time. To aid collection of various serum and plasma samples for assays, I created a template map for the boxes in which the samples were stored for the same assay (i.e., one map for a “lipids” box, one map for a “glucose” box, etc.). Although this was more organized than previous methods used by our group, it could still be greatly improved. In the future, I would make a map for each and every box of samples. Thus, if there were seven boxes of samples to be analyzed for lipid levels, I would have seven individual boxmaps instead of one template map. I also would suggest having the individual responsible for aliquoting and boxing the serum and plasma samples initialize on the map for each sample he/she handled. Since a few individuals may be responsible for such duties this would aid organization and enhance accountability for each task at hand. In addition to initializing datapoints collected, I would recommend managing data entry the same way. Since there was a large volume of data collected in this study, various research assistants entered data throughout the intervention. Although the data files were set-up prior to data entry, some assistants altered them in a way in which the files could not be merged or analyzed with the statistics program I used. Consequently many datapoints needed to be re-entered and in turn delays analysis and manuscript preparation.

Overall, I think intensive training for all staff involved in any aspect of the research project is an excellent use of time. Training helps to standardize all study activities and to prepare study staff for anticipated challenges and to potentially provide the knowledge for handling unanticipated issues that may arise. During training, it is very important to emphasize consistency with the research protocol and participant confidentiality during all study activities (i.e., recruitment, enrollment, education sessions, training sessions, data collection, data management, and data analysis).

APPENDIX

INFORMED CONSENT FORM FOR CLINICAL RESEARCH STUDY

Title of Project:	Development, implementation, & testing an education program to teach weight loss using the 2005 Dietary Guidelines to pre-menopausal women (IRB 22588)
Principal Investigator:	Penny Kris-Etherton, PhD, RD Email: pmk3@psu.edu S-126 Henderson University Park, PA 16802 814-863-2923
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ORP USE ONLY: IRB# 22588 Doc.# 1
The Pennsylvania State University
Office for Research Protections
Approval Date: 03/16/06 M. Becker
Expiration Date: 02/15/07 M. Becker
Biomedical Institutional Review Board

This is to certify that you, ______________________________ (**print your name**), have been given the following information regarding your participation as a volunteer in a program of investigation under the supervision of Drs. Kris-Etherton and Lohse.

This consent form may contain words you do not understand. Please ask the study personnel to explain any words or information you do not clearly understand.

PLEASE READ EVERY PAGE CAREFULLY AND INITIAL THE BOTTOM OF EACH PAGE WHEN YOU HAVE HAD ALL OF YOUR QUESTIONS ANSWERED TO YOUR SATISFACTION.

Purpose of the Study

You have been invited to participate in a clinical research study to test the effectiveness of two diets and physical activity on weight-loss. You will be assigned to one of the two diets and must follow these diets during the entire study.

Procedures to be Followed

Screening

You understand if you agree to participate in this study your participation will be expected to last for 12 months once you are enrolled into the study. The screening for this study will consist of an initial telephone screening and then if eligible, you will be scheduled for an initial assessment visit at the General Clinical Research Center (GCRC) at Noll lab. The initial screening visit will consist of: reading and signing the consent form; filling out forms (medical history, eating attitudes test, personal information, dietary information); measuring height and weight so your body mass index (BMI) can be calculated; physical activity profile obtained by interview; and measuring your blood pressure (BP). If after these measurements, it is determined that you are eligible, a blood sample will be taken from your arm for a blood test for a complete blood count, to check liver and kidney function and for a blood fat panel (total cholesterol, LDL-cholesterol, HDL-cholesterol and triglycerides). You will be contacted within 3-5 days with the results of the screening blood sample. A clinician at the GCRC will review all of the screening data to determine if you are still eligible for the study. If you are still eligible for the study (and if needed), you will be scheduled for a second appointment consisting of a 12 lead EKG procedure done – this is a test to record the rhythm of your heartbeat and to look for any abnormalities – and a physical exam. If after this second appointment, you are still eligible for the study you will be assigned to one of two diet groups, either moderate-fat or low-fat. An appointment for your baseline assessment will be scheduled as soon as you qualify for the study.

Weight-Loss Period

The weight-loss period will last approximately 4 months. The weight loss goal for this period will be 1-2 pounds per week and to attain approximately 10% of body weight loss. Once the weight-loss period ends, you will move into the period of weight maintenance. If you regain weight, you will be counseled about the appropriate calorie intake and ways to achieve this by reviewing the information already given to you from study personnel.

During the weight-loss period of the study, you will be expected to attend a weekly group education session for diet and physical activity counseling. You will be asked to choose a set time to attend the weekly meeting. At this meeting you will be weighed and receive a 60-minute education program about healthy lifestyle habits for eating and exercising. The education program will be based on the *2005 Dietary Guidelines* and tailored to your diet assignment. You will be provided with dietary information, such as the food groups, recipes, and sample meals/menus/snacks, at the education sessions and be required to work through problems in small groups.

You will be expected to attend 2 supervised physical activity sessions each week. Additionally, you will be expected to exercise 3 additional times a week on your own time. The exercise program will consist of walking and stretching. You will be instructed on gradually increasing the amount of time that you walk by a few minutes each day if you have not been in the habit of walking for exercise. You will have to fill out a activity form to record your physical activity.

Weight-Maintenance Period

The weight-maintenance period will last for 8 months and will begin at the 5th month of the study. During the first four months of the weight-maintenance period (months 5-8), you will be expected to attend bi-monthly meetings for group diet and physical activity counseling. You will attend the session at the same time and day you selected at the start of the study. However, you will have 2 alternative times for a make-up session if you have an unavoidable commitment during your regularly scheduled meeting.

During the second four months of the weight-maintenance period (months 9-12), you will be expected to attend monthly meetings for diet and physical activity counseling at your pre-selected day and time.

<u>Research Testing</u>

Blood Sampling

At the beginning of the study (month 0) and every 4 months (months 4, 8, and 12), after a twelve hour fast (consumption of no food or drinks except water), a blood sample will be taken from your arm on two consecutive days. This will be done at the General Clinical Research Center on the PSU campus. You understand that you cannot drink alcohol during the 48 hours prior to having your blood taken and that you cannot engage in vigorous physical activity 24 hours prior to having your blood taken. Approximately 80 ml (about 5 tablespoons) of blood will be collected every four months [40 mls (2.5 tablespoons) <u>on two consecutive days</u>]. Therefore, over the12-month study, blood will be taken on 8 days. Blood samples will be frozen and analyzed at the end of the study (when all 100 subjects have completed the study). The results of the study will only be available at the end of the entire study (which may take up to 3 years). Your blood will be tested for the following: blood fats (total cholesterol, LDL-cholesterol, HDL-cholesterol), blood sugar (glucose), a hormone regulating blood sugar (insulin) and inflammation markers (C-reactive protein).

Body Composition (DXA Scans)

At the beginning of the study (baseline) and the end of weight-loss (month 4) and the end of weight-maintenance (month 12), body composition will be determined by dual energy x-ray absorptometry (DXA). DXA is the state-of-the-art method for measurement of body composition. This procedure requires that you lie flat on a padded table without moving for 20 minutes while an x-ray scanner moves across your body. You will need to be dressed in a paper gown and this will be provided to you. The DXA test will be performed in the GCRC and will be administered by a licensed operator. Since you are a female of childbearing age you will have to have a urine pregnancy test done by the study personnel before you undergo the DXA procedure. The DXA will only be done if you test negative for pregnancy.

Dietary Assessment

At the beginning of the study and the end of weight-loss (month 4) and the end of weight-maintenance (month 12), diet assessment will be conducted. You will be contacted by the Penn State Diet Assessment Center 9 times over the course of the study to complete 24-hr dietary recalls by telephone at baseline, middle and end of the study. Data will be collected on two weekdays and one weekend day (for a total of 9 days).

Fitness (Graded Exercise Tests)

You will be asked to perform an exercise test on a research treadmill to assess your cardiovascular fitness and to rule out any blood pressure or heart abnormalities. This test will occur at baseline, month 4, and month 12. During this test, the grade and/or speed of the treadmill will gradually increase until you reach maximal effort. Your heart will be continuously monitored via a 12 lead EKG (electrical tracing of your heart's activity). Ratings of perceived effort and your blood pressure will be recorded each minute. You will also be asked to wear a mouthpiece and a nose clip during this test so that your expired air can be measured.

Questionnaires

You will be asked to complete several questionnaires during the screening visit. You will be asked to complete questionnaires assessing the way in which you eat (eating habits and behavior) your ability to do physical activity and if you have feelings of depression and a brief medical history form at the beginning on the study.

You will be asked to complete a diet satisfaction questionnaire and appetite questionnaires assessing your liking of the diet, hunger, and fullness at the start of the study and at the end of months 4, 8, and 12. The diet satisfaction questionnaire will be completed on one day; while the appetite questionnaire will be completed on 3 days. You will also be asked to complete a quality-of-life questionnaire at the start of the study and at the end of weight-loss and weight-maintenance.

Compliance with Study Protocol

You will be expected to follow the study protocol that includes attending 28 educational meetings with the study personnel, attending 2 weekly exercise sessions and doing 3 additional sessions on your own, recording daily physical activity and maintaining your weight during the weight maintenance part of the study. The average time commitment will be approximately 2.5 hours a week. Every effort will be made to give you a chance to comply with the study protocol but if you do not follow the above study protocol you may be dropped from the study.

Discomforts and Risks

Blood Sampling

The risks involved with taking blood from you include some local pain and bruising where the blood is taken. Well-trained, experienced clinical staff at the GCRC will draw your blood sample. Blood sampling may cause light-headedness and dizziness and if this occurs, your symptoms will be alleviated by having you lie flat with your feet raised. As with any procedure involving taking blood, infection is possible. Standard hospital procedures will be used to avoid infections.

DXA Scans

The DXA bone density procedure exposes you to a small amount of radiation where the x-ray beam crosses your body. The total radiation dose for the 3 DXA scans planned over the course of a year is equivalent to a whole-body radiation dose of approximately 4.5 mrem (millirem). A mrem is a unit of whole-body radiation dose. For comparison purposes, 4.5 mrem is less than you would receive from 5 days worth of natural background radiation in central Pennsylvania. You will be asked to remove all clothing and wear a paper gown during this procedure. A room will be available for you to change and efforts will be made to make sure you are comfortable with this arrangement. Another female will always be in attendance when you are having a DXA scan done.

Exercise Program

There is a possibility of having some pain and discomfort from sore muscles when engaging in the exercise program. The study staff will recommend a slow, gradual increase in the amount and intensity of the exercise that you do. During the early educational sessions, preventive measures will be discussed.

Graded Exercise Tests

There is discomfort associated with graded exercise testing to maximum effort, including temporary muscle fatigue and shortness of breath. These feelings go away very quickly after exercise is stopped. It is possible that you may also experience lightheadedness, chest discomfort, cramping in the legs, irregular heartbeats, and irregular blood pressures during this test. The risk of life-threatening problems (such as a heart attack) is very rare (1 in 2500 tests). Other potential risks, including fainting, nausea, muscle strain, and muscle soreness, will be minimized by proper warm-up, familiarization procedures, and cool-down. A research assistant will closely watch you throughout exercise and recovery.

Every attempt will be made to reduce the risk associated with exercise testing by using proper medical screening procedures. Pre-exercise screening will be done according to the guidelines of the American College of Sports Medicine (ACSM). A review of your medical history, as well as a physical exam with a resting 12 lead EKG will be conducted by a GCRC clinician prior to the graded exercise test. Proper procedures for stopping the test will be observed should you become lightheaded or faint. Should an emergency situation occur, access to further medical care at the GCRC or Mount Nittany Medical Center is available via a telephone located in the testing laboratory. Overall, the risks of this exercise test are minimal and probably less than if you were to exercise outside of a medical facility by yourself.

Benefits to Me

You will receive diet counseling, food intake analysis, screening laboratory analysis and interpretation of blood fat values and determination of body composition free of charge.

Potential Benefits to Society

It is hoped that the information from this study will increase our understanding of specific diets on weight loss and weight maintenance. Also, it is hoped that the nutrition education materials developed in the study will be altered for specific populations to be used to teach healthy lifestyle habits.

Statement of Confidentiality

Your participation in this research is confidential. All records are coded with a unique ID number and no names are used. Records containing names or other identifying information are kept under lock in Dr. Kris-Etherton's office and the GCRC. Only the investigators and their assistants will have access to your identity and to information that can be associated with your identity. The Office of Human Research Protections in the U.S. Department of Health and Human Services, the U.S. Food and Drug Administration (FDA), the Office of Research Protections at Penn State and the Biomedical Institutional Review Board may review records related to this project. All records associated with your participation in the study will be subject to the usual confidentiality standards applicable to medical records. In the event of publication of this research, no personally identifying information will be disclosed. Your blood specimens, DXA, dietary intake printouts and records of physical activity will be coded with your unique ID number and will be maintained until three years after the date from when the study is published, and then destroyed. At the end of the study, your will be given your laboratory results without cost, informed of the study results, and advised of the implications for your future care.

Section 1.01 Right to Ask Questions

You have been given an opportunity to ask any questions you may have, and all such questions have been answered to your satisfaction. You understand that Dr. Kris-Etherton is available to answer any questions that you have during the time of participation in this study or if you have questions in the future. You will be informed of any new information that may affect your willingness to participate. For further information about your rights as a research participant, you may call the Office of Research Protections at 814-865-1775.

Compensation

You will receive diet and exercise counseling at no charge during the study. In addition, screening laboratory results will also be given to you at no charge. You will also receive $100.00 for your time pro-rated as follows: $40.00 after completing the 4 month time point and $60.00 after completing the 12 month time point.

Injury Statement

You understand that medical care is available in the event of injury resulting from research but that neither financial compensation nor free medical treatment is provided. You also understand that you are not waiving any rights that you may have against the University for injury resulting from negligence of the University or the investigators.

Voluntary Participation

You understand your participation in this study is voluntary and that you may decline to answer any questions during the screening process or during the study. You are aware that refusing to answer a question may keep you from being able to participate in the study. You understand that you may withdraw from this study and your refusal to participate will in no way affect your care or access to medical services. You understand that you may be asked to leave the study at any time if you do not comply with the study protocol.

In the event that abnormal lab test results are obtained during the initial screening or subsequently throughout the study, you will be informed as quickly as possible of these results and instructed to contact your private physician for further assessment. The lab test results will be made available to your private physician at your request.

This is to certify that you consent to and give permission for your participation as a volunteer in the study entitled "Development, implementation, & testing an education program to teach weight loss using the *2005 Dietary Guidelines* to pre-menopausal women". You certify that you are 18 years of age or older. You understand that you will receive a copy of this consent form. You have read and understand the contents of this consent form.

_____________________________________ __________________

Signature of Volunteer Date

____

Printed Name of Volunteer

I, the undersigned, have defined and explained the study involved to the above volunteer.

_________________________________ __________________

Signature of Person Obtaining Consent Date

Initials_____

VITA

Tricia L. Psota

EDUCATION: The Pennsylvania State University

PhD, Nutritional Sciences, August 2009

- Graduate Research Assistant, Department of Nutritional Sciences, Kris-Etherton Research Group
- Guest Lecturer, "Nutrition and Atherosclerosis," a graduate nutrition course
- Teaching Assistant,"Assessment of Nutritional Status," an undergraduate nutrition course
- Research Assistant, Laboratory for the Study of Human Ingestive Behavior

BS, Nutrition (Science option) & BS, Biology (Vertebrate Physiology option), May 2003

AWARDS & HONORS

Kligman Fellowship & Kappa Omicron Nu, Honor Society	08-09
The Chancellor's List	05-07
Huck Institute of Life Sciences Fellowship	03-05
Ruth L. Pike Scholarship Recipient	02-03

PUBLICATIONS

- Layman, DK, Evans, EM, Erickson, D, Seyler, J, Weber, J, Bagshaw, D, Griel, A, **Psota, T**, Kris-Etherton, P. A Moderate Protein Diet Produces Sustained Weight Loss and Long-term Changes in Body Composition and Blood Lipids in Obese Adults. *J Nutr*. 139:514-21, 2009.
- **Psota, TL**, Lohse, B, Kris-Etherton, PM. Associations Between Eating Competence and Cardiovascular Disease Risk Factors and Psychological Measures. *J Nutr Edu Behav*. 40:S84. 2008.
- Griel, AE, **Psota, TL**, Kris-Etherton, PM. *Research: Successful Approaches 3rd ed.,* "Designing, Managing, and Conducting a Clinical Nutrition Study," Am Dietetic Association, pgs.101-116, 2008.
- Gebauer, S, **Psota, T**, Kris-Etherton, P. Diversity of Health Effects of Individual *TFA* Isomers. *Lipids*. 42:787-99. 2007.
- **Psota, TL**, Gebauer, SK, Kris-Etherton, PM. Dietary Omega-3 Fatty Acid Intake and Cardiovascular Risk, *Am J Cardiology*. 98(4 Suppl 1):3-18. 2006.
- Gebauer, SK, **Psota, TL**, Harris, WS, Kris-Etherton, PM. n-3 Fatty Acid Dietary Recommendations and Food Sources to Achieve Essentiality and Cardiovascular Benefits, *Am J Clin Nutr*.83:1526S–35S. 2006.
- **Psota, TL**, Gebauer, SK, Meyer, G, Kris-Etherton, PM. *Nutritional Health: Strategies for Disease Prevention, 2nd ed*, "Diet and the Control of Blood Lipids," Humana Press, Inc., pgs. 91-110. Jan 2006.
- Kris-Etherton, PM., Griel, AE., **Psota, TL**, Gebauer, SK, Zhang, J, Etherton, TD. Dietary Stearic Acid and Risk of CVD: Intake, Sources, Digestion, and Absorption, *Lipids*. 40:1193-1200. 2005.

PRESENTATIONS

- **Psota, TL**, Lohse, BA, Williams, N, Kris-Etherton, PM. "Clinical Results of a Year-long, Weight Management, Lifestyle Intervention Based on 2005 Dietary Guidelines," Am Heart Assoc NPAM: 2009.
- **Psota, TL**, Lohse, BA, Williams, N, Kris-Etherton, PM. "The WORLD Study: Clinical results after four months of weight loss following either a lower-fat or moderate-fat diet," Am Diet Assoc FNCE: 2008.
- **Psota, TL**, Lohse, BA, Kris-Etherton, PM. "Associations Between Eating Competence and Cardiovascular Disease Risk Factors and Psychological Measures," Society of Nutr Education: 2008.
- **Psota, TL**, Lohse, BA, Kris-Etherton, PM. "Preliminary Results of the WORLD Study" USDA/CREES NRI Human Nutrition & Obesity: 2008.
- **Psota, TL**, Lohse, BA, Kris-Etherton, PM. "*Your Healthy WORLD*: A Nutrition Education Program for Weight Management Based on the *2005 Dietary Guidelines*," Am Dietetic Assoc FNCE: 2007.
- **Psota, TL**. "Translational Research: Clinical Nutrition Interventions at Penn State," Penn State University/Wageningen University Nutritional Sciences Seminar: 2007.
- **Psota, TL**, Lohse, BA, Kris-Etherton, PM. "Development and Formative Evaluation of a Theory-Based Nutrition Education Intervention to Manage Weight," Experimental Biology: 2007.
- **Psota, TL**, Layman, DK, Griel, AE, Kris-Etherton, PM. "Diets With Differing Macronutrient Profiles Elicit Differential Changes in Lipid Ratios – TC:HDL-C and TG:HDL-C," Experimental Biology: 2006.

ACTIVITES

American Society of Nutrition's Student Interest Group Executive Committee (Chair 08-09)	06-10
Graduate Program in Nutrition: Student Representative for Steering Committee	06-07
Nutrition Graduate Student Association, (Secretary 04-05, President 06-07)	03-09