

A REVIEW OF PLANT-BASED NUTRITION INTERVENTIONS ON  
HEART DISEASE, OBESITY AND DIABETES.  
SUGGESTIONS FOR AN EDUCATIONAL CURRICULUM.

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June 2014

## ABSTRACT

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Mandes, T.: A REVIEW OF PLANT-BASED NUTRITION INTERVENTIONS ON HEART DISEASE, OBESITY AND DIABETES. SUGGESTIONS FOR AN EDUCATIONAL CURRICULUM.

Master's thesis, 69 pages, 1 attachment (70 pages).

Instructors: Arja Erkkilä, PhD and Pamela Popper, PhD, ND

June 2014

Key words: vegan, vegetarian, plant-based diet, obesity, heart disease, diabetes, intervention, controlled trial

A REVIEW OF PLANT-BASED NUTRITION INTERVENTIONS ON HEART DISEASE, OBESITY AND DIABETES. SUGGESTIONS FOR AN EDUCATIONAL CURRICULUM.

A whole foods, plant-based (WFPB) diet may be effective in preventing, halting and reversing chronic diseases. In this review, a WFPB diet is defined as a diet composed of whole, plant foods (vegetables, fruit, legumes, nuts, seeds),  $\leq 1$  optional serving of animal foods per day and the avoidance of refined foods (refined grain products, sugar and vegetable oils) and no calorie or portion restriction is imposed. The nutritional composition of the diet is  $\leq 15\%$  of energy from fat; 70-80% of energy from carbohydrates and 10-15% of energy from protein. I aimed to analyze the intervention's nutrition education techniques and diet effectiveness, which was measured by changes in nutrient intake and clinical measurements, and the diet acceptability. It was sought to be determined if and which nutrition education techniques aided in nutrient and biomarker outcomes, as well as participant's acceptability of a WFPB diet, for suggestions for a WFPB nutrition education curriculum. A systematic review was conducted for controlled trials utilizing a WFPB diet on coronary heart disease (CHD), type II diabetes (T2DM) and obesity for at least 12 weeks. The search yielded 6 studies. Results found a WFPB diet significantly reduced total fat to  $\leq 15\%$  of total energy, significantly reduced saturated fat, dietary cholesterol and protein and significantly increased carbohydrate and fiber intakes compared to controls. A WFPB diet was found to be highly effective in achieving weight-loss in individuals motivated to change their diet and effective in lowering serum cholesterol concentrations and reducing or eliminating antihypertensive and diabetes medications compared to controls. A WFPB diet was found to be as acceptable as the National Cholesterol Education Program's (NCEP) Step II Diet and the American Diabetes Association's (ADA) diabetes diet. When appropriately planned, a WFPB diet is nutritionally adequate. It was inconclusive which education techniques were meaningful in affecting outcomes and acceptability, however, all 6 interventions utilized weekly group support and most studies utilized individual support, differing food interactions and diet monitoring which are suggested to be components in any proceeding WFPB nutrition education curriculums. Additional randomized controlled trials (RCTs) using a WFPB diet need to be conducted with larger population sizes, especially in individuals with CHD. Nutrition interventions need to report the totality of their education techniques so future interventions have a replicable model for implementation.

## ACKNOWLEDGEMENTS

I would like to thank my supervisors Arja Erkkilä, PhD and Pam Popper, PhD for their support, guidance, critiques and challenging personal nutritional perspectives that enriched my learning experience. I am forever grateful to my mother, brother and step father for their endless love and support throughout this process. I would not be here if it weren't for them. I would like to thank Cameron Smith, my loving partner, for his continuous support, motivation and belief in me, especially while living on opposite sides of the world. Many thanks to Sohaib Khan and Annika Männikkö for their continuous support throughout my Master's education and Heikki Laitinen for his kind assistance with the study search. I am profoundly and forever grateful to Finland and the University of Eastern Finland for providing me with this educational opportunity and enriching life experience.

I became interested in WFPB nutrition after attending a conference in 2008 where T. Colin Campbell, Ph.D. and Caldwell Esselstyn, M.D. presented their and other's, scientific evidence on the effectiveness of WFPB nutrition. I continued to further my WFPB nutrition education from leading researchers and physicians in the field and began teaching WFPB nutrition, helping groups and individuals adopt a WFPB diet.

## LIST OF ABBREVIATIONS AND SYMBOLS

A1c: glycated hemoglobin

ADA: American Diabetes Association

ADD: average Danish diet

AHEI: alternative healthy eating index

BMI: body mass index

CBT: cognitive behavioral therapy

CHD: coronary heart disease

CVD: cardiovascular disease

EPIC: European Prospective Investigation into Cancer and Nutrition (EPIC)-Oxford Study

FAQ: food Acceptability questionnaire

FBG: fasting blood glucose

FFQ: food frequency questionnaire

GEICO: Government Employees Insurance Company

HR: hazard ratio

IHD: ischemic heart disease

NCEP: National Cholesterol Education Program

NIDDM: non-insulin dependent diabetes mellitus

NND: New Nordic Diet

OR: odds ratio

RCT: randomized controlled trial

RD: registered dietitian

RR: relative risk

T2DM: type 2 diabetes

USDA: United States Department of Agriculture

WFPB: whole foods, plant-based (diet)

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## 1. INTRODUCTION

Chronic conditions such as obesity, coronary heart disease (CHD) and type 2 diabetes (T2DM) are the leading causes of death and disability in the United States (CDC 2014a). In 2013, 69% of U.S. adults were overweight, 35% were obese (CDC 2014b) and about 17% of children ages 2 to 19 were obese from 2011 to 2012 (Ogden et al. 2014). Heart disease is the leading cause of death in men and women, killing 1 in every 4 people each year (Murphy et al. 2013). Diabetes affects 25.8 million people in the U.S.--8.3% of the population. In 2010, 1.9 million new cases of diabetes were diagnosed in people over the age of 20 (CDC 2013). Diabetes is a major cause of stroke and heart disease and is the leading cause of non-traumatic lower-limb amputation, kidney failure and new cases of adult blindness (CDC 2013).

Not only are CHD, T2DM and obesity deadly, they are expensive too. Heart disease and stroke were estimated to cost \$315.4 billion in 2010 (AHA 2014). Diabetes cost an estimated \$245 billion in 2012 (AHA 2014b) and obesity is estimated to have cost \$147 billion in 2008 (Finkelstein et al. 2009). Medical costs for people who are obese were \$1,429 higher per capita in 2006 than those of normal weight (Finkelstein et al. 2009).

Despite the severity of chronic disease rates and their financial implications, no country has successfully reversed obesity or T2DM trends through public health measures (Swinburn et al. 2011). Finland was successful in reducing the prevalence of heart disease, however, obesity and T2DM rates increased simultaneously (Puska et al. 2009). Nutritional changes used for treating one chronic disease should be effective in preventing and treating other chronic diseases while providing adequate amounts of nutrients (Turner-McGrievy 2008).

A whole foods, plant-based (WFPB) diet, consisting of whole-grains, legumes, fruits, vegetables, nuts and seeds, has been called the most effective diet for reducing chronic diseases (Tuso et al. 2013) and the healthiest diet that has ever been studied (Campbell 2013). However, a WFPB diet is the least prescribed and least recommended diet for public health programs and by physicians (Tuso et al. 2013). Physicians in the U.S. are generally, not properly trained in nutrition and have a suboptimal understanding of how nutrition, especially a WFPB diet, is effective in preventing, arresting and reversing chronic disease (Adams et al.



2010). Additionally, the research and effectiveness of a WFPB is most likely not taught to nutrition students in academia who later become registered dietitians (RD) and nutritionists. The reasons as to why this is, are reviewed in the discussion.

The effectiveness of a WFPB diet is supported by peer-reviewed, published literature at all levels of scientific evidence. Even so, a lack of education materials and resources for patients is a barrier to informing the public about the benefits and implementation steps of a WFPB diet (Tuso et al. 2013). Health care professionals need to be equipped with proper educational tools to properly inform their patients of a WFPB diet, especially if they lack the knowledge or time to fully explain it themselves. WFPB educational curriculums are also necessary for improving chronic disease prevention strategies, interventions and research studies.

This review makes suggestions for a WFPB nutrition curriculum based on findings from WFPB controlled trials in individuals with heart disease, T2DM or obesity. The settings, nutrition techniques and intervention processes of WFPB controlled trials are reviewed. Changes in nutrient intakes and clinical measurement outcomes are assessed for effectiveness. The acceptability of the diet and what factors assisted in adherence to the diet are also explored. The outcomes of these findings will be reviewed and consolidated to determine what information and techniques are best suited for a WFPB nutrition education curriculum and what information is still needed. Suggestions from these findings will be provided for a WFPB nutrition education curriculum.

## 2. THEORETICAL BACKGROUND

### 2.1 Definition of a WFPB Diet

A WFPB diet consists of a variety of whole, plant foods including whole-grains, legumes (beans, peas and lentils), fruits, vegetables, nuts and seeds. Animal foods, including fish, eggs and dairy products are generally avoided but may be included in minimal amounts. Refined foods are also avoided and include sugar, vegetable oils, and flour and grain products that do not contain all of their original nutrients. A WFPB diet yields 10-15% of energy from fat, 75-80% of energy from carbohydrates and 10-15% of energy from protein (Campbell 2013 & Barnard et al. 2004). Additionally, there is no portion size restriction or calorie counting when consuming a WFPB diet.

The definition of a plant-based diet varies in the scientific literature. Dean Ornish for example, permits minimal amounts of skim milk or egg whites for coronary artery disease reversal (Ornish et al. 1998) while Nicholson et al. (1999), Barnard et al. (2004, 2005, 2006, 2009a), Ferdowsian et al. (2010) and Mirsha et al. (2013a) omit all animal products and high-fat plant foods for individuals with T2DM or obesity. All of these authors advocate whole, plant foods as the bulk of the diet and both are considered plant-based diets. The terms vegan or vegetarian may also be included in the plant-based diet definition, although these terms are defined only by what is not included in the diet, while neglecting the foods that are actually consumed. A WFPB diet on the other hand, focuses on what foods are both included and excluded in the diet.

### 2.2 Prevention and Reversal of Chronic Disease with a WFPB Diet

Varying types of evidence exist and support the claim that a WFPB diet may have the ability to prevent and reverse chronic diseases. Ecological studies reveal large populations consumed a WFPB diet and experienced a low to almost non-existent rate of obesity (Connor et al. 1978), coronary artery disease (Toshima et al. 1995 & Campbell et al. 1998), diabetes (Schulz et al. 2006) and cancer (Yamori et al. 2001). Large, longitudinal, cohort studies reveal vegans

and vegetarians have the lowest body mass indexes (BMI) (Tonstad et al. 2009) and lowest prevalence of T2DM (Vang et al. 2008) compared to those eating animal-based diets. Longitudinal cohorts also find an increased risk of early death from meat consumption (Rohrmann et al. 2013).

Non-controlled, clinical trials using a WFPB diet have been successful in arresting and reversing heart disease documented by angiograms (Esselstyn 1999); reducing and eliminating hypertension medication (Lindahl et al. 1984); significantly reducing weight (Lindahl et al. 1984), BMI (Chainani-Wu et al. 2011), blood pressure (Lindahl et al. 1984) and blood cholesterol concentrations (Chainani-Wu et al. 2011) compared to baseline measurements. Most recently, RCTs have documented a WFPB diet in arresting and reversing CHD (Ornish et al. 1998), reducing more medications compared to control (Barnard et al. 2006), lowering blood cholesterol levels (Mirsha et al. 2013b), weight (Barnard et al. 2005) and BMI (Barnard et al. 2005) compared to usual care treatment (Ornish et al. 1998) and compared to the low-fat diets recommended by the ADA (Barnard et al. 2006) and the NCEP (Barnard et al. 2005).

### 2.2.1 Ecological Studies

Some of the world's healthiest populations consume a WFPB diet such as the Tarahumara Indians of Mexico (Connor et al. 1978), the rural Chinese (Campbell et al. 1998), the Tanushimaru of Japan (Menotti et al. 1993), the Centenarians of Okinawa, Japan (Chuanxin 2001) and the Papua highlanders of New Guinea (Sinnott & Whyte 1973).

#### The Tarahumara Indians of Northern Mexico

The Tarahumara Indians of the Sierra Madre Occidental Mountains, experienced a “virtual absence of the hypertension, obesity, and the usual age rise of the serum cholesterol in adults” in the 1970s (Connor et al. 1978). Beans and corn constituted about 90% of the Tarahumaran's diet with the addition of vegetables. Meat products and dairy foods were rarely eaten. An average of 2 eggs per week were consumed. The diet consisted of 12% of energy from fat (2% of energy from saturated fat), 75 to 80% of energy from carbohydrates

(mainly starch) and an adequate 13% of energy from protein (Connor et al. 1978). Adults age 19 to 70 years old, experienced a mean total cholesterol concentration of  $136 \pm 28$  mg/dl (3.52 mmol/l) and mean triglycerides concentrations were  $126 \pm 57$  mg/dl (1.42 mmol/l). Hypertensive blood pressure above 140/90 mm/Hg was not seen in the Tarahumara Indians (Connor et al. 1978). The Tarahumara Indians were also competitive runners, so health outcomes cannot solely be contributed by the diet.

### The Rural Chinese

Campbell et al. (1998) refers to Chen et al. (1990) when describing coronary mortality rates in China in the 1970s. From 1973 to 1975, there were 4.0 deaths from CHD per 100,000 men and 3.4 for women for ages 0 to 64. During the same 3 year period in the province of Guizhou in rural China, there was no recorded deaths from coronary artery disease for males  $\leq 64$  years old (Campbell et al. 1998). In the neighboring Chinese county of Sichuan, there were no recorded deaths from coronary artery disease for females  $\leq 64$  years old in a population of 181,000 from 1973 to 1975 (Campbell et al. 1998). The rural Chinese were reportedly consuming a diet in which 14% of calories came from fat, 71% from carbohydrates and 10% from protein. These rural Chinese populations were consuming a mean fiber intake of 33 g per day in 1983. About 1% of the total calories came from animal protein (Campbell et al. 1998). Total blood cholesterol concentrations in rural China were on average, 127 mg/dl (2.8 mmol/l) in 1983 and the mean BMI was  $20.5 \text{ kg/m}^2$  (Campbell et al. 1998).

### Tanushimaru of Japan

The people in Tanushimaru in Japan, the county with one of the lowest mortality rates from CHD in the Seven Countries Study (Papandreou & Tuomilehto 2014), consumed a diet comprised of 80% whole plant foods, 13% animal foods and 7% 'junk' foods (edible fats, sugar products, pastries, 100% alcohol and 'rest') in 1964 (Kromhout et al. 1989). The Tanushimaru in Japan experienced an age-adjusted CHD death rate of 45 per 1000 in 25 years compared to 288 per 1000 in Eastern Finland during 25 years (Menotti et al. 1993). At that time, the men of North Karelia in Eastern Finland experienced the highest CHD death rate in

the world (Puska 2010). The mean cholesterol concentration in Tanushimaru, Japan was 167 mg/dl (4.32 mmol/l) (Toshima et al. 1995) and 267 mg/dl (6.9 mmol/l) in North Karelia, Finland in 1972 (Puska et al. 2009). Contrary to the plant-based diet of the Tanushimaru, the North Karelian population was consuming a diet that was 35% plant foods, 55% animal foods and 10% ‘junk’ foods (Kromhout et al. 1989).

### Centenarians of Okinawa, Japan

Females in Okinawa, Japan have the longest life-expectancy in the world (85.08 years) (Yamori et al. 2001) and experience a low rate of CHD and all-cancer mortality rates (Yamori et al. 2001). According to a retrospective study on 34 Okinawan centenarians, the diet of the Okinawan centenarians is high in fiber and minerals and low in calories, protein and fat (Chen 2001). According to Chen (2001), the participants ate 712 g of whole, plant foods (210 g of which were dried sweet potato slices), 16 g of meat and 15 g of fat per day.

### 2.2.2 Prospective Cohort Studies

Prospective cohort studies on Western populations and their accompanying dietary patterns, provide valuable insight on specific foods and food groups that promote health and promote disease.

### The Adventist Health Study I and II

The Adventist Health study followed a cohort of 8401 non-diabetic, Seventh Day Adventist, adult church members for 17 years (Vang et al. 2008). Consuming all meat types at least weekly for 17 years was associated with a 74% increase in odds (OR = 1.74; 95% CI 1.36 to 2.22) of diabetes relative to vegetarians consuming no meat, which remained significant after adjusting for obesity and weight gain (OR = 1.38; 95% CI 1.06 to 1.68). Weekly intake of red meat and poultry was associated with a 27% increased odds (OR = 1.27; 95% CI 1.06 to 1.53) of diabetes (Vang et al. 2008).

The Adventist Health Study II followed a cohort of 22 434 men and 38 469 women from 2002 to 2006 (Tonstad et al. 2009). A normal BMI was seen only in the vegan group (23.6 kg/m<sup>2</sup>) who restrained from all animal products. BMI incrementally increased as the amount of animal foods in the diet increased. Lacto-ovo vegetarians experienced a BMI of 25.7 kg/m<sup>2</sup>; pesco-vegetarians (26.3 kg/m<sup>2</sup>); semi-vegetarians (27.3 kg/m<sup>2</sup>) and non-vegetarians (28.8 kg/m<sup>2</sup>). Similarly, the vegan group had the lowest prevalence of T2DM (2.9%) compared to lacto-ovo vegetarians (3.2%), pesco-vegetarians (4.8%), semi-vegetarians and non-vegetarians (7.6%). After adjusting for ten different factors including weight and physical activity, vegans had a 49% lower risk of diabetes (OR = 0.51; 95% CI 0.40 to 0.66) compared to non-vegetarians (Tonstad et al. 2009).

Fraser (1999) reviewed associations between diet, ischemic heart disease (IHD) and all-cause mortality amongst 34 192 Californian Seventh Day Adventist members. The lifetime risk of IHD was reduced by about 37% in male vegetarians compared to non-vegetarians (Fraser 1999). Again, obesity also increased as meat consumption increased. Non-vegetarian men weighed 6.4 kg (14 lbs) more than vegetarian men ( $P < 0.0001$ ). Hypertension and diabetes prevalence were both about 2-fold greater in the animal food consumers group and the prevalence of rheumatoid arthritis was about 50% greater compared to vegetarians (Fraser 1999). Results were statistically significant. Consuming plant foods was associated with a decreased risk of certain cancers while animal foods were associated with an increased risk. Fruits were negatively associated with prostate, pancreatic and lung cancer and legumes were associated with a lower risk of colon and pancreatic cancer. Non-vegetarians were significantly more likely to experience colon and prostate cancer (RR of 1.88 and 1.54, respectively) and frequent beef consumers had a higher risk of bladder cancer (Fraser 1999).

#### The EPIC-Oxford Cohort Study

The European Prospective Investigation into Cancer and Nutrition (EPIC)-Oxford Study followed 44 561 men and women for an average of 11.6 years (Crowe et al. 2013). Thirty-four percent of the cohort consumed a self-reported vegetarian diet at baseline. At follow-up, vegetarians experienced a 32% lower risk (HR: 0.68; 95% CI 0.58 to 0.81) of IHD compared

to non-vegetarians. After adjusting for BMI, vegetarians experienced a 28% lower risk of IHD (HR: 0.72; 95% CI 0.61 to 0.85).

Rosell et al. (2006) reviewed weight changes in 21 966 health-conscious men and women consuming meat-containing, fish-containing, vegetarian or vegan diets in the EPIC study. Participants were followed for a median duration of 5.3 years. At follow-up, adjusted weight gain was lowest in the vegan group (284 g in men, 303 g in women) ( $P < 0.05$  for both sexes) compared to meat eating men (406 g) and women (423 g). The amount of weight increased least in the following order: converted eaters (decreased meat consumption in some way,  $P < 0.001$  for both sexes); vegans ( $P < 0.05$  for both sexes); fish-eaters ( $P < 0.001$  for women only), vegetarians, meat eaters and those who reverted their diets (increased meat consumption) (Rosell et al. 2006).

Rohrmann et al. (2013) followed 44 8568 men and women age 35 to 69 years old to research the the association of red meat, processed meat and poultry consumption and the risk of early death, as part of the EPIC study. Participants were followed for a median of 12.7 years. After a multivariate adjustment, all-cause mortality was highest in the subjects with the highest amount of processed meat ( $>160$  g) compared to the lowest amount (10 to 19.9 g/day) (hazard ratio (HR) = 1.44; 95% CI 1.24 to 1.66) (Rohrmann et al. 2013). The researchers calculated that if all participants consumed less than 20 g of processed meat per day, 3.3% of deaths could be prevented (95% CI 1.5 to 5.0%) (Rohrmann et al. 2013).

Although these cohort studies measure the effects of differing vegetarian diets compared to animal centered diets, they do not fully capture the difference between WFPB diets and animal-based diets. It is likely vegetarians in these studies were consuming refined foods including white flour products, sugar and oils, eating a more ‘Westernized’ vegetarian diet compared to a WFPB diet. However, these cohorts do contribute evidence of the health difference seen between people eating more, less and no animal products.

### 2.2.3 Non-controlled Intervention Studies

Non-controlled trials have shown favorable effects from a WFPB diet in arresting and reversing heart disease documented by angiograms (Esselstyn et al. 1995); reducing and eliminating hypertension medication (Lindahl et al. 1984); reducing and eliminating insulin treatment in diabetic subjects (Anderson & Ward 1979); significantly reducing weight (Lindahl et al. 1984 & McDougall et al. 1995), BMI (Chainani-Wu et al. 2011), blood pressure (Lindahl et al. 1984 & McDougall et al. 1995) and blood cholesterol concentrations (Anderson & Ward 1979, McDougall et al. 1995 & Chainani-Wu et al. 2011) compared to baseline measurements. Although chronic diseases other than heart disease, T2DM and obesity are not reviewed in this thesis, it is important to recognize that a WFPB diet has also shown favorable effects on individuals with rheumatoid arthritis (McDougall et al. 2002a) and prostate cancer (Ornish et al. 2005).

#### Reversing Coronary Artery Disease

Twenty-two individuals with angiographically documented severe coronary artery disease were prescribed a low-fat, WFPB diet while on cholesterol-lowering medication. Eleven of the 22 patients completed angiographs at baseline and at follow-up at an average of 5.5 years (Esselstyn et al. 1995) and again at 12 years (Esselstyn 1999). Six participants continued the intervention diet but did not complete data-collection and 5 individuals left the study within the first 2 years. At baseline, these 11 participants had documented progressive, severe triple-vessel CHD and experienced multiple cardiac events under the advice of standard care (Esselstyn et al. 1995).

Of the 25 lesions available for analysis, the mean percent stenosis decreased from 53.4% ( $\pm 14.8\%$ ) to 46.2% ( $\pm 16.8\%$ ) from baseline to 5 year follow-up. The mixed-effects model, which adjusted for correlations between lesions in the same participant, found the mean stenosis percent reduction was 7% (95% CI 3.3 to 10.7,  $P < 0.05$ ) (Esselstyn et al. 1995). There was no stenosis progression in 11 of the 11 participants. Eight individuals experienced a decrease in stenosis, suggesting a reversal of the disease, and the remaining 3 participant's



stenosis remained unchanged (Esselstyn et al. 1995). Mean total cholesterol concentrations remained below 150 mg/dl (3.88 mmol/l) at 5 years (Esselstyn et al. 1995) and 12 years (Esselstyn 1999).

### Reducing Hypertension Medication

Swedish researchers prescribed a vegan, plant-based diet to 29 individuals who experienced hypertension for an average of 8 years prior to the study (Lindahl et al. 1984). Participants were on an average of 2.6 medications each and were all on hypertension medication long-term at baseline. Participants met for 12 days at a health center and again for another 12 days 4 months later and again after one year for the intervention. Participants were on a fruit-juice-only fast the first 7 days at the center. Following the juice-fast, participants began a low-fat, animal free, plant-based diet that also excluded caffeine, sugar, salt and chocolate (Lindahl et al. 1984).

Twenty of the 29 participants eliminated their hypertension medications completely and 6 participants reduced their dosage at 1 year (Lindahl et al. 1984). Both systolic and diastolic blood pressure decreased significantly at 4 and 12 months (Lindahl et al. 1984). Weight decreased by -10.2 kg ( $P<0.001$ ) at 4 months and by -7.8 kg at 12 months ( $P<0.001$ ). Triglycerides decreased significantly at 4 months ( $P<0.01$ ), but not at 12 months. Total blood cholesterol concentrations were significantly less at 4 and 12 months ( $P<0.001$ ) compared to baseline (Lindahl et al. 1984).

### 2.3 Education and Support Techniques in Nutrition Interventions

Education and support is needed when making diet and lifestyle changes. The educational techniques that are most successful in helping people achieve long-term adherence to meet their health goals should be used. Many forms of nutrition education exist and have been used for many different types of diets. Research is beginning to track which education techniques and theories are most successful in helping participants achieve diet changes and improve clinical measurements.

### 2.3.1 Nutrition Education Techniques

Nutrition education techniques include in-person or live teaching for individuals and groups. Podcast or recorded audio is a newer technique (Turner-McGrievy et al. 2009) as well as online education programs (Turner-McGrievy & Campbell 2009). Both live and video lectures are additional education techniques.

### 2.3.2 Behavior Change Theories and Strategies

Behavior change theories and strategies are used to facilitate nutrition-related behavior change. Cognitive behavioral therapy (CBT) is the oldest and most studied behavior change theory in nutrition. CBT helps individuals identify and change dysfunctional patterns of thinking and acting. It focuses both on external stimuli and internal thoughts and has been found to be the most effective strategy for creating nutrition-related behavior change in a systematic review of 87 studies (Spahn et al. 2010).

The transtheoretical model of change theory, ranks steps of nutrition-related behavior change in a continuum of phases: pre-contemplation, contemplation, preparation, action and maintenance. By identifying the phase of change an individual is in, a health care provider can develop a more appropriate action plan (Trapp et al. 2010). Only one high-quality RCT was available assessing the transtheoretical model in Spahn et al.'s (2010) review. More studies are needed to demonstrate its effectiveness (Spahn et al. 2010). The social learning theory believes people learn by observing others and little research is available on its effectiveness (Spahn et al. 2010).

Behavior change strategies include self-monitoring of dietary intake, physical activity, thoughts, emotions or biomarker measurements to identify patterns and triggers that can be used to help change behavior and modify goals and research has found it to be effective (Spahn et al. 2010). Meal replacements such as shakes, bars or frozen meals are traditionally used in nutrition-related behavior change as well as and structured meal plans listing the exact portion size and type of food to be consumed. Meal replacements and structured meal plans

are not applicable to a WFPB diet because a WFPB diet does not restrict portion sizes nor does it encourage meal replacements. Financial reward incentives have not shown to be effective in aiding in weight loss (Spahn et al. 2010).

### 2.3.3 Additional Supportive Components

Food interactions include but are not limited to providing pre-made meals, sharing meals, taste-testing foods and cooking demonstrations. Individual diet plans can be made to help accommodate allergies and individual food preferences and can be provided with recipes. Diet monitoring is a strategy used by a provider such as 24 hour diet recalls or, a strategy employed by an individual such as food journaling. Goal setting, group discussion, family and spousal involvement are additional supportive components. Environmental changes such as providing meals in cafeterias, eliminating vending machines or making physical activity opportunities more accessible are also ways diet and lifestyle changes can be modified more easily. Regular monitoring of biomarkers such as serum cholesterol concentrations and blood pressure as well as weighing are other optional techniques. One of the newest supportive components is the use of mobile applications and social media for nutrition change support (Turner-McGrievy 2013).

### 2.3.4 Curriculum Information, Educators and Settings

The type of information that can be taught in conjunction with nutrition education techniques, behavior change strategies and the additional supportive components is vast. Some of the most highlighted information includes the role of nutrition in chronic diseases; understanding nutrition labeling; changing grocery shopping techniques; how to maintain adherence to a prescribed diet in social situations, at work, while traveling and in restaurants; the importance of nutrition in conjunction with physical activity, sunlight and stress management; problem solving techniques and new cooking skills.

Different types of professionals have been shown to administer nutrition education and offer support during diet and lifestyle changes. The educator may be a cooking instructor, physician

or a RD (Barnard et al. 2006), a psychologist (Ornish et al. 1990), a nutrition educator or a licensed mental health professional (Chainani-Wu et al. 2011). Other professionals that are not listed may also be appropriate educators.

Pignone et al. (2003) reviewed 21 nutrition RCTs and assessed factors affecting responses to dietary change and found that studies conducted in research clinics produced larger effects, in large part because these interventions were of greater intensity (the amount and duration of the counseling contacts) (Pignone et al. 2003). Interventions in research clinics produced the largest effects, while interventions using interactive health communications had the next largest effect and primary care settings produced the smallest effects (Pignone et al. 2003).

Pignone et al. (2003) further reviewed each study for the study's effect size based on the number of counseling components included. Studies using a greater number of components were found to be more effective. Study groups using at least 3 components showed large (67%) and medium sized (33%) effects and no small effects. Study groups using 1 or 2 components yielded mostly medium (46%) and large (17%) effects as well as small (37%) effects (Pignone et al. 2003). The intensity of the interventions was also strongly associated with the degree of dietary change. Medium- to high-intensity interventions were found to produce larger changes compared to low-intensity interventions.

Despite the evidence provided by Spahn et al. (2010) and Pignone et al. (2003), none of the studies reviewed included participants implementing a WFPB diet. The educational components and settings that are most effective in WFPB nutrition education is still unknown.

### 3. AIMS

This study aims to analyze the existing controlled trials using a WFPB diet on obesity, heart disease and T2DM to make suggestions for a WFPB nutrition curriculum.

Objectives include:

1. Review the setting, nutrition education techniques and intervention processes of WFPB RCTs.
2. Review changes in nutrient intake and clinical measurements from baseline to follow-up.
3. Review participant's acceptability of a WFPB.
4. Explore which nutrition techniques and intervention processes may have contributed to greater nutrient intake improvements, clinical measurement changes and diet adherence.
5. Provide suggestions for a WFPB nutrition education curriculum.

## 4. METHODS

In this thesis review, a WFPB diet is defined as the inclusion of whole, plant foods (vegetables, fruit, legumes, nuts, seeds);  $\leq 1$  optional serving of animal foods per day; and the avoidance of refined foods (refined grain products, sugar and vegetable oils). The nutritional composition of the diet is  $\leq 15\%$  of calories from fat; 70-80% of calories from carbohydrates and 10-15% of energy from protein. A study meeting this nutrient profile is considered adherent in this review.

No portion size restriction or calorie counting is imposed and participants are encouraged to eat to satisfaction.

### 4.1 Search Strategy and Study Selection

A systematic search in PubMed was conducted on March 3rd, 2014. The search words and the search query can be found in Appendix 1. The initial search identified 569 publications. Titles and abstracts were read to determine if the study met the following inclusion and exclusion criteria.

#### Inclusion Criteria

- Controlled interventions only
- At least 12 weeks in duration
- Human participants only
- Eighteen years of age or older
- Participants with heart disease, T2DM and/or obesity
- Diet recommendations advocating for  $\leq 15\%$  of energy from fat, 70-80% of energy from carbohydrates and 10-15% of energy from protein
- Diet recommendations advocate a WFPB diet: whole, plant-based foods (fruits, vegetables, whole-grains, legumes, nuts and seeds);  $\leq 1$  optional serving of animal foods per day

- Intervention participants must have been able to eat freely without calorie counting or portion restriction
- Published in the English language

#### Exclusion Criteria

- No control group
- Less than 12 weeks in duration
- Publications on healthy individuals
- Diet recommendations containing >15% of energy from fat
- Diet recommendations containing >1 serving of animal products a day
- Diet recommendations with more than 15% of total energy from animal products including meat, fish, dairy products and/or refined foods including vegetable oils, sugar and refined grain products
- Iso-caloric or calorie restricted diets
- Studies that do not disclose the totality of the intervention diet or diet recommendations

Fifty-one publications were further reviewed by analyzing the full publication to determine eligibility. Of these 51 publications, 17 full-text articles fit the required inclusion criteria and are included in this review. Two additional publications, which met the required criteria, were identified from the references of included studies, but were not revealed in the PubMed search (Ornish et al. 1998 & Turner-McGrievy et al. 2011). These 2 studies are also included, totaling 19 publications in the review. The 19 publications are on 6 main intervention studies.

#### Excluded Studies

Most of the 51 studies that were further analyzed focused on an increase of fruits, vegetables, whole-grains and low-fat dairy products. Such studies did not meet the dietary inclusion criteria for this review. Examples of excluded publications include those recommending diets such as the NCEP diet; Dietary Approaches to Stop Hypertension diet; the Nordic diet

(NORDIET); the Women's Health Initiative; and the PREvención con DIeta MEDiterránea or 'Prevention with Mediterranean Diet'. Studies that did not specify the dietary goals were excluded. Studies recommending the 'Mediterranean diet' were read fully to determine if diet recommendations complied with the WFPB diet definition. Many uncontrolled WFPB diet interventions were revealed in the search results. WFPB controlled trials were also found, but were less than 12 weeks in duration.

### Included Studies

Of the 6 interventions, 1 study intervened on participants with heart disease (Gould et al. 1992 & Ornish et al. 1990, 1998); 1 study focused on postmenopausal overweight women (Barnard et al. 2004, 2005 & Turner-McGrievy et al. 2004, 2007) and Nicholson et al. (1999) was on T2DM. One study was on participants with T2DM but also reviewed cardiac risk factors (Barnard et al. 2006, 2009a, b, c & Turner-McGrievy et al. 2008, 2011). The 5th study by Ferdowsian et al. (2010), Katcher et al. (2010) and Levin et al. (2010); and the 6th study by Mirsha et al. (2013a, b), both included overweight individuals or people with T2DM. Three of the 6 controlled trials were further extended. Ornish et al. (1990) was extended for an additional 4 years; Barnard et al. (2004) extended follow-up of 1 and 2 years and Barnard et al. (2006) and extended follow-up for 1 additional year.

### Data Extraction from Included Studies

Each publication was reviewed thoroughly. Data was extracted from each publication on the education techniques and intervention processes reported; the change in nutrient intakes including energy, total fat, saturated fat, carbohydrates, protein, cholesterol and dietary fiber from baseline to the reported follow-up time; changes in clinical measurements from baseline to follow-up including weight, BMI, total serum cholesterol concentrations, triglycerides, systolic and diastolic blood pressure, fasting blood glucose (FBG) concentrations and hemoglobin A1c. Data was extracted on participant's acceptability of a WFPB diet when applicable. Data extracted from different publications in regards to a specific study were then compiled for a greater understanding of the totality of each study.



## 5. RESULTS

Study characteristics, intervention education and support characteristics, changes in nutrient intake and changes in clinical biomarkers of the 6 interventions are summarized below in tables 1, 2, 4 and 5, respectively. Five of the 6 studies were randomized and all 6 used control groups. Participants in all 6 studies were free-living individuals and were willing to change their diet. All 6 studies used a low-fat WFPB diet. Two studies were held in corporate work environments (Ferdowsian et al. 2010 & Mirsha et al. 2013a). Exercise was controlled for in 5 of the 6 studies (Ornish et al. (1990) did not control for exercise). Intervention group participants in the 6 studies ate a WFPB diet with no portion size restriction. Characteristics of the studies are represented in more detail in Table 1.

Table 1. Study Characteristics of WFPB Diet Controlled Trials

<b>Intervention</b>	<b>Lifestyle Changes for Reversal of Coronary Heart Disease</b>	<b>Pilot Intervention: Low-fat, Vegetarian Diet in NIDDM</b>	<b>Low-Fat Vegan Diet v. Step II Diet in Overweight Post-menopausal Women</b>	<b>Low-Fat Vegan Diet Improves Glycemic Control &amp; CVD Risk Factors in T2DM</b>	<b>Multicomponent Intervention Reduces Weight &amp; CVD Risk at a GEICO Corporate Site</b>	<b>Plant-Based Nutrition Program to Reduce Weight &amp; CVD Risk. GEICO Study</b>
<b>Authors, Year</b>	Ornish et al. 1990 Gould et al. 1992 Ornish et al. 1998	Nicholson et al. 1999	Barnard et al. 2004 Turner-McGrievy et al. 2004 Barnard et al. 2005 Turner-McGrievy et al. 2007	Barnard et al. 2006 Turner-McGrievy et al. 2008 Turner-McGrievy et al. 2011 Barnard et al. 2009a Barnard et al. 2009b Barnard et al. 2009c	Ferdowsian et al. 2010 Katcher et al. 2010 Levin et al. 2010	Mirsha et al. 2013a Mirsha et al. 2013b
<b>Randomized</b>	Yes	Yes	Yes	Yes	No *	Yes
<b>Duration</b>	1y, 5y	12 wks	14 wks, 1y, 2y	22 wks, 74 wks	22 wks	18 wks
<b>Participants</b>						
Intervention	n = 28	n = 7	n = 31	n = 49	n = 68	n = 142
Control	n = 20	n = 4	n = 31	n = 50	n = 45	n = 149
<b>Mean Age</b>						
Intervention	57.4	51	57.4	56.7	46	43.3
Control	59.8	60	55.6	54.6	42	45.1
<b>Condition</b>	CHD	T2DM	Obesity	T2DM	Overweight and or T2DM	Overweight and or T2DM
<b>Diet †</b>						
Intervention	WFPB: +A	WFPB: -A	WFPB: -A	WFPB: -A, LGI	WFPB: -A	WFPB: -A
Control	Usual treatment	Conventional low-fat	NCEP	ADA	habitual	habitual

<b>Completed ‡</b>						
Intervention	5y: 71%	100%	14 wk: 90.6%	22 wk: 100%	96%	66%
Control	75%	66.6%	14 wk: 93.7%	22 wk: 100%	98%	79%
Intervention			1y: 84%	72 wk: 86%		
Control			1y: 87%	72 wk: 90%		
Intervention			2y: 74%			
Control			2y: 81%			
<b>Exercise</b>	No	Yes	Yes	22 wk: Yes	Yes	Yes
<b>Controlled</b>				72 wk: No		

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\* = Due to setting location

† = Diet definitions: WFPB = whole-food, plant-based diet; +A =  $\leq 1$  serving animal food per day; -A = no animal foods (vegan);

LGI = low glycemic index; habitual = regular baseline diet

‡ = Completed: % of participants who completed study's anthropometric and or laboratory measurements

## 5.1 Education and Intervention Techniques

This review gathers published data to understand which nutrition education strategies have been utilized in WFPB nutrition interventions and to analyze which techniques foster greater effects. Table 2 provides different education and support characteristics utilized in WFPB controlled trials. The table however does not capture all of the important details of the interventions. To provide further information regarding the design, process, protocols and education techniques of each intervention examined in this review, further details describe each individual study.

Table 2. Intervention Education and Support Characteristics in WFPB Diet Controlled Trials

	<b>Lifestyle Changes for Reversal of Coronary Heart Disease</b>	<b>Pilot Intervention: Low-fat, Vegetarian Diet in NIDDM</b>	<b>Low-Fat Vegan Diet v. Step II Diet in Overweight Post-menopausal Women</b>	<b>Low-Fat Vegan Diet Improves Glycemic Control &amp; CVD Risk Factors in T2DM</b>	<b>Multicomponent Intervention Reduces Weight &amp; CVD Risk at a GEICO Corporate Site</b>	<b>Plant-Based Nutrition Program to Reduce Weight &amp; CVD Risk. GEICO Study</b>
<b>Setting of education</b>	Hotel & university medical center	University medical center	NR	NR	Corporate work site	Corporate work site
<b>Group Meetings</b>	Yes	Yes	Yes	Yes	Yes	Yes
Duration	4hr 2x/wk (1y)	1hr 2x/wk (12 wks)	1hr/wk (14 wks) 1hr/2wk (1y)	1hr/wk (22 wks) 1hr/2wk (52 wks)	1hr/wk (22 wks)	1hr/wk (18 wks)
<b>Group Discussion</b>	Yes	NR	Yes	NR	Yes	Yes
<b>Individual Support</b>	Yes	Yes	Yes	Yes	Yes	NR
<b>Family Involvement</b>	NR	Yes	Yes	NR	NR	NR
<b>Food Interactions *</b>	Yes	Yes	Yes	No	Yes	Yes
<b>Diet Monitoring †</b>	NR	Yes	Yes	Yes	Yes	Yes
<b>Reported Dietary Information Topics Taught</b>	2	2	6	5	3	7
<b>Who administered education?</b>	Clinical Psychologist	NR	Physician, RD	Physician, RD and/or cooking instructor	Physician, RD and/or cooking instructor	Physician, RD and/or cooking instructor

\* = Food interactions: taste-tests, shared meals, pre-made meals provided or meals available in work cafeteria

† = Diet monitoring: any type of data collection in reference to what participants are eating

### Setting of Education

Ornish et al. (1990) conducted the first week of education in a hotel and then completed the nutrition education in a university medical center. Nicholson et al. (1999) also completed the intervention in a university medical center. Two studies educated in corporate employment offices (Ferdowsian et al. 2010 & Mirsha et al. 2013a) and 2 studies did not report the location of the education (Barnard et al. 2004 & 2006). However, both the unreported studies were not in a confined research lab and reported participants were free-living.

### Group meetings and duration

All 6 studies utilized group meetings. Four of the 6 studies met once per week for 1 hour. Two studies met twice per week (Ornish et al. 1990 & Nicholson et al. 1999). Nicholson et al. (1999) met for 1 hour, 2 times per week while Ornish et al. (1990) met 2 times weekly for 4 hours. Ornish et al. (1990) also conducted 1 full week of group education at the beginning of the study and Nicholson et al. (1999) also had a half-day group orientation with family at the study's onset.

### Group discussion

Group discussion was reported in 4 of the 6 studies. One of the 4 studies described group discussion as a place for participants to express their feelings regarding work and home relationships (Ornish et al. 1990). The remaining 3 studies said nothing other than 'group discussion' (Barnard et al. 2004, Ferdowsian et al. 2010 & Mirsha et al. 2013a).

### Individual Support

Individual support of different types were reported in 5 of the 6 studies. Two studies described individual support that was not for the diet, but for exercise (Ornish et al. 1990) and medication safety (Nicholson et al. 1999). The remaining 3 studies used 24 hour dietary phone recalls as a means of checking participant's adherence to the diet and providing encouragement (Turner-McGrievy et al. 2004). When non-adherence was reported, an individual meeting was then made with the participant and a RD for additional support.

## Family Involvement

Family involvement was reported in 2 of the 6 interventions. Nicholson et al. (1999) encouraged all participants to invite a friend or family member to accompany them to group sessions and in eating their assigned diets. In Barnard et al. (2005), family and friends were invited to accompany participants to attend 2 nutrition lectures on the assigned diets and study procedures before the weekly 1 hour group meetings began.

## Food Interactions

Food interactions are defined as taste-tests, pre-made meals or meals available in work cafeterias. Five studies reported differing food interactions. Ornish et al. (1990) reported take-home meals being available for participants who wanted them. A shared meal was provided at every group session in Nicholson et al. (1999). In addition, participants in both groups were offered pre-made, microwavable lunches and dinners that met dietary guidelines. Intervention meals included lentil soup, cucumber salad and rice crackers for lunch, garbanzo stew, bulgur and leafy greens for dinner (Nicholson et al. 1999). Participants could prepare their own meals, but most chose the prepared meals (Nicholson et al. 1999). Barnard et al. (2004) reported the taste-testing of novel food items as the only food interaction. Participants prepared their own meals and ate at restaurants (Barnard et al. 2005). The two corporate worksite studies also offered taste-tests during group sessions as well as offering WFPB meals in their cafeterias (Katcher et al. 2010 & Mishra et al. 2013b).

Katcher et al.'s (2010) cafeteria meal's included oatmeal, lentil soup, minestrone soup, veggie burgers, portobello mushroom sandwiches, salads, bean burritos and rice and beans. Approximately one breakfast item, two lunch entrees and two lunch side dishes that met the dietary guidelines, were available daily amongst the traditional fare. Adherent daily offerings were left up to the cafeteria food service teams. The WFPB meals were highlighted in the cafeteria. The menus varied between the intervention sites (Mishra et al. 2013a). A sample menu is provided in Table 3.

Table. 3 A WFPB Menu Sample in a Corporate Worksite's Cafeteria

Breakfast options	<ol style="list-style-type: none"> <li>1. oatmeal with cinnamon, raisins &amp; soy/rice milk with <ul style="list-style-type: none"> <li>- pumpernickel toast with jam</li> <li>- grapefruit or</li> </ul> </li> <li>2. whole-grain bagel with apple butter with <ul style="list-style-type: none"> <li>- veggie bacon</li> <li>- cantaloupe</li> </ul> </li> </ol>
Lunch options	<ol style="list-style-type: none"> <li>1. whole-wheat pita with veggies and hummus with <ul style="list-style-type: none"> <li>- carrot sticks or</li> </ul> </li> <li>2. bean burritos (corn tortilla filled with black beans, salsa, tomatoes and lettuce) with <ul style="list-style-type: none"> <li>- spinach salad and a low-fat dressing</li> </ul> </li> </ol>
Dinner options	<ol style="list-style-type: none"> <li>1. baked sweet potato or baked beans with <ul style="list-style-type: none"> <li>- steamed collard greens &amp; lemon juice</li> <li>- baked apple or</li> </ul> </li> <li>2. chinese stir-fry over brown rice (tofu, broccoli, pea pods, water chestnuts, bok-choy) with <ul style="list-style-type: none"> <li>- cantaloupe</li> </ul> </li> </ol>
Snack options	<ol style="list-style-type: none"> <li>1. dried figs</li> <li>2. fruit salad or</li> <li>3. baked corn tortillas with salsa</li> </ol>

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Recreated from Mishra et al. (2013a).

### Diet Monitoring

Five out of the 6 studies monitored participant's diet which may have influenced participant's adherence. Twenty-four hour diet recalls were administered via phone in Barnard et al. (2004) 3 times in 14 weeks; 7 times in 74 weeks in Barnard et al. (2006) and Ferdowsian et al. (2010) administered 24 hour diet recalls 3 times in 22 weeks. Mirsha et al. (2013a) conducted online 24 hour diet recalls 4 times over an 18 week period. Nicholson et al. (1999) administered self-reported questionnaires handed out at the weekly group meals. Ornish et al. (1998) did not report any type of diet monitoring throughout the study.



## Information Taught

Each study reported briefly on what information was taught. Ornish et al. (1990 & 1998) only reported adherence measures and communication skills in regards to diet being taught. Cooking instruction and nutrition information was reportedly taught in the remaining 5 studies. Additional differences in the educational curriculum ranged from animal food substitutions (Mirsha et al. 2013b) to getting support from family and friends (Ferdowsian et al. 2010). The number of taught topics reported varied between studies and is presented in Table 2.

## Who Administered Education?

Educators varied in each of the studies including physicians, RDs, cooking instructors and clinical psychologists. Barnard et al. (2005) noted that other nutritional professionals can also play an important role in assisting participants in weight-loss programs. Nicholson et al. (1999) did not report who administered the program education.

### 5.1.1 Education and Intervention Techniques Summary

Each study reported using various nutrition education techniques (live lectures, video lectures, audio cassettes, in-person group and individual education), behavior change strategies (diet monitoring) and additional support components such as food interactions, group discussion and diet monitoring. Different information was taught such as cooking techniques, the role of nutrition in chronic disease and how to maintain diet adherence in restaurants, while traveling and at work. Financial and reward incentives, mobile applications, meal replacement and structured meals plans with calorie restricted diets were not employed in any of the 6 intervention groups.

Neal Barnard was involved in 5 of the 6 studies (Nicholson et al. 1999, Barnard et al. 2004, 2006, Ferdowsian et al. 2010 & Mirsha et al. 2013a), 4 of which reported similar education administrators, ‘group meeting duration,’ ‘diet monitoring’ and ‘information taught’ (Barnard et al. 2004, 2006, Ferdowsian et al. 2010 & Mirsha et al. 2013a). We can only assume that the

education curriculum and intervention protocol may have been the same in these studies. Trapp et al. (2010) published a paper on plant-based diets “to provide educators with the knowledge and tools to utilize plant-based nutrition education as an intervention for type 2 diabetes” which Neal Barnard co-authors. This guide is based on Barnard et al. (2009a) which is reviewed in this study.

## 5.2 Changes in Nutrient Intake

Changes in nutrient intakes are summarized below and in more detail in Table 4.

### Carbohydrate

Four of the 6 studies conducted statistical analysis on changes in carbohydrate intake. Of those 4, all 4 showed a significant increase of carbohydrate intake compared to control. All 6 studies showed an increase of carbohydrate intake within the WFPB groups and compared to control groups. Three of the 6 studies increased carbohydrate intake above 70% of energy (75 to 78%) at follow-up, meeting carbohydrate adherence and the remaining 3 increased carbohydrate intake between 55 to 69% of energy (57 to 68%) at follow-up.

### Protein

Protein intake decreased in all 6 studies. Of the 4 studies reporting significance, all 4 decreased protein intake significantly compared to baseline and more than the control groups at follow-up. All 6 studies reduced protein intake to  $\leq 15\%$  of calories.

### Fat

Fat consumption decreased in all 6 interventions. Five of the 6 studies conducted between group differences and all 5 intervention groups decreased fat significantly more than control. Three of the 6 controlled trials reduced intake to  $\leq 15\%$  of total energy (9 to 11%), 2 studies reduced fat to 16 to 25% of energy (21 and 22%) and 1 study reduced fat intake to 31% of energy. Saturated

fat fell to <10% of energy in all 5 studies, ranging from 2 to 9% of energy. Four studies conducted statistical analyses, and saturated fat intake fell significantly more in all 4 WFPB groups than in control groups.

#### Dietary cholesterol

Dietary cholesterol decreased in every WFPB intervention group. Dietary cholesterol fell significantly more in the WFPB groups compared to control in the 5 studies that conducted analysis.

#### Dietary fiber

Dietary fiber intake was reported in 5 studies and increased in all 5. Four studies documented significant differences between groups and all 4 of these WFPB groups increased fiber intake significantly more than controls.

#### 5.2.2 Nutrient Intake Summary

Protein, total fat, saturated fat and dietary cholesterol fell significantly more in the WFPB groups in all of the studies. Carbohydrate and fiber intake increased significantly more in all of the WFPB groups compared to control. All 6 studies met WFPB adherence criteria for fat at  $\leq 15\%$  of total energy; all 6 adhered to protein guidelines at 10-15% of calories and 3 studies met carbohydrate recommendations at 70-80% of calories from carbohydrates.

Table 4. Energy and Nutrient Intakes at Baseline and Follow-Up in WFPB Controlled Trials

	<b>Lifestyle Changes for Reversal of Coronary Heart Disease *</b>	<b>Pilot Intervention: Low-fat, Vegetarian Diet in NIDDM *</b>	<b>Low-Fat Vegan Diet v. Step II Diet in Overweight Post-menopausal Women †, ‡</b>	<b>Low-Fat Vegan Diet Improves Glycemic Control &amp; CVD Risk Factors in T2DM †</b>	<b>Multicomponent Intervention Reduces Weight &amp; CVD Risk at a GEICO Corporate Site †</b>	<b>Plant-Based Nutrition Program to Reduce Weight &amp; CVD Risk. GEICO Study†</b>
<b>Energy</b> (kcal/day)	No (J/day)		No (MJ/d)	No, No	Yes	No
Intervention	1y: 8159 to 7623	1683 to 1409	7.42 to 5.89 §	22 wk: 1746 to 1432 §	1857 to 1451 §	1978 to 1647 §
Control	1y: 7159 to 7004 P = 0.64	1430 to 1526	7.37 to 5.96 § P = NS	22 wk: 1844 to 1458 § P = 0.43	1728 to 1584 P = 0.01	1835 to 1712 P = 0.41
Intervention	5y: 7724	NA	NR	72 wk: 1798 to 1366 §	NA	NA
Control	5y: 6581 P = 0.86			72 wk: 1840 to 1422 § P = 0.90		
<b>Carbohydrate</b> %E			Yes	Yes, Yes	Yes	Yes
Intervention	NR	46 to 75	53 to 78 §	22 wk: 203 to 245 (g/d)	48 to 68 §	50 to 57 §
Control		46 to 51	53 to 62 § P <0.001	22 wk: 210 to 170 § (g/d) P <0.0001	48 to 48 P <0.0001	48 to 47 P = 0.006
Intervention	5y: 53 to 77	NA	NR	72 wk: 48 to 66 §	NA	NA
Control	5y: 51 to 52 P = NR			72 wk: 46 to 47 P <0.0001		
<b>Protein</b> %E			Yes	Yes, Yes	Yes	Yes
Intervention	NR	20 to 14	16 to 12 §	22 wk: 77 to 53 § (g)	16 to 14 §	16 to 15 §
Control		23 to 18	17 to 18 P <0.001	22 wk: 85 to 74 § (g) P <0.0001	18 to 18 P = 0.03	17 to 17 P = 0.03
Intervention	5y: 17 to 15	NA	NR	72 wk: 17 to 15 §	NA	NA
Control	5y: 19 to 18 P = NR			72 wk: 19 to 21 § P = 0.0003		
<b>Total fat</b> %E	Yes		Yes	Yes, Yes	Yes	Yes
Intervention	1y: 30 to 6	34 to 11	30 to 11 §	22 wk: 71 to 32 § (g)	36 to 21 §	35 to 31 §
Control	1y: 31 to 29 P <0.001	31 to 31	29 to 20 § P <0.001	22 wk: 74 to 56 § (g) P = 0.0001	36 to 36 P <0.0001	38 to 37 P = 0.02
Intervention	5y: 9	NA	NR	72 wk: 36 to 22 §	NA	NA
Control	5y: 25 P <0.001			72 wk: 35 to 34 P <0.0001		

<b>Saturated fat %E</b>			Yes	Yes, Yes	Yes	Yes
Intervention	NR	10 to 3	11 to 2 § (g)	22 wk: 24 to 7 § (g)	12 to 5 § (g)	11 to 9 §
Control		11 to 8	10 to 6 § (g)	22 wk: 23 to 16 § (g)	13 to 13 (g)	12 to 12
			P <0.01	P <0.0001	P <0.0001	P = 0.006
Intervention	NR	NA	NR	72 wk: 12 to 5 §	NA	NA
Control				72 wk: 11 to 10		
				P <0.0001		
<b>Dietary cholesterol (mg/d)</b>			Yes	Yes	Yes	Yes
Intervention	1y: 211 to 3	289 to 4	131 to 12 §	22 wk: 296 to 45 §	132 to 27 §	136 to 43 § ‡
Control	1y: 213 to 181	310 to 122	131 to 84 §	22 wk: 310 to 203 §	157 to 182	137 to 134 ‡
	P <0.001		P <0.001	P = 0.001	P <0.0001	P = 0.009
Intervention	5y: 19	NA	NR	72 wk: 159 to 36 § ‡	NA	NA
Control	5y: 139			72 wk: 168 to 170 ‡		
	P = 0.002			P <0.0001		
<b>Fiber (g/d)</b>			Yes	Yes, Yes	Yes	Yes
Intervention	NR	14 to 26	12 to 22 §	22 wk: 19 to 35 §	10 to 21 §	10 to 15 § ¶
Control		12 to 20	11 to 14 §	22 wk: 19 to 18	9 to 10	10 to 10 ¶
			P <0.001	P <0.0001	P <0.0001	P = 0.001
Intervention	NR	NA	NR	72 wk: 11 to 22 § ¶	NA	NA
Control				72 wk: 11 to 13 § ¶		
				P <0.0001		

\* = within group differences not reported

† = within group differences reported

‡ = participants were followed for nutrient measures for 14 weeks and followed for 1 and 2 years for weight and adherence measurements only

§ = statistically significant change within group reported

‖ = mg/1000 kcal

¶ = g/1000 kcal

No = the difference between groups was not statistically significant at the follow-up times

Yes = the difference between groups was statistically significant at the follow-up times

NR = not reported

NA = not applicable

### 5.3 Changes in Clinical Measurements

#### Weight

Weight decreased significantly more in the WFPB groups in 5 of the 6 interventions (Table 5) despite none of the WFPB groups portion restricting. In the 1 study that did not meet a significant change ( $P = 0.08$ ) (Barnard et al. 2006), the WFPB group was compared to the portion restricted and energy deficit diet of the ADA.

#### BMI

BMI was reported in 3 of the 6 studies. Of these 3, 2 showed the WFPB groups to have reduced BMI significantly more than control. Again, in the 1 study that did not see a significant difference ( $P = 0.08$ ) (Barnard et al. 2006), the WFPB group was compared to the portion restricted and calorie deficit diet of ADA. When analyzing for participants whose medications remained unchanged, all of the 3 studies showed a significant decrease in BMI compared to controls (Barnard et al. 2006).

#### Total Blood Cholesterol Concentrations

Blood cholesterol concentrations were reported in 5 of the 6 interventions. Two of these 5 studies showed significantly lower cholesterol concentrations in the WFPB groups. Total serum cholesterol concentrations reduced significantly within the WFPB groups in all 3 studies reporting serum cholesterol. Follow-up blood cholesterol concentrations ranged between 157 mg/dl (4.06 mmol/l) and 188 mg/dl (4.86 mmol/l) in the WFPB groups.

When separate analyses were performed to control for the effects of cholesterol lowering medications, 3 of the 5 interventions significantly lowered cholesterol concentrations more in the WFPB groups. Total cholesterol levels decreased significantly more ( $P = 0.01$ ) in the WFPB group when Barnard et al. (2006) analyzed participants whose medications did not change throughout the course of the 22 week study. When controlling for medications, Levin et al.

(2010) found no significant difference in cholesterol levels between the groups ( $P = 0.09$ ). Blood cholesterol concentrations were significantly lower ( $P < 0.001$ ) in the WFPB group in an additional study when adjusted for medication and other factors (Mishra et al. 2013a).

### Triglycerides

One of 5 studies reporting triglyceride levels found a significant increase in triglyceride levels in the WFPB group (Mirsha et al. 2013a). There was no significant differences in triglyceride levels between groups in the remaining 4 studies.

### Blood Pressure

Systolic and diastolic blood pressure was reported in 5 of the 6 studies. The study by Ferdowsian et al. (2010) showed a significant difference between the groups, finding the systolic and diastolic blood pressures increased in the control group. Changes were not significant between groups in 4 of the 5 studies. The WFPB group's blood pressure did not increase in any study. When adjusting for medications, blood pressure differences remained non-significant between groups in the same 4 studies.

### Fasting Blood Glucose

FBG was reported in 3 of the 6 controlled trials. Using an intention-to-treat analysis, 1 of the 3 studies found a significantly greater decrease in FBG in the WFPB group compared to control. The 2 remaining studies found the same, except results were not significant. Results remained the same when controlling for medication changes.

### Hemoglobin A1c

Three of 6 studies reported changes in hemoglobin A1c measurements. Hemoglobin A1c decreased the same or more in the WFPB group compared to control in all 3 studies. The decrease was significant in 1 of the 3 studies. When analyzing hemoglobin A1c only in

participants whose medications remained unchanged, hemoglobin A1c decreased significantly more in 2 of the 3 studies for the WFPB participants.

### 5.3.1 Medication Changes

In Ornish et al.'s (1998) 'Lifestyle Changes for the Reversal of CHD' study, blood cholesterol concentrations decreased significantly more in intervention group at 1 year ( $P = 0.04$ ) when none of the experimental group participants were on statin lipid-lowering drugs. At 5 years, serum cholesterol concentrations were not significant ( $P = 0.60$ ). However, none of the experimental group participants needed to be prescribed statins throughout the 5 year study, while 60% of the control group participants were prescribed statin drugs between years 1 and 5.

During a pilot intervention (Nicholson et al. 1999), oral hypoglycemic medications were discontinued in 1 and lowered in 3 of the 6 experimental group participants on these drugs. Insulin dose decreased on both intervention patients on insulin. No reductions in medication could be made in all 4 control patients. Antihypertensive medications were discontinued in 2 of the 5 WFPB group members while 1 of the 4 people in the control group eliminated 1 of their 4 prescribed anti-hypertensive medications (Nicholson et al. 1999).

In Barnard et al.'s (2006) 22 week intervention comparing a WFPB diet to that of the ADA, 43% of the WFPB group and 26% of the ADA group reduced diabetes medications, mainly out of necessity from hypoglycemia. Eight percent of the intervention group and 8% of the ADA group increased diabetes medications without investigator permission (Barnard et al. 2006). At 74 weeks, a greater number of intervention participants reduced diabetes medication (35%) compared to control (20%), while more ADA participants increased medications (24%) compared to the WFPB group (14%) (Barnard et al. 2009a).

Of the 3 studies reporting medication changes, the WFPB group either avoided starting medication (Ornish et al. 1998) or reduced or eliminated more medications compared to controls (Nicholson et al. 1999 & Barnard et al. 2006).



Table 5. Clinical Measurements at Baseline and Follow-Up in WFPB Controlled Trials

	<b>Lifestyle Changes for Reversal of Coronary Heart Disease *</b>	<b>Pilot Intervention: Low-fat, Vegetarian Diet in NIDDM *</b>	<b>Low-Fat Vegan Diet v. Step II Diet in Overweight Post-menopausal Women †, ‡</b>	<b>Low-Fat Vegan Diet Improves Glycemic Control &amp; CVD Risk Factors in T2DM †</b>	<b>Multicomponent Intervention Reduces Weight &amp; CVD Risk at a GEICO Corporate Site †</b>	<b>Plant-Based Nutrition Program to Reduce Weight &amp; CVD Risk. GEICO Study †</b>
<b>Weight (kg)</b>	Yes, Yes	Yes	Yes, Yes, Yes	No, No § §	Yes §	Yes
Intervention	1y: 91.4 to 80.6	96.7 to 89.5	14 wk: $-5.8 \pm 3.2$	22 wk: $-5.8 \pm 4.4$ §	$-5.1 \pm 0.6$ §	$-2.9 \pm 0.34$ §
Control	1y: 75.7 to 77	97.0 to 93.2	14 wk: $-3.8 \pm 2.8$	22 wk: $-4.3 \pm 4.4$ §	$+0.1 \pm 0.6$	$-0.06 \pm 0.33$
	P = 0.001	P <0.005	P = 0.012	P = 0.08	P <0.0001	P <0.001
Intervention	5y: 85.6		1y: -4.9	72 wk: $-4.4 \pm 0.9$		
Control	5y: 77		1y: -1.8	72 wk: $-3.0 \pm 0.8$		
	P = 0.001		P = 0.021	P = 0.25		
Intervention			2y: -3.1			
Control			2y: -0.8			
			P = 0.022			
<b>BMI (kg/m2)</b>			Yes	No, No		Yes
Intervention	NR	NR	14 wk: $-2.2 \pm 1.2$	22 wk: $-2.1 \pm 1.5$	NR	$-1.04 \pm -0.1$ §
Control			14 wk: $-1.4 \pm 1.0$	22 wk: $-1.5 \pm 1.5$		$-0.01 \pm 0.1$
			P = 0.012	P = 0.08		P <0.001
				72 wk: $-1.6 \pm 0.3$		
				72 wk: $-1.1 \pm 0.3$		
				P = 0.25		
<b>Total Blood Cholesterol (mg/dl)</b>	Yes, No	No	NR	No, No	No	Yes
Intervention	1y: 225 to 163	203 to 179		22 wk: $-27.7 \pm 28.5$ §	$-9.8 \pm 3.6$ §	$-8.0 \pm 2.1$ §
Control	1y: 248 to 244	215 to 191		22 wk: $-24.2 \pm 30.5$ §	$-1.6 \pm 3.5$	$-0.01 \pm 1.5$
	P = 0.004	P >0.05		P = 0.56	P = 0.13	P <0.001
Intervention	5y: 188			72 wk: $-21.6 \pm 4.2$		
Control	5y: 217			72 wk: $-14.8 \pm 5.1$		
	P = 0.60 §			P = 0.31		

<b>Triglycerides (mg/dl)</b>	No, No	No		No, No	No	Yes
Intervention	1y: 228 to 258	188 to 167	NR	22 wk: $-28.5 \pm 80.0$ §		
Control	1y: 223 to 166	203 to 164		22 wk: $-25.1 \pm 124.7$	$-4.4 \pm 6.5$	$+9.9 \pm 3.8$ §
	P = 0.17	P >0.05		P = 0.87	$+3.5 \pm 10.1$	$-1.4 \pm 3.3$
Intervention	5y: 236			72 wk: $-33.9 \pm 12.7$	P = 0.49	P = 0.02
Control	5y: 212			72 wk: $-7.8 \pm 28.9$		
	P = 0.78			P = 0.41		
<b>BP systolic (mmHg)</b>	No, No	No		No, No	Yes	No
Intervention	1y: 135 to 126	137 to 126	NR	22 wk: $-3.8 \pm 12.6$ §	$0 \pm 1.4$	$-1.7 \pm 0.7$ §
Control	1y: 137 to 129	150 to 131		22 wk: $-3.6 \pm 13.7$	$5.7 \pm 2.2$ §	$-2.8 \pm 0.9$ §
	P = 0.96	P >0.05		P = 0.93	P = 0.03	P = 0.38
Intervention	5y: 130			72 wk: $-0.0 \pm 2.0$		
Control	5y: 123			72 wk: $3.7 \pm 1.9$		
	P = 0.19			P = 0.19		
<b>BP diastolic (mmHg)</b>	No, No	No		No, No	Yes	No
Intervention	1y: 82 to 77	84 to 78	NR	22 wk: $-5.1 \pm 8.3$ §	$-0.4 \pm 1.1$	$-2.4 \pm 0.6$ §
Control	1y: 80 to 75	86 to 75		22 wk: $-3.3 \pm 8.8$ §	$+5.1 \pm 1.2$ §	$-2.0 \pm 0.5$ §
	P = 0.91	P >0.05		P = 0.30	P = 0.002	P = 0.54
Intervention	5y: 77			72 wk: $-3.9 \pm 1.3$		
Control	5y: 74			72 wk: $-2.7 \pm 1.1$		
	P = 0.74			P = 0.48		
<b>FBG (mg/dl)</b>		Yes	No	No, No		
Intervention	NR	193 to 140	$-6.5 \pm 11.7$ §	22 wk: $-35.5 \pm 48.3$ §	NR	NR
Control		177 to 156	$-1.8 \pm 9.5$	22 wk: $-34.6 \pm 44.7$ §		
		P <0.05	P = 0.10	P = 0.92		
Intervention				72 wk: $-19.5 \pm 7.1$		
Control				72 wk: $-14.0 \pm 8.2$		
				P = 0.61		
<b>Hemoglobin A1c (%)</b>				No, No	No	Yes
Intervention	NR	NR	NR	22 wk: $-1.0 \pm 1.2$ §	$-0.3 \pm 0.6$	$-0.60 \pm 0.17$ §
Control				22 wk: $-0.6 \pm 1.1$ §	$-0.3 \pm 0.2$	$-0.08 \pm 0.09$ §
				P = 0.09	P = 0.97	P = 0.004
Intervention				72 wk: $-0.34 \pm 0.19$		
Control				72 wk: $-0.14 \pm 0.17$		
				P = 0.43		

**Medication  
Changes**

Intervention	No ↑ ‖	Yes ↓	NR	22 wk: 43% ↓, 8% ↑	NR	NR
Control	Yes ↑	No ↓		22 wk: 26% ↓, 8% ↑		
Intervention	No ↑ ‖	NA		72 wk: 35% ↓, 14% ↑		
Control	Yes ↑	NA		72 wk: 20% ↓, 24% ↑		

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\* = within group differences not reported

† = within group differences reported

‡ = participants were followed for nutrient measures for 14 weeks and followed for 1 and 2 years for weight and adherence measurements only

§ = statistically significant change within group reported

‖ = 60% of control participants were placed on lipid-lowering statin drugs between years 1 and 5 and no participant in the intervention group was on statin drugs

No = the difference between groups was not statistically significant at the follow-up times

Yes = the difference between groups was statistically significant at the follow-up times

In addition to the clinical measurements reported in Table 5., Ornish et al. (1998) measured changes in cardiac disease outcomes.

#### Anginal episodes

The WFPB group reduced the frequency of anginal episodes by 91% at one year and 72% at five years. The control group experienced a 186% increase in angina frequency at one year and 36% decrease at five years. The reduction at five years in the control group was partly from coronary angioplasties that three of the five participants with angina underwent (Ornish et al. 1998).

#### Angiographic changes

The WFPB group's average percent diameter stenosis regressed from 40.0% to 37.8% during a 1 year period (Ornish et al. 1998). This change was positively correlated with lifestyle change (Ornish et al. 1998). The control group receiving standard health care, saw a progression of their average percent diameter stenosis, increasing from 42.7% to 46.1% (Ornish et al. 1998). The intervention group showed more disease regression at 5 years than at 1 year (Ornish et al. 1998). The control group experienced disease progression and twice as many cardiac events at five years (Ornish et al. 1998). The results were statistically significant between-groups at one year ( $P = 0.02$ ) and five years ( $P = 0.001$ ) (Ornish et al. 1998).

#### Cardiac Events

There were significantly less cardiac events at five years in the plant-based group compared to the standard care group (0.89 vs. 2.25 events per patient.  $P < 0.001$ ). The control group experienced significantly more angioplasties ( $P < 0.05$ ) and cardiac hospitalizations ( $P < 0.001$ ). At 5 years, there were significantly less cardiac hospitalizations ( $P < 0.001$ ) and significantly less 'any cardiac event' ( $P < 0.001$ ) (Ornish et al. 1998).

The worsening outcomes in the control group were seen even though these participants were meeting the "risk reduction behavior" of the American Heart Association and the NCEP's Step II

Diet. Control group participants were consuming 25% of calories from fat at five years and exercised 3.5 times a week (Ornish et al. 1998). Ornish et al. (1998) stated “these data are consistent with other studies that indicate that moderate changes in diet and lifestyle may not be sufficient to stop the progression of coronary atherosclerosis unless combined with lipid-lowering drugs.”

### 5.3.2 Clinical Measurements Summary

Weight decreased significantly more in the WFPB in 5 of the 6 studies. BMI decreased significantly more in 2 of the 3 studies; total cholesterol concentration decreased significantly more in 2 of the 5 studies; blood pressure decreased significantly more in 1 of the 5 studies; FBG decreased significantly more in 1 of the 5 studies; and hemoglobin A1c decreased significantly more in 1 of 3 studies reporting these measurements. Triglycerides increased significantly more compared to control in 1 of the 5 studies.

When controlling for medication use, BMI decreased significantly more in the WFPB group in 3 of the 3 studies; blood cholesterol concentrations decreased significantly more in 3 out of the 5 studies; blood pressure decreased significantly more in 1 out of the 5 studies; FBG decreased significantly more in 1 out of the 3 studies; and hemoglobin A1c decreased significantly more in 2 out of the 3 studies reviewing these measurements.

These results suggest a WFPB diet is an effective diet for reducing weight and BMI and may be an effective diet for simultaneously improving blood cholesterol concentrations, FBG and hemoglobin A1c concentrations, especially in participants whose medications are unchanged. In addition, WFPB participants are more likely to avoid lipid-lowering drugs, reduce or eliminate more medications compared to controls (Nicholson et al. 1999 & Barnard et al. 2006). Triglyceride concentrations may increase on a WFPB diet.

#### 5.4 Adherence to a WFPB Diet

Each study used its own criteria for analyzing and determining adherence to a WFPB diet making it difficult to compare adherence results according to studies' reported adherence rates. Using the nutrient composition definition set forth by this report ( $\leq 15\%$  of energy from fat, 70-75% from carbohydrates and 10-15% of energy from protein), all 6 studies adhered to fat and protein recommendations and 50% of the studies adhered to carbohydrate recommendations. These findings suggest participants are successful in adhering to a WFPB diet for at least 12 weeks (Table 4). Additionally, significantly greater decreases in weight were found in 5 of the 6 studies (Table 5) which also suggests worthy adherence to the WFPB diet. Three studies reported which aspects of the intervention they believed, solicited greater adherence to a WFPB diet.

Three studies discussed what the researchers believed assisted in diet adherence. For example, Barnard et al. (2006) suggests the lack of portion restriction may make adhering to a WFPB diet easier for diabetics compared to the ADA's energy restricted diet. Ferdowsian et al. (2010) credits a high completion rate from a supportive group environment combined with a centralized location, health information from medical professions and interactive activities such as cooking demonstrations. Ornish et al. (1998) measured adherence rates against percent diameter stenosis. A correlation was observed at 5 years in a dose-response relationship. The tertile of participants with the greatest level of adherence experienced the most disease regression and the tertile adhering least, halted the progression of the disease, but did not reverse it ( $P = 0.04$ ) (Ornish et al. 1998).

#### 5.5 Acceptability of a WFPB Diet

Any diet is only clinically useful if it is acceptable to those it is prescribed to. Three of the 6 interventions quantifiably measured the acceptability of a WFPB compared to control diets (Barnard et al. 2004, 2009b & Katcher et al. 2010).

## Acceptability of a WFPB Diet Compared to the NCEP Step II Diet

Barnard et al. (2004) researched the acceptability of a WFPB diet and the NCEP's Step II diet using an eating inventory questionnaire and a food acceptability questionnaire (FAQ). The FAQ measured dietary restraint (the extent to which participants felt constrained by their diet) and disinhibition (overeating in response to stress); and the hunger factor (the subjective feeling of hunger). Dietary restraint increased significantly more in the NCEP group compared to the WFPB group ( $P < 0.01$ ). No change was seen in restraint within the WFPB group. This result suggests that a WFPB diet is less constraining than the NCEP's diet and that a WFPB is not any more constraining than the baseline diet. Both disinhibition and hunger scores decreased both groups (disinhibition:  $P < 0.001$  in each group) (hunger:  $P < 0.01$  in each group). The differences between groups were not significant (Barnard et al. 2004).

The outcomes of the FAQ questionnaire (Barnard et al. 2004) found no significant differences between groups, suggesting that a WFPB diet is as acceptable as the NCEP diet, specifically in regards to how much participants liked the current diet, how easy it was to prepare and how easily it would be to continue the diet. Ninety-three percent of the WFPB group reported the diet was either extremely good, good or moderately good at 14 weeks. Eighty-six percent of the WFPB participants reported they could continue this diet in the future at least most of the time and 75% of the intervention group found their food to be fairly, moderately or extremely easy to prepare. Although there was not a significant difference between groups for the ease of preparing food, there was a significant difference from baseline to 14 weeks within the plant-based group ( $P < 0.05$ ). The intervention group reported preparing foods was less easy at the end of 14 weeks compared to their baseline diet. Seventy-one percent of the intervention group found continuing to purchase, prepare and eat the assigned foods to be fairly easy, moderately easy or extremely easy. Eighty-nine percent of the intervention participants were mostly or completely use to the diet at 14 weeks (Barnard et al. 2004). Both the intervention and control group reported a significant within group increase in energy, weight loss and better sleep. However, only flatulence was significantly different between groups ( $P < 0.05$ ) with the WFPB group experiencing a greater increase (within intervention group:  $P < 0.01$ ) (Barnard et al. 2004).

### Acceptability of a WFPB Diet Compared to the ADA's Diabetes Diet

Barnard et al. (2009b) quantified the adherence and acceptability of a WFPB diet and the ADA's diabetes diet with a FAQ, an eating inventory questionnaire and a food-craving inventory that were completed at baseline, 22 and 74 weeks (Barnard et al. 2009b). The FAQ found the WFPB group had a significantly more difficult time preparing foods compared to control at 22 weeks ( $P = 0.02$ ), although the median answer was the same for both groups: "fairly easy." There was no difference between groups for the remaining 9 questions suggesting a WFPB diet is as easy to follow as the ADA's diabetes diet (Barnard et al. 2009b).

The eating inventory found dietary restraint increased significantly within both groups, although the change was significantly greater within the ADA group. Both groups experienced a significant within group decrease in disinhibition and hunger at 22 weeks (Barnard et al. 2009b) but between group differences were not significant. The food-craving inventory found cravings did not increase for any food in either group. The WFPB group experienced a significantly greater decrease in fat cravings at 22 weeks compared to control ( $P = 0.05$ ). No other craving differences were found between groups. Within group analysis found the WFPB group experienced a significant decrease in cravings for fats, sweets and total cravings compared to a significant decrease only in cravings of fast food within the ADA group (Barnard et al. 2009b). There were no significant differences between groups at 74 weeks in the FAQ, the eating inventory or the food-craving inventory (Barnard et al. 2009b).

### Acceptability of a WFPB Diet Compared to a Habitual Diet in a Corporate Worksite

The 22 week GEICO study's (Katcher et al. 2010) FAQ found no change within the WFPB group for how well the participants liked the food; the food's appearance; the boringness of the food; the difficulty in preparing food; difficulty in purchasing food; maintaining the diet at restaurants; effort to stay on the diet; and satisfaction after eating. There was a significant increase in the satisfaction of the diet within the WFPB group ( $P < 0.001$ ) and a significant decrease in the cost of the diet ( $P < 0.05$ ). The only difference between the WFPB and the control group's habitual diet was in the difficulty of maintaining the diet at restaurants, which was more



difficult in the WFPB group ( $P = 0.04$ ). Additional questions from the FAQ found that between groups, the WFPB group experienced a significantly greater amount of increased energy ( $P = 0.02$ ); a greater improvement in digestion ( $P < 0.001$ ); and improved sleep ( $P = 0.03$ ) (Katcher et al. 2010). The WFPB group experienced significantly more energy ( $P < 0.001$ ); better digestion ( $P < 0.001$ ); significantly more flatulence ( $P < 0.05$ ); and significantly better sleep than usual ( $P < 0.01$ ) in the within group analysis. The only improvement the control group experienced within its group was better digestion ( $P < 0.05$ ).

The eating Inventory questionnaire found the WFPB group experienced significantly more restraint with their diet; disinhibition and hunger compared to the control group (Katcher et al. 2010). Changes in restraint in the intervention group were weakly correlated but significantly related to meeting attendance ( $r = 0.33$ ,  $P = 0.008$ ) and weight loss ( $r = -0.23$ ,  $P = 0.07$ ). However, participants overall, reported a high satisfaction with their diet (median = 6 on a scale of 1 to 7) and experienced significant weight loss (Katcher et al. 2010).

#### 5.5.1 Acceptability Summary

A WFPB diet was found to be as acceptable as the NCEP's Step II diet and the ADA's diabetes diet (Barnard et al. 2004 & 2009b). Participants were satisfied with a WFPD diet (Katcher et al. 2010) finding it could be continued in the future and tasted good (Barnard et al. 2004) while experiencing decreased cravings (Barnard et al. 2009b) and decreased impairment at work (Katcher et al. 2010). A WFPB diet was also found to be less easy to prepare (Barnard et al. 2004 & 2009b) and more difficult at restaurants (Katcher et al. 2010). WFPB diet participants experienced more flatulence (Barnard et al. 2009b). Two studies found dietary restraint increased within the WFPB group (Barnard et al. 2009b & Katcher et al. 2010) while one study found dietary restraint decreased in the WFPB compared to control (Barnard et al. 2004).

#### 5.6 Suggested Components for a WFPB Nutrition Education Curriculum

### 5.6.1 Suggestions Based on Intervention and Education Techniques

No firm conclusion can be made about the effects of used intervention techniques due to the variability in reporting of the intervention structure, the nutrition education techniques and the information taught. A lack of consistency in behavior change definitions and terminology further inhibits comparability. However, suggestions can be made based on what techniques were most utilized.

#### Participants, Setting and Educators

Participants in all 6 studies were willing to make dietary changes. The intervention setting does not have to be confined to a research laboratory. A university medical center or even a corporate worksite location is applicable. The trio of a RD, cooking instructor, and physician have been used together to teach the intervention, however other knowledgeable professionals may be adequately effective.

#### Weekly Group and Individual Support

Weekly group meetings are highly suggested as all 6 interventions met at least once per week for at least the duration of the study. Turner-McGrievy et al. (2007) found both a WFPB group and the NCEP lost significantly more weight within groups when attending group meetings compared to those who did not at 1 year follow-up. It is worth noting that the NCEP supported group, lost more weight (-3.3 kg) than the vegan unsupported group (-2.1 kg) at one year and at two years (-2.7 kg versus -0.35 kg), although no statistical analysis was made to determine significance (Turner-McGrievy et al. 2007). Varying types of individual support were used in 5 of the 6 studies, mostly through 24-hour diet recalls which were followed-up with an individual appointment. Individual support may be helpful in providing additional guidance that may not be appropriate during group meetings.

## Providing Food Interactions and Diet Monitoring

Varying types of food interactions were identified in 5 of the 6 studies and are highly suggested for incorporating into a WFPB nutrition curriculum. Food interactions may range from taste-tests, to take-home meals to cafeteria food changes. Diet monitoring were found in 5 of the 6 studies, 4 of which utilized 24-hour diet recalls. Participants filling out weekly food questionnaires or personal daily food journals may be more feasible for some interventions, however food journaling was not reported in any of the 6 controlled trials.

### 5.6.2 Suggestions Based on Results of Clinical Measurements

Participants should also be taught what changes are to be expected when transitioning to a WFPB diet based on the evidence. Participants should know weight loss is highly likely and that total serum cholesterol concentrations and blood pressure may decrease. Additionally, the WFPB diet should be prescribed in a way that triglyceride levels are most likely to be retained at low-risk levels. Participants should be taught that flatulence may increase and be provided ways to prevent or best minimize it (Katcher et al 2010).

### 5.6.3 Suggestions Based on Acceptability Results

The results from the acceptability studies suggest that a WFPB nutrition and intervention education should include teaching participants how to maintain a WFPB diet in restaurants as this was found to be more difficult in the WFPB groups (Barnard et al. 2004, 2006 & Mirsha 2013a). The acceptability studies also found WFPB participants will need extra support for learning how to prepare foods. Cooking instruction was reported to have been taught in 5 of the 6 intervention studies (Ornish et al. 1998 did not report teaching cooking instruction) and should be included as a central part of the curriculum.

#### 5.6.4 Summary of Suggestions for a WFPB Nutrition Education Curriculum

Individuals willing to change their diet may benefit from a WFPB nutrition education curriculum that includes weekly group meetings, individual support, diet monitoring, food interactions, meal preparation and cooking skills. Frequently reviewing changes in clinical measurements with participants is suggested as improved changes may positively influence dietary adherence. It is important to inform individuals of anticipated benefits and challenges that may be expected from a WFPB diet change. It is suggested to apply multiple components together, as all 6 interventions used many different techniques congruently.

## 6. DISCUSSION

### 6.1 Aims and Major Findings

This report aimed to analyze the existing WFPB controlled trials on obesity, heart disease and T2DM for nutrition education techniques, nutrient intake and clinical measurement changes and diet acceptability to make suggestions for a WFPB nutrition curriculum based on the intervention and education techniques applied in the studies.

The major findings include a significant reduction in total fat to  $\leq 15\%$  of total energy, a significant reduction in saturated fat, dietary cholesterol and protein and significant increases in carbohydrate and fiber intake. A WFPB diet was found to be an effective diet for reducing weight and BMI and may be effective in simultaneously improving additional clinical measurements (Ornish et al. 1998) and preventing, reducing or eliminating medication use. A WFPB diet was found to be as acceptable as other therapeutic diets. A magnitude of nutrition education intervention techniques are suggested to be included in a WFPB nutrition education curriculum, however research needs to be conducted to determine these strategies' effectiveness.

### 6.2 Under-Reporting of Education Techniques in Intervention Studies

There were many problems in identifying, defining, categorizing and comparing the education and support techniques of the 6 interventions. Information was not described in sufficient detail to understand which components were or were not included in the interventions. More details accumulated after reading all of the publications for each intervention, however a lot of information was still not revealed. This is a common problem seen in nutrition intervention reporting (Pignone et al. 2003). For example, Ornish et al. (1998) reported very little on how the diet and lifestyle changes were actually taught and how the diet and lifestyle changes were implemented. All that is known is that strategies for maintaining adherence and communication skills were used (Ornish et al. 1990).

Published descriptions of the education techniques and structure of the intervention should become common practice and would provide many benefits. Extensive publication of the steps of the intervention, the education techniques and psychological theories used, nutrition information topics etc., would allow for evidence-based comparisons to be made between studies and their educational components. Findings need to be made replicable to understand the process of behavioral change taking place and to understand which specific components are effective and ineffective and at what intensity (Michie et al. 2009). Others interested in implementing a WFPB nutrition intervention would then have a standardized platform from which similar results could be expected. It would also make it easier to conduct larger intervention studies. A commonality of terms for describing intervention techniques and education is also needed. Currently, different labels can be used for a range of terms and techniques making categorizing and comparability difficult (Michie et al. 2009).

### 6.3 Nutritional Adequacy and Intake

Concerns regarding the nutritional adequacy of vegetarian and vegan diets exist. It is important to remember that vegetarians can consume different dietary patterns and some may be healthier than others. A WFPB may or may not be vegan, but more importantly, it focuses on the inclusion of healthy foods such as whole-grains, legumes, fruits and vegetables which could be different than a typical vegetarian diet.

According to the Academy of Nutrition and Dietetics, when appropriately planned, vegetarian and vegan diets are nutritionally adequate at all stages of the lifecycle and may offer benefits for the prevention and treatment of certain diseases (American Dietetic Association 2009). The Academy of Nutrition and Dietetics recommends the consumption of walnuts, flax seed and soy products to increase consumption of n-3 fatty acids to meet the recommended 1.6 g and 1.1 g of ALA recommended for males and females respectively, which may be marginal in a vegan or vegetarian diet (American Dietetic Association 2009). Protein needs are adequately met when enough calories are consumed and a variety of plant foods are eaten. All essential amino acids are consumed throughout one day so no complimentary proteins need to be consumed together at each meal (McDougall 2002, American Dietetic Association 2009 & Norden 2012).

Iron intake is not more of a concern for vegetarians (American Dietetic Association 2009). Iron-deficiency anemia is seen in similar rates between vegetarians and non-vegetarians and serum ferritin levels have been found to be in normal range in vegetarians (American Dietetic Association 2009). Four controlled trials included in this review examined iron intake (Turner-McGrievy et al. 2004, Barnard et al. 2009, Levin et al. 2010 & Mirsha et al. 2013b). Two interventions found significantly increased iron intakes in the WFPB group compared to a habitual diet ( $P < 0.001$ ) (Levin et al. 2010) and the ADA's diabetes diet at 22 weeks ( $P = 0.05$ ) (Turner-McGrievy et al. 2008) and 74 weeks ( $P = 0.002$ ) (Barnard et al. 2009). However, these intakes are not reflective of iron absorption. Iodine deficiency is possible in vegans not consuming iodized salt or sea vegetables and B12 supplements are needed for individuals eating a WFPB diet with no animal foods.

The WFPB groups in this review significantly reduced total fat, saturated fat and dietary cholesterol, while significantly increasing dietary fiber, more closely meeting the Institute of Medicine's recommendations, compared to controls. Additionally, Turner-McGrievy et al. (2008) computed the Alternative Healthy Eating Index (AHEI) of the assigned WFPB and ADA diets. The AHEI estimates chronic disease risk based on a dietary index used to rate foods and macronutrients. Scores can range from 2.5 to 87.5 with the later being the healthiest. The WFPB group made significant improvements in all 7 AHEI diet categories (fruit, vegetables, nuts and soy protein, ratio of white to red meat, cereal fiber, trans fat and polyunsaturated to saturated fat ratio) while the ADA group improved in two (nuts and soy protein and polyunsaturated to saturated fat ratio). The WFPB group significantly increased their fruit and vegetable servings from 4 to 7.5 per day, while the ADA group made no significant changes. The WFPB group significantly increased its total AHEI score from  $31.6 \pm 11.8$  to  $54.1 \pm 17.9$  ( $P < 0.001$ ) while the ADA did not ( $35.1 \pm 10.1$  to  $34.2 \pm 17.9$ ). The between group difference was statistically significant ( $P < 0.0001$ ). The female WFPB group scored in the highest AHEI quintile possible and the WFPB men scored in the second highest quintile. The ADA group scored in the lowest quintile for men and the second lowest for women (Turner-McGrievy et al. 2008).

When comparing a WFPB diet to a habitual diet in a corporate worksite Levin et al. (2010) found the intervention group significantly increased mean intakes of total vitamin A activity, B-carotene, folate, vitamin C, iron, sodium, magnesium and potassium. Protein intakes decreased to an adequate proportional percentage of calories and Vitamin D and zinc intakes were below the Institute of Medicine's nutrition recommendations at baseline and at 22 weeks for both groups.

#### 6.4 Weight Loss

These findings suggest a WFPB diet is highly effective in helping individuals with heart disease, T2DM and obesity lose weight compared to standard care recommendations from physicians, a conventional low-fat diet, the NCEP's Step II diet and the habitual diets of corporate worksite employees. Five of the 6 controlled trials found the WFPB group lost significantly more weight compared to controls despite no portion size restriction and not increasing exercise.

Compared to other ad libitum weight loss RCTs, a WFPB group exhibits similar results. In 2014, the New Nordic Diet (NND), comprised of organic, whole, plant foods, meat, fish and dairy products, was compared to an average Danish diet (ADD) in obese adults for 26 weeks. At follow-up the NND showed a mean weight loss of -4.74 kg compared to the ADD (-1.52 kg). Barnard et al. (2006) and Ferdowsian et al. (2010) found a mean weight loss of -5.8 kg and -5.1 kg respectively, in the WFPB groups at 22 weeks and Barnard et al. (2004) found a mean weight loss in the WFPB group of -5.8 kg at 14 weeks.

The Finnish Diabetes Prevention Study aimed to reduce weight and T2DM prevalence in a RCT utilizing individualized support. Participants were instructed to consume low-fat animal products, use low-fat cooking methods and eat less cakes and pastries (Lindström et al. 2005). Moderate to vigorous physical activity at  $\geq 0.5$  hr/day was also prescribed (Lindström et al. 2005). The study found a mean weight loss of -4.5 kg at 1 year (Lindström et al. 2005) and -3.5 kg at 3 years (Lindström et al. 2003). Turner-McGrievy et al. (2007) found a mean weight loss of -4.9 kg at 1 year in a WFPB group and -3.1 kg at 2 years when participants were advised to



maintain ‘tolerable’ exercise level. Ornish et al. (1998) prescribed a weekly exercise regimen to participants along with a WFPB diet and at 5 years, weight dropped from 91.4 kg to 85.6 kg.

The WFPB weight loss results seen in this review support earlier observational findings that individuals with little to no animal intake have lower BMIs (Fraser 1999, Rosell et al. 2006 & Tonstad et al. 2009). Uncontrolled weight loss studies have also demonstrated effective weight loss from a WFPB diet (Lindahl et al. 1984 & McDougall et al. 1995).

Weight loss may be more effective from a WFPB diet due a multitude of mechanisms. An additional 14 g of fiber a day has been found to decrease energy intake by 10% (Howarth et al. 2001). A WFPB is high in dietary fiber. A WFPB diet is also high in satiety and naturally low in fat. The low energy density of a WFPB diet allows for a greater volume of food to be consumed while still being lower in calories than meals with animal products and refined foods. The increased volume of food has not been found in the short term at least, to compensate for the energy deficit that occurs from low energy, WFPB meals (Duncan et al. 1983). The thermic effect of a WFPB diet may also provide an advantage for weight loss by increasing the insulin sensitivity of cells, allowing a faster metabolism of glucose to occur, rather than storing it as body fat (Mishra et al. 2013).

## 6.5 Serum Lipids and Blood Sugar

Serum cholesterol levels ranged from 159 mg/dl to 188 mg/dl at follow-up (4.11 mmol/l to 4.86 mmol/l) in the WFPB groups. The serum cholesterol lowering effects of a WFPB diet may be attributable to the cholesterol lowering effects of certain plant foods, the avoidance of dietary cholesterol from animal products and the low saturated and trans fat intake in a WFPB diet (Barnard et al. 2006).

One study found a significant increase in triglyceride levels in a WFPB group compared to a habitual diet (Mirsha et al. 2013a) in a corporate worksite setting. Triglycerides may increase from consuming table sugar, flours and fruit juices. Studies made suggestions for reducing triglyceride levels by choosing low-GI foods (Mirsha et al. 2013a & Barnard et al. 2009),

minimizing simple carbohydrates (Ornish et al. 1998) and increasing high-fiber foods (Barnard et al. 2009).

The weight-lowering effect of a WFPB diet may influence insulin sensitivity and be partly responsible for the reduction in FBG and hemoglobin A1c seen in some of the WFPB studies (Barnard et al. 2006). Insulin resistance can be related to the lipid build-up in muscle cells (intramyocellular lipid) from food. Insulin resistance may be due to a decrease in mitochondrial activity, which has been identified before the onset of T2DM (Peterson et al. 2004) and is responsive to diet.

## 6.6 Current Use of WFPB Diets in Health Care

Tuso et al. (2013) writes that “many physicians are not stressing the importance of plant-based diets as a first-line treatment for chronic illnesses.” Researchers also claim that people “are not willing and/or able to make extreme changes in their food intake pattern” (Lindström et al. 2005). However, findings from this review reveal that significant changes can be made when implementing a WFPB diet and that it is as acceptable and effective as other therapeutic diets including the NCEP’s Step II diet, the ADA’s diabetes diet (Barnard et al. 2004 & 2009b) and the habitual diets of corporate employees (Katcher et al. 2010). Therefore, acceptability and effectiveness should not be viewed as a barrier to clinical use. Overweight participants or those with T2DM were satisfied with a WFPB diet (Katcher et al. 2010) and obese participants reported being able to continue the diet in the future (Barnard et al. 2004). A WFPB diet has not been reported as ‘extreme,’ ‘radical,’ or ‘unacceptable’ amongst research participants in these findings.

Barnard et al. (2004) suggests that a WFPB diet may actually meet greater acceptance by patients because more effective symptom relief and weight loss may occur. Additionally, Barnard et al. (2004) suggests a WFPB diet may generally be easier to follow, because it focuses on the inclusion and exclusion of certain foods, versus reducing fat from common foods and restricting portion sizes. However, health care practitioners and RDs first need to know that a WFPB diet as a therapeutic option even exists before patients can be informed.

Reasons why physicians, RDs and other health care professionals may be unaware of a WFPB diet are vast. Physicians are taught to manage chronic disease, not halt its progression or reverse it. Medical doctors are trained in medical school to prescribe pharmaceutical drugs to slow the progression of chronic disease and reduce risk factors, not address the underlying cause. Physicians are rarely educated in nutrition (Dimaria-Ghalili 2013), especially in the totality of evidence regarding a WFPB diet or how to arrest or reverse chronic disease via diet (Kiraly 2014).

The prevailing reductionist, scientific paradigm influences research and what is taught in academia. Reductionism, focusing on isolated, separate parts, fails to see how the complexities of nutrition affects the whole body, not just one body system or biomarker (Campbell, 2013). What is most commonly taught and supported, are studies and recommendations focusing on isolated nutrients affecting specific biomarkers, such as saturated fat and serum cholesterol concentrations or salt intake and blood pressure, compared to dietary patterns or food groups affecting long-term health and disease outcomes. This is not to say reductionist studies are not useful. They are. However, relying on reductionism alone, fails to see the whole picture and may miss valuable information.

Conflicts of interest within the health and medical field exacerbate the problem and influences the authorities responsible for providing dietary recommendations. Food corporations sit on the advisory panel for the United States' Department of Agriculture's (USDA) nutrition recommendations (Herman, 2010), while health and medical agencies such as the Academy of Nutrition and Dietetics and the ADA are funded in part by corporate sponsors from the pharmaceutical, meat, dairy and 'junk food' industries (Academy of Nutrition 2013 & ADA 2014). Corporate interests combined with the prevailing reductionist scientific paradigm, a lack of funding for WFPB research and a lack of education focusing on preventing, arresting and reversing disease, influences the dissemination of WFPB and all nutrition information.

## 6.7 Study Strengths and Limitations

This review's strengths include the systematic search and the comparability between dietary recommendations. Limitations include only 1 database being searched; missing eligible studies that were reported in other languages; a very small sample size ( $n = 9$ ) in 1 study (Nicholson et al. 1999) and populations and settings that may not be representative of the general public. Additionally, the totality of the intervention structures and education techniques were not reported, including but not limited to the types of nutrition education used, the curriculums and the information taught. No behavior change theories were reported in any of the 6 studies and 5 of the 6 studies were conducted by the same research group from the U.S.

## 6.8 Future Research

More WFPB RCTs are needed. Only 1 WFPB RCT has been conducted on a population with CHD. A larger population sample is also needed in future RCTs. The initial study populations were small, and may not have provided enough participants to produce statistically adequate power. However, the study size populations are steadily increasing and Mirsha et al. (2013a) reached a favorable study size. It would be beneficial to conduct a RCT comparing a WFPB diet to the USDA's Dietary Guidelines or a Mediterranean style diet and to have additional research teams conduct studies. Additional research into how people best adopt and maintain a WFPB diet, as well as why people do not adhere to the diet, is highly needed.

## 7. CONCLUSION

A WFPB diet is highly effective in achieving weight loss in individuals with CHD, T2DM and or obesity that are motivated to change their diet. A WFPB diet is effective in lowering serum cholesterol concentrations, reducing or eliminating antihypertensive and diabetes medications and reducing dietary total fat, saturated fat and cholesterol intakes. A WFPB diet is as acceptable as other therapeutic diets in motivated individuals and when appropriately planned, is nutritionally adequate. The findings on which education techniques were meaningful in positively effecting outcomes were inconclusive. However, all 6 interventions utilized weekly group support and most studies utilized individual support, differing food interactions and diet monitoring and are suggested to be components in any proceeding WFPB nutrition education curriculum. Future research needs to analyze how individuals will best maintain the diet and why others will not. More RCTs and studies with larger populations need to be conducted, especially in individuals with CHD. Nutrition interventions need to report the totality of their education techniques so future studies can be replicable.

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## Appendix 1. Search Terms and Search Query

Plant-based diet - searched on March 3rd, 2014

diet, vegetarian OR vegetarian\* OR vegan\* OR vegetable\* OR fruit\* OR "whole grain" OR "whole grains" OR whole-grain\* OR legume\* OR cereal\* OR plant OR plants OR plant-based OR lacto-ovo OR pesco-ovo OR soy foods OR soy\*

AND

diabetes mellitusdiabet\*glucose intoleranceblood glucosemetabolic syndrome x OR "metabolic syndrome"obes\* OR overweight OR body weightheart diseases OR coronary diseasecholesterolblood pressure OR hypertens\*diet, fat-restricted OR "fat restricted" OR low-fat  
intervention studies  
clinical trials OR clinical trials as topic

Recent queries				
Search	Add to builder	Query	Items found	Time
<a href="#">#17</a>	<a href="#">Add</a>	Search <b>#11 OR #12 OR #13 OR #14 OR #15 OR #16</b>	<a href="#">569</a>	03:57:11
<a href="#">#16</a>	<a href="#">Add</a>	Search <b>#10 AND (randomized controlled trial OR randomized controlled trials as topic)</b>	<a href="#">389</a>	03:52:50
<a href="#">#15</a>	<a href="#">Add</a>	Search <b>#10 AND clinical trial</b>	<a href="#">452</a>	03:51:57
<a href="#">#14</a>	<a href="#">Add</a>	Search <b>#10 AND clinical trials as topic</b>	<a href="#">67</a>	03:50:50
<a href="#">#13</a>	<a href="#">Add</a>	Search <b>#10 AND clinical trials</b>	<a href="#">456</a>	03:50:28
<a href="#">#12</a>	<a href="#">Add</a>	Search <b>#10 AND intervention*[tiab]</b>	<a href="#">318</a>	03:50:03
<a href="#">#11</a>	<a href="#">Add</a>	Search <b>#10 AND intervention studies</b>	<a href="#">143</a>	03:49:29
<a href="#">#10</a>	<a href="#">Add</a>	Search <b>#9 AND (diet, fat-restricted OR "fat restricted" OR low-fat)</b>	<a href="#">1253</a>	03:48:58
<a href="#">#9</a>	<a href="#">Add</a>	Search <b>#2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8</b>	<a href="#">56402</a>	03:48:17
<a href="#">#8</a>	<a href="#">Add</a>	Search <b>#1 AND (cholesterol OR blood pressure OR hypertens*)</b>	<a href="#">22885</a>	03:43:53
<a href="#">#7</a>	<a href="#">Add</a>	Search <b>#1 AND (heart diseases OR coronary disease)</b>	<a href="#">9228</a>	03:43:17
<a href="#">#6</a>	<a href="#">Add</a>	Search <b>#1 AND (obes* OR overweight OR body weight)</b>	<a href="#">25814</a>	03:42:12
<a href="#">#5</a>	<a href="#">Add</a>	Search <b>#1 AND (metabolic syndrome x OR "metabolic syndrome")</b>	<a href="#">1006</a>	03:41:43
<a href="#">#4</a>	<a href="#">Add</a>	Search <b>#1 AND blood glucose</b>	<a href="#">7958</a>	03:39:53
<a href="#">#3</a>	<a href="#">Add</a>	Search <b>#1 AND glucose intolerance</b>	<a href="#">278</a>	03:39:32
<a href="#">#2</a>	<a href="#">Add</a>	Search <b>#1 AND diabetes mellitus</b>	<a href="#">6894</a>	03:38:20
<a href="#">#1</a>	<a href="#">Add</a>	Search <b>diet, vegetarian OR vegetarian* OR vegan* OR vegetable* OR fruit* OR "whole grain" OR "whole grains" OR whole-grain* OR legume* OR cereal* OR plant OR plants OR plant-based OR lacto-ovo OR pesco-ovo OR soy foods OR soy*</b>	<a href="#">805527</a>	03:37:35