11-2014

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November 25th, 2014

A Literature Review

A Paper Presented to Meet Partial Requirements

NRSG 594-A

MSN Capstone

Southern Adventist University

School of Nursing

Chapter 1 INTRODUCTION

Every year millions of Americans die from occlusive vascular disease related to the effects of atherosclerosis. According to Englert et al. (2004, p.432) " soft, lipid-rich plaques have now emerged as being considerably more vulnerable and prone to rupture than hard, collagen-rich plaques; and they are responsible for 80-90% of all MI's." In today's society, time is truly of the essence. With current on the go trends, who can find time to incorporate healthy eating habits? On every corner, there is a fast food restaurant conveniently waiting for their next customer. Although convenience of fast food restaurants and microwave dinners are a luxury undertaken by many Americans, it is this luxury that is becoming one of the causes of cardiovascular disease and obesity in our country. A primary concern is the eating habits of our youth. Young people are a particularly important group, as poor eating habits established during teenage years may be maintained into adulthood predisposing them to the risk of developing Hypertension, Diabetes Mellitus, Hypercholesterolnemia, and Obesity later in life. An additional health risk factor is stress, which when chronic can suppress immune response, resulting in increase susceptibility to infection, cancer, and cardiovascular disease (Campisi, Bravo, Cole, & Gobeil, 2012).

Purpose/Rationale

In America today, according to the CDC (Centers for Disease Control), more than 1/3 of U.S adults are obese (BMI >30), 71 million have high LDL-C levels (160-189), 67 million have high blood pressure (>140/90), and 29.1 million have Diabetes Mellitus (cdc.gov). Poor eating habits can contribute to obesity, which in turn contributes to

coronary artery disease, hypercholesterolemia, hypertension, and diabetes. Therefore, a closer look at changes in dietary habits and its relation to the prevention of such diseases and its implication in clinical practice deserves attention. Hence, because of increasing interest in the relationship between diet and its implication on a multitude of healthcare issues, the nursing faculty of Southern Adventist University proposed the Zoe project study to evaluate the effects of a natural, whole food diet with a component of spiritual growth and prayer on university students.

The purpose of the study is to determine the effects of natural, whole foods on the resting metabolic rate (RMR), cortisol levels, C-reactive protein (CRP), interleukin 6 (IL-6), lipids, and lipoprotein-associated phospholipase A2 (Lp-PLA2) levels of university students involved in a 28 day lifestyle modification project. The hypothesis of the research study was that the RMR, inflammatory markers, and serum lipids would decrease after the 28-day whole-food plant based diet.

The study also included the impact of spiritual factors on stress levels. The hypothesis on this aspect of the research study was that the spiritual component will serve to enhance the participants focus on the dietary challenge and that they would experience an increase in strength and self control from their prayer times and activities during times of temptation and weakness.

According to the CDC, having high cholesterol, especially low density lipoprotein-cholesterol (LDL-C, puts one at risk for heart disease and stroke (cdc.gov). Due to cholesterol not being able to dissolve in the blood, it must be transported via carriers called lipoproteins. There are two types of lipoproteins: low density lipoprotein (LDL) and high density lipoprotein (HDL). LDL is most often considered the “bad” type

of cholesterol because it contributes to a thick, hard deposit that can clog arteries and make them less flexible a condition also known as atherosclerosis (www.heart.org). Diets high in fat contribute to the increase in LDL-C levels of individuals with poor dietary habits. Therefore, this review of literature was sparked by interest in investigating whether or not adults who eat a whole-food plant based diet have lower LDL-C levels compared to those who do not.

Theoretical Framework

The Zoe project was not based on any one theoretical framework. Therefore, the theoretical framework that could serve as the basis of this study is Myra Levine's Theory of Conservation. The model is based on promoting adaptation and maintaining wholeness using the principles of conservation (nursingtheories.blogspot.com).

The four principles that make up Levin's conservation theory are: conservation of energy (refers to balancing energy input and output to avoid excessive fatigue); conservation of structural integrity (refers to maintaining the structure of the body preventing physical breakdown and promoting healing); conservation of personal integrity (recognizes the individual as one who strives for recognition, respect, self-awareness, and self determination); and, conservation of social integrity (refers to an individual who is recognized as someone who resides with family, community, religious group, ethnic group, or political system (www.currentnursing.com). The conservation principles of personal and structural integrity, this author believes, have the greatest impact on the Zoe project. The participants within the study were challenged to partake in a study that could enhance their quality of life. This, in relation to the conservation principles of personal and structural integrity, showed that the participants had a self

determination and the mindset to improve their lifestyle habits through structured lifestyle modifications.

It is hypothesized that dietary habits play a role in affecting inflammatory and metabolic markers which in turn lead to such problems as cardiovascular disease, hypertension, obesity, and hypercholesterolemia. Therefore, by employing Levine's theory, it is the moral duty of healthcare providers to research the effects of dietary habits on such conditions, communicate this information to their patients, help those who present with dietary challenges, and attempt to find ways in promoting a healthy dietary lifestyle.

Chapter 2 LITERATURE REVIEW

Shurney et al. (2004) conducted a case study at Vanderbilt University to examine the feasibility of a comprehensive, work place-based, intensive lifestyle training program, in order to help type 2 diabetics alter the course of their disease. The application of the program that was used was CHIP (Complete Health Improvement Project) that had an emphasis on a whole-food plant based diet. Biometric data and lab work measuring HgbA1C, total cholesterol, LDL, HDL, and triglycerides were obtained and evaluated at baseline, eight weeks, and 26 weeks. Twenty-one voluntary participants were involved in the study and participated in educational health training sessions, given the official CHIP cookbook for home use, watched videos while eating that pertained to healthy lifestyle behaviors, and received detailed instruction in whole-food plant based nutrition and exercise.

The results of the study showed that at baseline+8 weeks 14 of the 21 patients (66.7%) had a median change of 15.0 in LDL levels with a statistical significance of $p<0.02$. At base+26 weeks, 8 of the 21 patients (38.1%) had a median change of 18.5 in LDL levels with a statistical significance of $p<0.02$. This study shows that, although focused toward type 2 diabetics, individuals who adhere to a whole-food plant based diet can achieve a reduction in LDL levels.

A similar study by Morton et al (2014), evaluated 971 participants in a CHIP intervention study, sourced through Seventh-day Adventist churches that assessed the effectiveness of the CHIP lifestyle interventions study for improving chronic disease risk factors. Participants in the study were representative of an at risk population in the obese population, pre-diabetic fasting blood sugar levels, elevated systolic blood pressure, and

low density lipoprotein cholesterol levels. Each participant was involved in 16 two-hour group sessions over a 30 day period that focused on positive lifestyle changes, particularly diet and physical exercise. The primary focus was a whole-food plant based diet that included such foods as whole grains, legumes, fresh fruits and vegetables in addition to at least 30 minutes of modest physical exercise. Pre and post blood tests were obtained measuring total cholesterol, LDL-C, HDL, triglycerides, and fasting blood sugar.

Significant reduction was noted in the post-test analysis of lipid levels from baseline to post intervention. During the 30 day period, participants showed a 20% improvement in triglyceride, LDL-C, and total cholesterol levels all of which showed a statistical significance of $p<0.001$. Most notable mean standard deviation changes were seen in LDL-C (baseline 1.34 vs. post intervention 1.21), triglyceride (baseline: 1.68 vs. post intervention: 1.54), and total cholesterol levels (baseline: 5.22 vs. post intervention: 4.63) Morton et al (2014).

According to Englert, et al (2004, p.433) "hyperlipidemia is increasingly being recognized as the primary, essential, and necessary cause of the current epidemic of occlusive vascular disease." Lifestyle modification requires individuals to assume responsibility for change. Because most individuals lack adequate education in regards to modification changes related to health, Enlgert et al (2004) conducted the Coronary Health Improvement Program (CHIP). This pilot study is just the first of four phases that intends to progress through seven years and aims to substantially reduce coronary risk factor levels through the adaptation of better health habits and lifestyle changes.

The study consisted of 242 participants (78 male/164 female) who attended four weeks of educational training to "develop a greater measure of intelligent self-care involving a clearer understanding of the nature and etiology of coronary artery disease (CAD), its epidemiology, its risk factors, and the potential for prevention, arrest, and reversal through better lifestyle choices in the areas of smoking, sedentary living, diet, and stress management" (Englert et al, 2004, p.434). In relation to diet and exercise, participants were instructed to implement at least 30 minutes a day of exercise and adhere to a diet that consisted of grains, legumes, vegetables, and fresh fruits.

The results of the study showed a mean change decrease in LDL levels in men of 19.1 mg% (baseline: 122.0 vs. 30 day: 102.9) with a statistical significance of $p<0.001$. In women, the mean change decrease in LDL levels was 10 mg% (baseline: 125.4 vs. 30 day: 115.4) with a statistical significance of $p<0.001$. Of note, a mean change decrease in total cholesterol in men was 28.6 mg% (baseline: 200.4 vs. 30 day: 171.8) with a statistical significance of $p<0.001$ and in regards to women the mean change decrease in total cholesterol was 16.7mg% (baseline: 209.7 vs. 30 day: 193.0) with a statistical significance of $p<0.001$.

Tempest (2012), a registered dietician, produced an article pertaining to the effects of incorporating a whole-food plant based diet and its effect on cardiovascular disease. The purpose of the article was to discuss the major categories of functional foods that can prevent cardiovascular disease and to share tips to help clients incorporate these foods into their diet.

According to the American Heart Association "whole-plant based diets have been shown to help reduce blood levels of atherosclerotic LDL cholesterol" (as cited in

Tempest, 2012, p.33). Yet when trying to educate patients about this type of diet, what foods have shown to have a positive effect on lowering LDL levels? Functional foods can be described as "whole, fortified, enriched, or enhanced foods that have a potentially beneficial effect on health when consumed as a part of a varied diet at effective levels on a regular basis" (Tempest, 2012, p.33). Mostly of importance in regards to LDL levels, whole grains, in particular oats, provide beneficial cardiovascular benefits related to the high content of beta glucan (soluble fiber) and avenathramide (antioxidant) which produces reductions in LDL cholesterol. Legumes, such as beans, lentils, and peas have also shown to have beneficial cardiovascular effects on lower LDL cholesterol levels. Foods rich in plant sterols and stanols have also been shown to reduce LDL cholesterol levels by approximately 6-15% without lowering levels of the good cholesterol HDL (Tempest, 2012). In educating adults in heart healthy diets, which include whole-foods with a plant based emphasis, it is important for providers to have an array of knowledge in directing patients in what foods will help them attain their goal of lowered LDL levels.

A study published by Gardner et al (2005) compared two differing low fat diets. The purpose of the study was to test whether a plant-based diet itself offers greater anti-cholesterol benefits than a more conventional low-fat diet for American consumers. The randomized trial included 120 adults aged 30-65 who had moderately high LDL-C levels between 130-150 mg/dl.. All members of the target population for food based approaches to lowering cholesterol. The participants were randomly divided into two groups: 61 focused on convenient diet, 59 followed the plant based diet. The 61 who focused on a convenient diet consumed a diet avoiding saturated fats and cholesterol including such foods as frozen waffles, turkey bologna sandwiches, and reduced-fat

prepared foods such as low-fat cheeses and high sugar snack foods. The 59 who focused on the plant based diet consumed a similar diet including the same proportions of saturated fat and cholesterol, but with the addition of high amounts of vegetables, fruits, whole grains. All participants' weight and exercise levels were kept stable throughout the study.

Results of the study showed that both diets lowered total and LDL cholesterol. However, those who participated in the conventional low-fat diet averaged a 4.6% LDL decrease compared to those who consumed foods in the plant-based diet who averaged a 9.4% decrease in LDL cholesterol levels with a statistical significance of $p<0.02$. No significant differences were noted in either triglyceride levels of HDL cholesterol levels. The only real limitation to this study was that it was based on a relatively small sample size of 120 adults.

According to Braun (2014) "Although conventional dietary advice has proven inferior to statin therapy for lowering serum cholesterol, studies have shown when certain foods are consumed in combination (dietary portfolio), serum LDL cholesterol is reduced to a similar degree as first generation statins". Jenkins et al (2011) conducted a six month clinical trial of 345 participants consisting of men and women who were free of CVD risks and not currently taking lipid lowering medications to determine whether diet counseling of foods associated with lower cholesterol attained a greater reduction in LDL levels than a control diet consisting of high fiber and whole grains. The participants were randomized into three groups: Group I (control) received dietary counseling for a low fat diet; Group II received dietary counseling on a dietary portfolio of cholesterol lowering foods with two visits; and Group III who were counseled in the same dietary portfolio as

Group II but attended seven visits. The dietary portfolio counseling focused on the incorporation of plant sterols via a sterol ester-enriched margarine, viscous fiber from oats, barley, psyllium, soy protein, nuts, peas, lentils, and beans. Pre and Post measurements of lipid levels were obtained.

Findings from the study showed that LDL-C levels were reduced 13.8% (95% CI 17.2% to 10.3% $p < 0.001$) for Group III, 13.1 % reduction (95% CI 16.7% to 9.5% $p<0.001$) in Group II, and 3% reduction in Group I control group (95% CI 6.1% to 0.1% $p=0.06$). Percentage LDL-C reductions for each dietary portfolio were significantly ($p<0.001$) more than the control diet (Jenkins et al, 2011).

Jenkins et al (2003) conducted a similar randomized control study of 46 healthy hyperlipidemic adults to determine whether a diet low in saturated fat coupled with plant sterols and viscous fiber leads to cholesterol reduction comparable to that of statin drugs. All participants currently undergoing the study were not on statin drugs and had an average LDL-C level of 158 mg/dl. Participants were randomly assigned to three different treatment groups based on diet: Control group (group 1)consisted of a diet very low in saturated fat, based on milled whole-wheat cereals and low-fat dairy foods (skim milk, fat free cheeses and yogurt, and egg substitutes); Group 2 had the same diet as group 1 but with the addition of lovastatin 20 mg/day; and Group 3 which included a diet that consisted of a diet high in plant sterols, soy protein, viscous fibers, and almonds (Jenkins et al, 2003). Pre and post tests of lipid markers were obtained and re-measured at the end of a four week period.

Findings from this study showed an 8.0% reduction in LDL-C levels in the control group ($p=.002$), a 30.9% reduction in group II ($p<0.001$), and a 28.4% reduction

in group III ($p<0.001$). Based on these results, the combination of a diet low in saturated fat with the addition of high viscous fibers (oats, barley), plant sterols, vegetable protein foods (soy) and nuts (almonds) has shown to reduce LDL-C levels similarly to the initial therapeutic does of a first generation statin. How the addition of these particular foods are important to note. According to Jenkins et al (2003) "viscous fibers increase bile acid losses, plant sterols reduce cholesterol absorption, and soy proteins reduce hepatic cholesterol synthesis and increase LDL receptor messenger RNA and so potentially increase uptake of cholesterol".

Saxena et al (2011) conducted a study of 800 adults to compare the parameters of lipid metabolism between vegetarians and non-vegetarians. In the context of this study, Vegetarianism "involves the practice of following a diet that includes fruits, vegetables, cereal grains, nuts, and seeds with or without dairy products or eggs…vegetarians do not eat meat including poultry, fish, crustacean and shellfish" (Saxena et al, 2011, pg.306). Overnight blood testing was conducted to determine the values between the two groups.

Results of the study found that those who consume a vegetarian diet compared to those who consume a nonvegetarian diet have lower total cholesterol (TC), free cholesterol (FC), esterified cholesterol (EC), serum triglycerides (TG), LDL cholesterol (LDL-C), VLDL cholesterol (VDL-C), free fatty acids (FFA) levels with a statistical significance of $p<0.01$.

Mishra et al. (2013) conducted a multicenter randomized controlled trial of men and women >18 years of age with a body mass index of 25 kg and or previous diagnosis of Type II diabetes to determine the effects of a low fat plant based diet program on anthropometric and biochemical measures in a multicenter corporate setting. The

participants were divided into two groups: 142 in the intervention diet group and 149 in the control diet group. The participants in the intervention group followed a low vegan diet consisting of whole grains, vegetables, legumes, and fruits with no restriction on energy intake for 18 weeks. They were asked to avoid animal products (meat, poultry, fish, dairy products and eggs) and the minimized the addition of oils. They also attended 18, one hour classes for group support led by either a registered dietician, physician, or cooking instructor which included educational materials on diet related to weight loss, diabetes, heart disease, and cancer. The control group had no required dietary changes and was not given dietary guidance. All participants were asked not to alter their exercise patterns during the study period. Due to varying reasons, 48 participants in the intervention group discontinued the study and 32 discontinued in the control group leaving 94 participants in the intervention group and 117 in the control group.

The results of the study showed a decrease in LDL of 13.0 mg/dl (baseline: 109 vs. 18wk: 96) in the intervention group vs. the control group with a decrease in LDL of 1.7mg/dl (baseline: 110 vs. 18wk: 108) with a statistical significance of $p<0.001$.

Chapter 3 METHODOLOGY

Design

The research design that was used for the Zoe transformation research study was a Pre-test/Post-test design. Non-random sampling and Non-random assignment was used in determining participant vs. control group. Students who participated in the study were allowed to eat ad libitum within guidelines. No added sugars or refined sweeteners were allowed. Tofu and 100% while grain breads were allowed. The primary beverage was water; however, 100% juices and unsweetened soy/nut milks were allowed. Participants also received daily emails with encouraging Bible scriptures and were given the book *Christ's Way to Pray* by Dr. Phillip Samaan.. The participants were invited to four weekly worship meetings to encourage and support one another and discuss and discuss the readings. Weekly challenge activities were also given to the participants to help them achieve there weekly prayer goals.

Ethical Considerations

The Zoe Project underwent a review by SAU's IRB (Institutional Review Board), in which physical, psychological, social, and spiritual risks were reviewed. Based on the review, it was deemed by the IRB that the risks of the research study were minimal and was approved to commence. All individuals were given informed consent of the study. If participants were minors, a Child Assent form was provided. Because spirituality and prayer are personal and sensitive issues based one's belief system, all participants had the option to participate in the spiritual/prayer aspect of the program or decline.

Population/Sample

The Zoe Project was conducted on university students at Southern Adventist University who agreed to participate in the Zoe Transformation Challenge from March 17th-April 13th, 2014. There was also a control group who was also recruited from SAU, who did not participate in the dietary or spiritual challenge to compare baseline and outcome measurements. Recruitment for participation included email solicitation and a verbal presentation by FNP student researchers on March 16th, 2014 during a program lunch at Hulsey Wellness Center. Consent forms were completed onsite during the program. No cost, compensation, or class credit was offered to any of the participants. However, a $10.00 gift card was offered to those participants who completed the study as a means of recruitment.

Procedures

All students participating in the research study were required to sign an informed consent prior to participating. Survey's related to diet, stress, physical activity levels, and spiritual experience were completed by participants before and after the study. Participants had blood drawn at the school of Nursing on March 17th, 2014 and again after the challenge on April 14th, 2014. All participants were required to participate in a recorded and taped interview at the completion of the challenge to discus the spiritual experience.

Measurements/Data Collection

Pre and post data will be collected on Biometric data (height, weight, BMI, body fat %, and blood pressure), fasting blood levels, RMR (resting metabolic rate), and differing questionnaires related to dietary, stress, and spirituality. The RMR is a non-

invasive test that involves lying down on a table for approximately 20-30 minutes. The RMR was performed at SAU's Human Performance Lab using the Parvo Medics TrueOne 2400 metabolic measuring system. Fasting blood test being studied are plasma cortisol levels, C-reactive protein, lipids, PLAC test, and IL-6 levels. Among the questionnaires used was the Dietary Screener (information on individuals physical activity level), Perceived Stress Scale (assesses stress to specific stressors), Daily Spiritual Experience Scale (measure's daily spiritual experiences), and the Spiritual Experience Reflection questionnaire, which was conducted at the conclusion of the study to explore the spiritual experience of the participants.

Analysis

The statistical analysis plan for the research study included double entry of all data gathered and then imported into SPSS for analysis. Preliminary diagnostics were run on interval/ratio group data to evaluate assumptions for parametric testing related to distribution normality and homogeneity of variance. Due to non-random sampling and non-random assignment, the intervention and control group demographics and biometric parameters were compared at baseline (chi square, fischer's exact test or independent t-test) to determine if the two groups were statistically different on demographic, biometric, or questionnaire characteristics; parameters with significant differences were used as covariates. Paired sampling t-testing was used to compare pre-versus post-intervention measurements of the primary biometric outcomes, whereas an analysis of covariance was used to compare interval/ratio data from the two groups, controlling for pre-intervention covariates. Multiple regression analysis was used to evaluate various

models for other quantitative predictors (stress, physical activity, and spiritual experience) of biometric outcomes.

exercise, and diet modification plans were better equipped at reaching lower LDL-C levels than those who did not receive the same guidance. As discussed, there are numerous studies with evidence supporting the efficacy of whole food plant based diets on lowering LDL-C levels. Therefore, based on current literature, it would be expected that adults who adhere to a whole-food plant based diet would have lower LDL-C levels than those who do not.

Chapter 4 RESULTS & DISCUSSION

As a research assistant for the Zoe Project, 60 hours were required to be documented regarding the activities performed in the research study. These activities included numerous communications via email, text, and phone calls regarding input, correction, and analysis of data with varying team members. Pre and post data collection were divided among group members including biometric measures (height, weight, BMI, body fat %, and blood pressure), resting metabolic rate (RMR), fasting blood tests (plasma cortisol level, C-reactive protein, lipids, glucose, PLAC, and IL-6), and varying questionnaires related to physical activity, stress, and spiritual experience. My portion of the data included double entry of the data within Microsoft Excel pairing the pre and post test data of the participants in the Zoe study in relation to biometric and blood test data. SPSS input of both biometric and blood tests were entered and examined for normality and outliers. After analysis of the data, tables were then made for use by the researchers to evaluate the outcome of the trial.

It is beyond the scope of this paper to present any findings of this study. At this time, no conclusions about dietary habits of young adult college students can be evaluated from this study. Furthermore, no conclusions pertaining to the effects of dietary or other changes can be made for the short or long-term impact of these changes on cardiovascular risks.

Learning and Experience

Throughout my time as a research assistant, I learned that the process of data entry required attention to detail. I learned quickly through trial and error that data input was a meticulous process that needed every i dotted and t crossed in order to provide

quality results for the research study. For a research study to be successful every member of the group must be in sync and that teamwork and communication is of upmost importance.

As a future Nurse Practitioner understanding how diet affects the cardiovascular health of our patients is vital. The key to success is the promotion of prevention with the patients we care for. It is vital that we educate our patients on healthy dietary lifestyles in order to help prevent the ongoing epidemic of heart disease. In understanding how dietary lifestyle can affect one's cardiovascular health, we can provide them with the education they need to so that might live a healthier lifestyle.

It is recommended that further studies investigate this assumption that adults who eat a whole-food diet have lower LDL-C levels than those who do not. This future research will be beneficial in improving the lives of those who already have high LDL-C levels and for those individuals who are at risk of developing atherosclerosis.

Chapter 5 EVALUATION

According to the CDC, cardiovascular disease is the major cause of death each year (cdc.gov). Much of what we eat plays a large role in the health state of our cardiovascular system. One of the causes of cardiovascular disease is the buildup of atherosclerotic plaque within the vessels of the heart. Diets high in saturated fat and cholesterol only worsen the progression of atherosclerosis by causing elevation of LDL-C levels which is one of the major mediators. Individuals who adhere to a whole-food plant based diet tend to have lower LDL-C levels. Decreases in LDL-C levels can also result from decreasing dietary intake of total fat, saturated fat, and cholesterol which are mainly found in animal meats. As an adjunct with reductions in these high fat, cholesterol rich foods, diets that involve whole-foods and plants such as high viscous fibers, plant sterols and stanols, vegetable protein foods, and legumes have shown to reduce LDL-C levels. Consumption of high viscous foods such as oats, psyllium, and barley, which are rich in beta glucan and avenathramide (antioxidant), provide beneficial cardiovascular benefits at lowering LDL-C levels. Vegetables and fruits which are rich in natural plant sterols and stanols have been shown to decrease LDL-C levels by 6-15%. The incorporation of foods such as nuts, especially almonds, and soy has shown to be beneficial in reductions in LDL-C levels. Although the incorporation of these types of foods have shown that they play a role in LDL-C reduction, it was also revealed that those individuals who were educated on the effects of cardiovascular disease, lifestyle modification such as daily

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