The Impact of a Sixty Day Nurse-Led Lifestyle Modification Program Emphasizing a Whole Food, Plant-Based Diet on the Cardiovascular Risk Factors of Adult Volunteers

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On my honor as a student I have neither given nor received unauthorized aid on this assignment.
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Abstract

Cardiovascular disease (CVD) is the leading cause of death in the United States for middle-aged (45-64 years) men and women. Fortunately, CVD is largely preventable by modifying risk factors through lifestyle change. One such lifestyle change is the adoption of a whole foods plant-based (WFPB) diet. The purpose of this study was to examine the effects of a nurse-led, sixty day dietary program emphasizing a low fat, WFPB diet on the cardiovascular risk factors of adult participants in the Hampton Roads area of VA. A quasi-experimental pre/post-test, single group design, was used to examine the effect of a weekly nurse-led lifestyle intervention program emphasizing a whole food, plant-based diet on the CVD risk factors of adult participants. Participants significantly reduced body weight, total cholesterol, LDL-C cholesterol, LDL-P count, and systolic and diastolic blood pressures ($p<0.01$). There was a significant ($p<0.01$) *increase* in fasting blood glucose before and after the 60 day intervention period and a non-significant ($p = 0.126$) increase in triglycerides. As for HbA1C, there was no significant change before and after the intervention. In conclusion, well-designed, nurse-led WFPB intervention programs can improve lifestyle choices and health habits. They can also markedly and rather quickly reduce the level of cardiovascular risk factors in a non-randomized population.

Dedication

This capstone is dedicated to my husband, Eric. Without your support, my journey to a DNP degree would still be but a dream! Thank you for supporting me, encouraging me, and for being my biggest cheerleader. I am so grateful for your love and support!

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Chapter 1

Introduction

One of the greatest health threats that Americans face today is cardiovascular disease (CVD). According to the American Heart Association (AHA), heart disease is the leading cause of death in the United States for both men and women (Roger et al., 2012). In 2007, one-quarter of all deaths (616,000) were from diseases of the heart (National Center for Health Statistics [NCHS], 2011). The majority (81%) of heart disease deaths were among people 65 years of age and over; however, disease prevalence can be found among people of all ages and backgrounds (NCHS, 2011). In fact, approximately 150,000 Americans killed by CVD in 2008 were less than 65 years of age.

Not only is heart disease a threat to America's health, it is also a threat to the economy. In 2010, heart disease will have cost the United States $316.4 billion, including the cost of health care services, medications, and lost productivity (Roger et al., 2012). The aging population, obesity epidemic, underuse of prevention strategies, and suboptimal control of risk factors will most likely exacerbate the economic burden of CVD on future generations of Americans (Roger et al., 2012). One of the best ways to combat the economic threat of CVD is to increase adherence to national and community-level guidelines and renew an emphasis on the policy, environmental, and lifestyle changes necessary for its effective prevention and control (Mensah & Brown, 2007).

Unfortunately, Americans as a whole are continuing to experience deteriorating quality of life and a rising incidence of risk factors for CVD. According to a report from the U. S.

Department of Health and Human Services (USDHHS) on health statistics from the 2009 National Health Interview Survey (NHIS), 55% of adults had never participated in any type of vigorous leisure-time physical activity, and 17% of adults did not have a usual place of health care (Pleis, Ward, & Lucas, 2010). Twelve percent of adults had been told by a doctor or health professional that they had heart disease, 24% had been told on two or more visits that they had hypertension, and 3% had been told they had experienced a stroke. Twenty-one percent of all adults were current smokers, and 21% were former smokers. Based on estimates of body mass index, 35% of adults were overweight, and 27% were obese (Pleis et al., 2010).

Fortunately, prevention and control of heart disease is largely achievable by modifying risk factors. The leading risk factors for heart disease include high blood pressure, high blood cholesterol, diabetes, diet high in saturated fat, physical inactivity, obesity, and tobacco abuse (Roger et al., 2012). It is critical to address all these risk factors early in life to prevent the potentially devastating complications of chronic CVD (USDHHS, 2011). All of these risk factors can be reversed and even prevented by making lifestyle changes that improve health habits. One such lifestyle change is the adoption of a low-fat, whole food, plant-based (WFPB) diet. This one lifestyle change alone can prevent the majority of the risk factors that lead to heart disease (Barnard et al., 2006; Ornish, 2009; Hooper et al., 2011).

The Role of APNs in Preventing Heart Disease

Advanced practice nurses (APNs) play a highly important role in the prevention and management of CVD. Whether caring for patients in an outpatient clinic or at the bedside during a patient's hospitalization, APNs frequently have the opportunity to educate patients about what they can do to improve their health and their lives. For some patients, an unexpected hospitalization for chest pain is often a wake-up call to make changes. APNs are in an ideal

position to capitalize on these opportunities in order to educate patients on how to make and sustain such lifestyle changes. Empowering patients to make lifestyle improvements is part of the holistic role that APNs play in the care of their patients. APNs play a tremendous role in prevention and risk factor reduction strategies (Artinian et al., 2010). Inherent in the practice of nursing is a commitment to the prevention of illness among the patients and families served across the continuum of care.

In all parts of the world, nursing has experienced a profound culture change over the past few decades. Nurses are increasingly expected to understand research and to base their professional practice on emerging research. Evidence-based practice is the cornerstone of the Doctor of Nursing Practice (DNP)-prepared APN. As the terminal practice degree for nurses, the DNP-prepared nurse has a strong commitment to locate the most effective evidence for any given problem. Whether practicing as a clinician, in a nursing leadership role, or in the community, the DNP-prepared nurse is prepared to affect practice, design and implement programs that improve health and health care delivery, apply data management and informatics skills to evaluate outcomes, and influence policy (American Association of Colleges of Nursing [AACN], 2006). Therefore, DNP-prepared nurses are perfectly positioned to improve adherence to national guidelines by leading patients to make more comprehensive lifestyle changes, including following a WFPB diet.

Purpose

The purpose of this study was to examine the effects of a nurse-led, sixty day dietary program emphasizing a low fat, WFPB diet on the cardiovascular risk factors of adult participants in the Hampton Roads area of VA. The modifiable CVD risk factors to be measured include weight, body mass index (BMI), systolic blood pressure (SDP), diastolic blood pressure

(DBP), total cholesterol (TC), triglycerides, low density lipoprotein concentration (LDL-C), high density lipoprotein concentration (HDL-C), LDL particle count (LDL-P) hemoglobin A1C, and fasting plasma glucose (Figure 1). Hampton Roads is located in southeastern Virginia and is comprised of 16 jurisdictions – the cities of Chesapeake, Franklin, Hampton, Newport News, Norfolk, Poquoson, Portsmouth, Suffolk, Virginia Beach and Williamsburg, and the counties of Gloucester, Isle of Wight, James City, Southampton, Surry and York. According to the U. S. Census Bureau, the Hampton Roads metropolitan statistical area has a population of about 1.7 million, making it the 36th-largest metropolitan area in the United States (U. S. Census Bureau, 2013).

Setting

Hampton Roads provides an ideal location for the study because of its large population and risk factor profile. According to the National Vital Statistics Report (NVSR, 2012), more than one out of four deaths in Virginia was due to heart disease in 2007. This same report revealed that 14,021 Virginians died from heart disease in 2006 (24.3% of total deaths in Virginia); this closely resembles national data where one-quarter of all deaths were from diseases of the heart (National Center for Health Statistics [NCHS], 2011). Within the state of Virginia, the Hampton Roads region ranked fourth out of eight regions for age-adjusted rate of cardiovascular deaths in 2010, with 237.1 deaths per 100,000 people (Virginia Center for Health Statistics, 2011).

When comparing this area of Virginia to the nation as a whole, the population of Hampton Roads tends to be younger and more diverse than the population of the United States (Virginia's Hampton Roads Regional Profile, 2009). The median age of Hampton Roads' resident population in 2007 was 35.2, over a year less than the national average of 36.7

(Virginia's Hampton Roads Regional Profile, 2009). The racial and ethnic composition in Hampton Roads is significantly different from that of the Unites States as well. Hampton Roads has proportionately more African Americans and proportionately fewer persons in every other racial category (Virginia's Hampton Roads Regional Profile, 2009). For these reasons as well as the fact that no similar study has been undertaken in this region to date make Hampton Roads an ideal setting for this study.

Conceptual Model

Making lifestyle changes is not necessarily an easy task. It requires motivation and persistence since the pay-off is often not immediately imminent. Prior research on health behavior modification has focused mainly on individual patient factors (Elder, Ayala & Harris, 1999; Sher et al., 2002). Bandura's Social Learning Theory (Figure 2) attempts to predict and explain behavior using several key concepts; among these are incentives, outcome expectations and self-efficacy expectations. Although all are important, the concept of self-efficacy expectations is of particular relevance to health education. Theories on self-efficacy, self-determination, readiness to change, and motivation to change have been used to understand factors that influence health behavior change (Elder, Ayala & Harris, 1999; Sher et al., 2002). Self-efficacy, in particular, has been shown repeatedly to be predictive of health behaviors (Bandura, 2004). When educating populations about how to improve their diet it is essential to address self-efficacy and motivation.

Self-efficacy beliefs are an important aspect of human motivation and behavior. Regarding self-efficacy, Bandura (1995) explains that self-efficacy "refers to beliefs in one's capabilities to organize and execute the courses of action required to manage prospective situations" (p. 2). More simply, self-efficacy is what an individual believes he or she can

accomplish using his or her skills under certain circumstances (Bandura, 2004). The basic principle behind Self-Efficacy Theory is that individuals are more likely to engage in activities for which they have high self-efficacy and less likely to engage in those they do not (Van der Bijl & Shortridge-Baggett, 2002).

Health behavior modification is a dynamic process requiring a tremendous amount of commitment from both the patient and his or her social network members. By providing social support, social networks serve as a valuable resource that can be used to motivate health behavior modification (Berkman, 1995). Bandura suggested that the development of new behavior is a result of exposure to significant role models and is sustained over time through reinforcement at both the individual and societal level (Bandura, 2004). He emphasized the importance of a favorable social setting for learning and of key opinion leaders in shaping new attitudes and behaviors that can be introduced into a community (Bandura, 2004).

It was around the concept of Social Learning Theory that this study was designed: the APN played the role of the key opinion leader in shaping new behaviors and the highly interactive weekly group meetings provided the favorable social setting for learning (Figure 2). The concept of "collective efficacy" has been identified as a phenomenon that promotes more effective change in a group setting than would happen in isolation. Collective efficacy is considered an extension of the self-efficacy construct (Bandura, 1995). Perceived collective efficacy is defined as "a group's shared belief in its conjoint capabilities to organize and execute the courses of action required to produce given levels of attainments" (Bandura, 1997, p. 477). Hopefully by providing the participants with a social environment conducive to the sharing of information as well as an APN leader to promulgate discussions, participants will be able to draw

on their own self-efficacy as well as the group's collective efficacy to make lasting lifestyle changes.

Chapter 2

Review of the Literature

A review of the literature was conducted focusing on research about using a plant-based diet in the treatment and/or prevention of CVD among middle-aged Americans. Since there are varying definitions of plant-based diets, for the purpose of this literature review the terms "vegetarian", "vegan", and "plant-based" are used inter-changeably. According to the Merriam-Webster dictionary, vegetarianism encompasses the practice of following a plant-based diet, with or without the inclusion of dairy products or eggs, and with the exclusion of red meat, poultry, and seafood (Vegetarianism, 2013). Someone who follows a vegan diet is a strict vegetarian who consumes no animal food or dairy products and also one who abstains from using animal products, such as honey and leather (Vegan, 2013). Plant-based diet is a general term that refers to an eating pattern dominated by fresh or minimally processed plant foods and no consumption of meat, eggs and dairy products (Lea, Crawford, & Worsley, 2006). There is no formal definition for the term.

In this literature review, the databases of CINAHL, Ovid MEDLINLE, and the Cochrane Library were searched. Ancestry searching was also used. The key word "cardiovascular diseases" was combined with the key word "vegetarian" and the key word "vegan" when searching the Ovid MEDLINE database. This search returned 92 citations. When searching the CINAHL database, the key words "cardiovascular diseases" and "vegetarian" were combined resulting in 60 retuned citations; searching "cardiovascular disease" and "vegan" yielded 24 citations. The Cochrane Library was then searched using the key terms, "cardiovascular disease" and "vegetarian" yielding 18 results. "Cardiovascular disease" and "vegan" was also searched, yielding three citations. Hand searching the ancestry of pertinent research reports and review

articles was also completed in order to identify additional studies. This yielded five additional studies.

Inclusion criteria were: 1) Any study that compared a vegan and/or vegetarian diet as the intervention to any other diet, and 2) any study comparing cardiovascular disease risk factors before and after an intervention involving a vegan and/or vegetarian diet. Exclusion criteria were: 1) Studies that did not measure reduction of cardiovascular disease risk factors as an outcome, 2) studies without an English language abstract, and 3) studies that reported overall cardiovascular disease risk factor incidence but did not analyze each risk factor incidence separately. The search was limited to articles in English, with human subjects that were middle-aged (45 plus years), and that were published between 1985 and the present. Randomized clinical trials and quasi-experimental (non-randomized comparison cohort studies) were included in this review. Case studies, multiple case series and descriptive studies were excluded. Fourteen studies and four systematic reviews were identified that met inclusion criteria.

Mortality and Morbidity Data – Vegetarians v. Non-vegetarians

All of the research studies that examined mortality compared vegetarians to non-vegetarians. While a vegetarian diet differs slightly from a WFPB diet in that it allows the consumption of dairy products (cheese, milk, butter, yogurt, etc.) and eggs, vegetarian diets still eliminate all other animal products as does the WFPB diet. Studies comparing the morbidity and mortality among vegetarians and non-vegetarians demonstrate that vegetarians have a lower mortality rate from ischemic heart disease than non-vegetarians (Key, Fraser, Thorogood, et al., 1999; Key, Thorogood, Appleby, & Burr, 1996). In a Cochrane Review by Hooper et al. (2011) the authors assessed the effect of change in dietary fats on cardiovascular mortality and morbidity. The authors concluded that reducing saturated fat by reducing and/or modifying

dietary fat (i.e., by reducing and/or eliminating animal products from the diet) reduced the risk of cardiovascular events by 14%. The protective effect was seen almost exclusively in those who continued to modify their diet over at least two years.

In a meta-analysis study comparing mortality among vegetarians and non-vegetarians, Key, Fraser, Thorogood, et al. (1999) combined data from five prospective studies and discovered that vegetarians had a 24% lower mortality from ischemic heart disease than non-vegetarians ($p < 0.01$). In contrast, another study by Key, Thorogood, Appleby, and Burr (1996) failed to demonstrate a significant difference in mortality. The researchers followed 11,000 vegetarians for 17 years in order to examine the association of dietary habits with mortality. The investigators did find that a vegetarian diet was associated with a 15% reduction in mortality from ischemic heart disease; however, the data failed to reach statistical significance and was less than the roughly 30% reductions reported in earlier analyses completed by the investigators of a similar cohort.

Risk Factors of Vegetarians v. Non-vegetarians

The research does demonstrate that vegetarians and vegans have lower rates of a number of health problems, including obesity, hypertension, type 2 diabetes, some cancers, gallstones, kidney stones, constipation, and diverticular disease (Marsh, Zeuschner, & Saunders, 2012; Leitzmann, 2005; Segasothy & Phillips, 1999). In fact, in Western countries, a vegetarian diet may present a significant advantage over meat-based diets, and a number of studies have shown increased longevity in vegetarians (Marsh, Zeuschner, & Saunders, 2012; Key, Fraser, Thorogood, et al., 1999; Key, Thorogood, Appleby, & Burr, 1996).

Interventional Studies – Using a Vegetarian Diet to Reduce Risk Factors for CVD

In terms of using a vegetarian/vegan diet as a clinical intervention, seven trials reported on the same comparison: examining a vegan or vegetarian diet as the intervention on the reduction of risk factors for CVD (Barnard, Cohen, et al., 2009; Bloomer et al., 2010; Chainani-Wu et al., 2011, Ferdowsian et al., 2010; Fontana et al., 2007; Govil et al., 2009; and Marshall et al., 2009). The results from these 7 studies demonstrated:

- Weight and BMI were significantly ($p<0.01$) lower in the intervention group in 6 of the 7 studies; one study (Barnard, Cohen, et al., 2009) showed greater improvements in BMI in the vegan diet group, but the results did not reach statistical significance when compared to the control group,
- Total cholesterol and LDL-C were significantly lower ($p<0.01$) in 6 out of 7 studies; one study (Barnard, Cohen, et al., 2009) once again saw greater improvements in plasma lipids in the intervention group but failed to reach statistical significance when compared to the control group,
- Systolic and diastolic blood pressures were significantly lower ($p<0.01$) in 6 of the 7 studies; this was not significantly different in either group in the Barnard, Cohen, et al., (2009) study,
- Hgb A1C and/or fasting plasma glucose was lower in the vegan/vegetarian groups compared to the control groups in four of the studies; only two of the four studies (Chainani-Wu et al., 2001; Govil et al., 2009) reached statistical significance ($p<0.01$).

Although the results were impressive, several of the studies failed to reach statistical significance in one or more risk factors. More rigorous, larger, and randomized long-term studies are needed.

The remaining three studies (Esselstyn et al., 1995; Lockheart et al., 2007; and Ornish et al., 1999) examined reduction of coronary artery disease after an intervention with a vegan/vegetarian diet as measured by changes in coronary artery percent diameter stenosis and cardiac events. The results from these studies demonstrate:

- In the Esselstyn et al. (1995) and Ornish et al. (1999) trials, percent diameter stenosis was improved significantly ($p<0.01$) in the intervention group within one year in the Ornish et al. study (1999) and within 5 years in both studies; both studies demonstrated a worsening of the percent diameter stenosis in the control groups,
- In the Lockheart et al. study (2007), investigators examined risk of first myocardial infarction as related to diet; MI was found to be significantly ($p<0.01$) inversely associated with intake of nutrient-rich plant foods and fish.

The successful results from these studies suggest that a vegetarian/vegan diet should be offered to all patients with coronary heart disease as a potential treatment.

Literature Summary – Strengths and Weaknesses

Low-fat, plant-based, vegetarian and vegan diets are associated with reduced body weight, increased insulin sensitivity, and reductions in cardiovascular risk factors including blood pressure and plasma lipids (Barnard, Cohen, et al., 2009; Bloomer et al., 2010; Chainani-Wu et al., 2011, Ferdowsian et al., 2010; Fontana et al., 2007; Govil et al., 2009; and Marshall et al., 2009). The potential cardiovascular benefits of plant-based diets may be especially important for individuals with documented CVD, for whom disease progression is a main cause of premature mortality; the effects of such diets on CVD appears to be significant in being able to halt progression and even reverse disease (Barnard, Cohen, et al., 2009; Bloomer et al., 2010;

Chainani-Wu et al., 2011, Ferdowsian et al., 2010; Fontana et al., 2007; Govil et al., 2009; and Marshall et al., 2009).

Even though longitudinal studies failed to reach significance in mortality reduction, the current evidence does support a plant-based diet as being an effective treatment to improve the risk factors and disease progression of CVD. The potential benefits seem to outweigh the risks making a low-fat, WFPB diet a safe and moderately effective treatment for CVD. Research also demonstrates that participants' perceived barriers to following a WFPB diet are relatively low (Lea, Crawford, & Worsley, 2006).

Clinical Implications

Even though none of the studies examined were nurse-led interventions, advanced practice nurses (APN) play a tremendous role in prevention and risk factor reduction strategies (Artinian et al., 2010). Consistent with national calls for action and with the longstanding focus on health promotion and disease prevention in nursing curricula and roles, APNs have a foundation in clinical prevention and population health that prepares them for their role of managing chronic illnesses and teaching people how to stay well (AACN, 2006). Inherent in the practice of nursing is a commitment to the prevention of illness among the patients and families served across the continuum of care through inpatient, ambulatory and public health settings. Therefore, nurses are perfectly positioned to improve adherence to guidelines by leading patients to make more comprehensive lifestyle changes, including following a WFPB diet.

The efficacy of a lifestyle intervention is influenced by the individual's ability to improve diet and make the necessary changes (Govil et al., 2009). When most patients are diagnosed with coronary artery disease, they are usually advised to follow the dietary guidelines of the AHA or the National Cholesterol Education Program (NCEP). However, these moderate changes in diet

usually result in only modest reductions in LDL cholesterol levels, at which point lipid-lowering drugs are usually prescribed (Ornish, 2009). In fact, research shows that most patients do not even receive the cardiovascular prevention treatment that is recommended by current guidelines (Voogdt-Pruis, Van Ree, Gorgels, & Beusmans, 2010). Improvement of adherence to guidelines by health care providers and patient compliance to lifestyle advice and prescribed treatment is therefore still necessary (Voogdt-Pruis, Van Ree, Gorgels, & Beusmans, 2010). Most patients are not given the option of making more intensive changes in diet and lifestyle such as a plant-based diet, because of the belief that patients will not follow the prescribed diet (Govil et al., 2009). This belief often becomes self-fulfilling (Govil et al., 2009).

The perspective that adherence to a medication regimen is more achievable for patients than changing diet and lifestyle lacks research support (Barnard, Gloede, et al., 2009; Barnard, Katcher, Jenkins, Cohen, & Turner-McGrievy, 2009; Ornish, 2009). In fact, research shows that up to 60% of patients prescribed lipid-lowering drugs stop taking them only 6 months after initiating treatment (Govil et al., 2009). However, when people make comprehensive lifestyle changes, including a plant-based diet, they often feel so much better within the first four to six weeks that it often becomes a sustainable change (Barnard, Gloede, et al., 2009).

Carefully planned group-based lifestyle modification programs may represent an important effort to help reduce the economic burden of CVD disease. The potential success of group-based lifestyle modification programs and their emphasis on lifestyle changes through education, understanding, skill acquisition and mutual support could be potentially important in effecting health in the community at large (Artinian et al., 2010). Group-based interventions are characterized by opportunities for social interaction, support from others who are experiencing similar challenges in modifying their lifestyle, role modeling, and positive observational learning

(Artinian et al., 2010). Group-based approaches are commonly used in randomized clinical trials employing standard behavioral interventions for weight loss (Artinian et al., 2010; Burke et al., 2006) as well as in other trials using diet and physical activity changes to target CVD risk factors such as BP or blood cholesterol (Artinian et al., 2010; Stevens, Glasgow, Toobert, Karanja, & Smith, 2003; Ornish et al., 1999). In a meta-analysis of studies that tested interventions to increase physical activity among older adults, group-based intervention delivery resulted in larger effect size than individual-based interventions (Artinian et al., 2010).

While the research demonstrates that plant-based diets are successful in reducing risk factors for CVD, all of the studies examined were short-term, mostly non-randomized, and small in sample size. Therefore, more research is needed in this area, especially on the use of a WFPB diet for cardiovascular risk factor reduction. More research is also needed on patient adherence to lifestyle and dietary changes involved with a WFPB diet.

Because of their diverse and unique placement within the healthcare arena, nurses have a unique opportunity to impact patient care by encouraging patients to adopt more significant lifestyle and dietary changes (Lloyd-Jones et al., 2010); particularly reductions in dietary saturated fat, trans fatty acids, and cholesterol as recommended by the 2013 update to the AHA/ACC guidelines for patients with CVD (Stone, et al., 2013). The intent of the present study is to examine what the impact of a nurse-led sixty day program emphasizing a low-fat, WFPB diet will be on the CVD risk factors of adult participants in the Hampton Roads area of Virginia.

Chapter 3

Methods

Purpose and Hypothesis

The purpose of this study was to examine the effects of a nurse-led, sixty day dietary program emphasizing a low fat, WFPB diet on the cardiovascular risk factors of adult participants in the Hampton Roads area of VA. The research hypothesis was that a low-fat WFPB diet will significantly lower participants' body weight, blood pressure, total blood cholesterol, LDL cholesterol concentration (LDL-C), LDL particle count (LDL-P), and blood sugar levels and raise high density lipoprotein (HDL) cholesterol and particle count (HDL-P).

Research Design

This study used a non-randomized quasi-experimental pre/post-test, single group design, to examine the effect of the dietary program on the CVD risk factors of adult participants.

Definition of Terms

Risk factors for CVD are defined as those listed by the NHLBI: high total blood cholesterol, high LDL cholesterol, high blood pressure, diabetes, smoking, and being overweight (NHLBI, 2012). To establish the risk factor profile for study participants, U.S. reference values were used for all variables. The following definitions were used to define participants' risk factors and thus determine participants' eligibility for this study.

High blood cholesterol. High blood cholesterol was defined as an LDL level greater than 160 mg/dL and total blood cholesterol greater than 240 mg/dL, as defined by the National Cholesterol Education Program (Cleeman, 2001).

High blood pressure. Blood pressures were defined according to the seventh report of the Joint National Committee on the prevention, detection, evaluation, and treatment of high

blood pressure (JNC 7): normal (<120/80), pre-hypertension (120/80–139/89), stage one hypertension (140/90–159/99), and stage 2 hypertension (≥160/100) (Chobanian et al., 2003).

Diabetes. The American Diabetes Association (ADA) definition of diabetes (both type 1 and type 2) is for a single raised fasting glucose reading of greater than or equal to 126 mg/dL (ADA, 2012).

Tobacco Abuse. The abuse of tobacco was defined as the practice of purposely using tobacco for its perceived physical and psychologic benefits, such as mental alertness, relaxation, and weight control. Repeated use often leads to addiction. The product may be taken into the body by inhaling the smoke from burning tobacco or by chewing a variety of smokeless tobacco products (Al-Ibrahim & Gross, 1990). Participants self-reported if they had ever abused tobacco in the past, including for how long and if/when they quit, as well as whether they were current tobacco abusers.

Being overweight. Being overweight was defined by body mass index (BMI) values. BMI definitions used in this study were those defined by the Center for Disease Control and Prevention (CDC) and fell into the following clinical categories: healthy weight, 18.5–24.9; overweight, 25.0–29.9; obesity (class 1), 30.0–34.9; obesity (class 2), 35.0–39.9; and severe obesity (class 3), ≥40.0 (NHLBI, 2012).

Description of the Sample

The sample size sought for this study was calculated a priori using G*Power (Faul, 2013) and was based on anticipated LDL reductions of 20% and standard deviations provided in the literature (Faul et al., 2007; Ferdowsian et al., 2010; Barnard et al., 2006). Using these parameters, it was calculated that a sample size of 34 would provide a minimum 80% power to

detect a difference between the pre-test and post-test results using a two-tailed *t* test with significance level of 0.05.

Inclusion criteria. Eligible participants were defined as:

- adults, between 35 and 85 years of age,
- having one or more risk factors for CVD as defined by the NHLBI, and/or previously diagnosed with CVD by a cardiologist,
- able to read and fill out questionnaires in English,
- and able to speak English.

Because social support is critical in achieving and adhering to the recommended lifestyle, investigators encouraged spouses and family members to attend the plant-based diet educational session and the weekly group meetings with participants.

Exclusion criteria. Participants were excluded if they:

- were younger than 35 years of age or older than 85 years of age,
- were non-English speaking,
- had plans to join another organized weight loss or exercise program,
- were pregnant,
- were medically unstable, defined as adults whose health impairment was severe enough to require prolonged dependency on medical care or technology and required intense nursing services at home in order to maintain health and well-being; the health impairment was characterized by periods of acute exacerbation or potentially life-threatening episodes that required frequent hospitalizations or prolonged recuperation periods at home (American Hospital Association, 2003),
- were currently taking prescription medications for Type 1 or Type 2 diabetes mellitus,

- or already followed a low-fat vegetarian diet.

Setting

This study was a field study and was conducted by a nurse practitioner-led multi-disciplinary team consisting of the nurse practitioner team leader, a board certified cardiologist, and a registered dietician. The informational session, pre- and post-intervention health screenings, and weekly group meetings were held at the Princess Anne office of Cardiovascular Associates, Ltd. This setting provided the appropriate amount of space, necessary audiovisual equipment, and kitchen accessories without incurring any additional cost to the investigators or participants.

Procedures and Intervention

Approval for the study was obtained through the Western Institutional Review Board (WIRB; Appendix A) and made exempt from the University of Virginia's IRB (Appendix B) upon WIRB approval. Following IRB approval, participant recruitment began. Participants were recruited directly from Cardiovascular Associates, Ltd. (CVAL), through promotional flyers posted in the office as well by direct recruitment by CVAL providers. Also, during the recruitment period the principal investigator spoke weekly at healthy eating seminars conducted at the Whole Foods Market grocery store in Virginia Beach, VA, allowing for direct recruitment of participants through these seminars. These healthy eating seminars were co-sponsored by CVAL and Whole Foods Market. Participants were also recruited through promotional flyers (Appendix C) that were posted on bulletin boards in restaurants, coffee shops, and YMCA's in the cities of Portsmouth and Norfolk, VA. Newspaper and television advertising was used as well. A study e-mail address was also created so that interested health care providers and

potential participants could directly contact study investigators with questions or concerns and obtain more information about the study.

Following the recruitment period, interested participants underwent an initial screening via e-mail or telephone by the APN in order to confirm eligibility. Once eligibility was confirmed, participants were then invited to attend a one day health screen and information session in order to be officially enrolled in the study. This initial health screen lasted approximately four hours and consisted of a comprehensive health screen to establish risk factor levels and collect outcome measures for each participant (Figure 1) as well as an educational session outlining study details and providing information on how to follow a low-fat WFPB diet. This health screen also included a review of current medications and a fasting laboratory evaluation. The educational session emphasized the nature and etiology of CVD, its epidemiology and its risk factors, and the potential for prevention, arrest, and reversal through the adoption of a plant-based diet. At one week and again at one day prior to the health screen, participants were notified by phone and/or e-mail reminding them to arrive in a fasting state. Participants were instructed to have nothing to eat or drink, except water, for at least 12 hours prior to the start of the health screen.

Upon arrival at the health screen, participants were provided with their participant notebook and asked to read and sign the Informed Consent (Appendix D). After signing the consent form, participants then completed the lifestyle evaluation and current medication form to provide data on each participant's demographics and current lifestyle (Appendix E). Following completion of the lifestyle evaluation form, participants then met with one of the investigators to have height, weight, and blood pressure measured as well as for review of their lifestyle form and current medications. Participants then had blood drawn and collected by a licensed

phlebotomist via venipuncture. Once all anthropometric measures and laboratory assessments were completed, participants were then able to eat and enjoy a low-fat WFPB meal provided by investigators. Once all participants had completed the health screen portion, the nutritional lecture was given by the advanced practice nurse.

The nutritional lecture instructed participants on the rules and expectations of the study as well as provided information on how to follow a low-fat WFPB diet and how a WFPB diet can prevent, arrest, and reverse heart disease. During the nutritional lecture, participants were also reminded that they were required to take a daily multivitamin to ensure adequate intake of vitamin B-12 since a low-fat WFPB diet is typically deficient in vitamin B-12. Participants were informed that a daily multi-vitamin would not be provided by investigators and adherence would only be measured by participant report. They were also asked, but not required, to moderate their consumption of alcohol and caffeine. Participants were also encouraged to include in their daily diet one serving of walnuts, two tablespoons of flaxseed meal, or two tablespoons of chia seeds to ensure sufficient intake of Omega 3 fatty acids. Again, participants were reminded that this would not be provided by investigators and adherence would only be measured by patient report in food diaries. Following the lecture, participants were given the opportunity to have any questions or concerns answered and addressed.

The initial health screen occurred on a weekend day during the first weekend of the month. The 60 day intervention period of the study then officially began the Monday following the health screen. Participants were expected to begin following the prescribed diet and to begin completing their daily food diaries on this day. By starting the intervention at the beginning of the month, investigators were hoping to allow participants the time and financial resources needed to complete any grocery shopping and food preparation required for the intervention.

The prescribed diet that participants were asked to adhere to was a low-fat WFPB diet that derived less than 10% of its calories from fat. Participants were instructed to avoid all oils, meat, fish, fowl, all processed foods, and dairy products. Grains, legumes, lentils, vegetables, and fruit comprised the major portion of the diet. In order to increase adherence, patients were given the option to slowly transition to the diet over a period of four weeks (Appendix F). The Transition Instruction form was provided to participants in the study notebook given to each participant at the initial health screen. The notebook also contained a section to record their food diaries, a list of fat-free recipes taken from cookbooks and other resources that focus on plant-based nutrition, a sample 30 day meal plan, and additional resources on how to successfully follow a low-fat, WFPB diet including strategies for eating out and celebrating with friends and family.

Once the intervention period began, participants were asked to keep daily food diaries for the first two weeks. Participants submitted their food diaries at the end of each week either via e-mail to the study e-mail address or in person at their weekly group meeting. A photocopy was made of the food diaries presented in person at the group meeting and given to the participant for his/her records. After the initial two weeks, participants were then asked to complete food diaries only three days per week (participants were able to choose which days) for the remaining six weeks. A weekly e-mail and/or phone call was initiated to participants at the beginning of each week reminding them to complete their food diaries.

As part of the intervention, participants were also expected to meet as a group once weekly for eight weeks to participate in an educational lecture, review food diaries with the APN, have any questions answered, and receive moral support from the APN and fellow group members. All of the weekly group meetings were held on a Sunday afternoon at the Princess

Anne office of Cardiovascular Associates, Ltd. For three of the eight weekly group meetings, a guest speaker was invited to provide the educational portion of the meeting. Those guest speakers included a cardiologist, a family physician, and a resident of the local community who had been following a plant-based diet for several years.

At the end of the sixty day intervention, a second comprehensive health screen was conducted to measure the changes in lifestyle, clinical outcomes, and medications over the sixty day intervention period. Study outcome measures were again collected (Figure 1) and the lifestyle evaluation and current medications form was again completed by participants. This data was then compared and analyzed to determine the effect of the program on clinical outcome measures and lifestyle measures.

Measures and Instruments

During the initial educational session and health screening, the investigators conducted an anthropometric assessment on each participant and reviewed each participant's current medications. Standing height was measured using a stadiometer. Test-retest reliability studies have been performed demonstrating high reliability ratings of stadiometers in measuring height (Voss, Bailey, Cumming, Wilkin, & Betts, 1990). Body weight was measured using a digital scale. No reliability data could be found on the use of digital scales and measuring weight; however, the same scale was used for both pre- and post-intervention measurements. Blood was collected by a licensed phlebotomist via venipuncture and the following standard laboratory tests were run on plasma or whole blood: A lipid panel which measured total cholesterol, HDL-C, LDL-C and triglycerides; direct measurement of LDL-C; hemoglobin A1C and fasting blood glucose. Serum lipoprotein particle concentrations (LDL-P and HDL-P) and other serum metabolites were determined by nuclear-magnetic resonance (NMR) spectroscopy. Following the

completion of the sixty day intervention, a second health screening was administered and all outcome measures were collected again. Participants once again arrived fasting for repeat blood draw as well as repeat anthropometric assessment, medication reconciliation, and completion of the lifestyle evaluation form.

All demographic and lifestyle data were collected via the lifestyle evaluation form (Appendix C). While no reliability or validity data is available for the lifestyle evaluation form, the form has been modeled after information obtained in evaluation forms used in previously published studies examining changes in lifestyle and diet and their impact on risk factors for cardiovascular disease (Rankin et al., 2012; Englert, Greenlaw, Diehl, Willich, & Aldana, 2007; Aldana et al., 2005; Englert, Greenlaw, & Diehl, 2004). The lifestyle evaluation form was used in this study to collect data on participants' age, race, education level, income level, marital status, current comorbidities, current exercise level, current weekly dietary intake of key sources of saturated fat, smoking status, and current medications.

Data Analysis

All data were entered and analyzed using Microsoft Excel 2010 and IBM SPSS Statistics (version 22, 2013, IBM, Chicago, IL). Demographic data, including race, education level, and income level, were reported as percentages with the exception of age. Age was reported as range and mean age by gender plus or minus one standard deviation. Changes in the outcome measures (fasting lipids, fasting glucose, and anthropometric measures) from baseline to 60 days were analyzed using a paired-samples *t* test. Participants were considered completers if they attended at least 75% (six of eight) of the weekly group meetings and submitted food diaries for at least 75% (six of eight weeks) of the intervention period. Significance was accepted at $p<0.05$.

Strengths and Weaknesses of the Design

Due to the small sample size, non-randomized design of the study, and the lack of a control group, the generalizability of the findings to other populations is limited. Because participants were self-selected, sample selection bias was unavoidable. Participants were likely more motivated to comply with the program and make the recommended lifestyle modifications than the general population. Also the short term of the intervention and follow-up period presented as a possible limitation. Investigators were not able to determine if this program could have any effect on changes made in the participants' CVD risk factors past the time the study ends.

Strengths of the study include its group-based intervention design. Since participants acquired new knowledge in a group setting and shared their experiences in a group discussion format, the potential for enhanced social support and increased long-term adherence was possible (Artinian, 2010). With adequate reinforcement and psychosocial support for the newly acquired lifestyle, adherence following program completion may be improved. All participants were encouraged to maintain contact following study end, for ongoing inspiration, and encouragement.

Chapter 4

Results

Sample

During the recruitment period, a total of 78 participants were screened and cleared for participation in the first health screen. Of those 78 potential participants, 63 (80.8%) actually enrolled and completed the initial health screen and were enrolled in the study. Recidivism for this study was low: of the 63 participants who were initially enrolled, only five (7.9%) participants failed to complete the study. The final number of program participants who were considered "completers" (attended at least six of eight [75%] of weekly group meetings, completed food diaries for at least six of eight weeks, and attended the second health screen) was 58. Of the five participants who did not complete the study, three failed to attend at least six of eight weekly group meetings and two failed to attend the second health screen. The following data were collected from September 2013 to January 2014 for the 58 study participants.

Demographics

The following results reported relate to data collected from the 58 participants considered "completers". The participants' ages ranged from 41 to 75 years, with a mean of 55.12 ± 6.29 (Table 1). Forty-seven participants were female (81.03%) and 11 were male (18.97%). The majority of the participants were Caucasian (82.76%, n = 48) and married (74.14%, n = 43). Most participants had attended college (81.03%, n = 47) and had an annual household income greater than $50,000 (72.41%, n = 42). Complete sample characteristics can be found in Table 1.

Disease Categories and Risk Factor Changes

The primary outcome variables for this study included the following cardiovascular disease risk factors: being overweight, elevated blood cholesterol, elevated blood pressure, diabetes, and tobacco abuse. The results are organized by their association with each

cardiovascular disease risk factor. The risk factor of current tobacco abuse will not be further discussed, since tobacco abuse was not a focus of this study. Participants were strongly encouraged to cease and/or avoid the abuse of tobacco; however, no further testing or intervention was applied to this risk factor.

Initial Cardiovascular Risk Factor Presentation

At the start of the study, comorbidities of the participants included one (1.72%) with current tobacco abuse, 29 (50.0%) with high blood pressure, 33 (56.90%) with high cholesterol and 53 with being overweight (91.38%). Since participants currently taking medication for diabetes were excluded from the study, this risk factor was absent in this sample with one exception: three participants reported having a medical diagnosis of diabetes, but were not taking any prescription medication for diabetes during the time of the study. According to each participants' BMI as measured at the initial health screen, 53 (91.38%) were overweight and/or obese. All of the participants in the study fell under the following classifications, according to the CDC's definition and classification of obesity (NHLBI, 2012): 15 (25.86%) participants were classified as being overweight, 20 (34.48%) were categorized as having class 1 obesity, 11 (18.97%) fell under class II, and seven (12.07%) fell under class III (Table 2).

Changes in Bodyweight

A paired samples *t*-test was conducted to compare changes in body weight before and after the 60 day intervention period (Table 3). There was a significant ($p<0.001$) difference in body weight before (M = 196.1 lbs) and after (M = 183.8 lbs) the 60 day intervention period. On average, the 58 participants who completed the 60 day intervention period lost 12.31 pounds, for an average individual percent weight loss of 6.47%.

As far as each participants' BMI classification as defined by the CDC, four (6.90%) participants moved from the overweight to the healthy weight category; eight (13.79%) participants moved from class I obesity to overweight; six (10.34%) participants dropped from class II obesity to class I obesity; and two (3.45%) participants dropped from class III (severe obesity) to class II obesity (Table 2).

Blood Cholesterol and Triglycerides

A paired samples *t* test was conducted to evaluate whether a WFPB diet could lower participants' cholesterol and thus lower their risk for cardiovascular disease. The test was run on the following variables: total cholesterol, triglycerides, direct HDL-C, direct LDL-C, and LDL particle count (LDL-P).

For total cholesterol, there was a significant ($p<0.01$) difference before and after the 60 day intervention period. Triglycerides, however, did not decrease significantly over the 60 day intervention period as expected. On the contrary, triglyceride levels actually increased. The mean triglyceride level for participants at the start of the study was 113.95 mg/dL and the mean level after the intervention period was 124.11 mg/dL. However, this upward change in triglycerides was not found to be significant ($p = 0.126$). Also contrary to what was predicted in the study hypothesis, HDL-C levels *decreased* over the course of the intervention period. Unlike the change in triglycerides, this decrease was statistically significant ($p<0.01$). The HDL particle count (HDL-P) also decreased significantly during the intervention period (Table 4).

As the cholesterol marker most associated with cardiovascular disease, investigators were highly interested in mean change in LDL-C before and after the intervention. For direct LDL-C, there was indeed a significant ($p<0.01$) decrease in LDL-C before (M = 123.28 mg/dL) and after (M = 105.40 mg/dL) the participants initiated a WFPB diet. The average drop in LDL-C for

participants after the intervention was 18.5 mg/dL, representing a 14.10% reduction in LDL-C. Another LDL marker tested was the LDL particle count (LDL-P). For this study sample, there was a significant (p>0.01) decrease in LDL-P after the 60 day intervention with a WFPB diet. The mean LDL-P count prior to the intervention was 1301.19 nmol/L. Following the intervention, the mean LDL-P count dropped to 1161.54 nmol/L.

Systolic and Diastolic Blood Pressures

At the start of the study, 32 (50.8%) of the participants indicated a history of high blood pressure on their Lifestyle Evaluation Form. The mean systolic blood pressure (SPB) for participants at the start of the study was 137.74 mm Hg . The mean diastolic blood pressure (DBP) was 79.52. Both SBP and DBP decreased significantly (p<0.001) after the 60 day intervention period. The mean SBP dropped to 122.76 mm Hg and the mean DBP dropped to 71.09 mm Hg. This represents a mean decrease in SDP and DBP of 14.98 and 9.50 mm of Hg, respectively. The most recent Joint National Committee (JNC) guidelines released in 2014 recommend lowering blood pressure to less than 140/90 mm Hg, which was achieved for 18 participants (31.03%) during the 60 day intervention period (James, et al., 2014).

Diabetes

Results from the initial health screen revealed that 10 (15.87%) of the 63 study participants had a fasting blood glucose greater than 100 mg/dL, while two of those 10 participants had a fasting blood glucose of greater than 126 mg/dL, meeting the criteria for a diagnosis of diabetes (ADA, 2012). There was a significant (p<0.01) *increase* in fasting blood glucose (M = 92.21 mg/dL) before and after (M = 96.84 mg/dL) the 60 day intervention period. Similarly to triglycerides, this change was not expected as indicated by the study hypothesis. As for HbA1C, there was no significant change before and after the intervention (Table 4).

Exercise Frequency and Intensity

While exercise was not promoted by investigators, exercise frequency and intensity was self-reported by participants on the lifestyle evaluation form completed before and after the 60 day intervention. It is important to note that there were no significant differences in reported exercise frequency (p=0. .437) and/or exercise intensity (p=0. .843) before and after the intervention (Table 5).

Chapter 5

Discussion

Risk Factor Reduction

Therapeutic lifestyle change can result in significant improvements in nutrition as well as in reductions in many cardiovascular disease risk factors. This has been well demonstrated in the literature in both short and long-term interventions (Artinian et al., 2010; Barnard, Cohen, et al., 2009; Bloomer et al., 2010; Chainani-Wu et al., 2011, Ferdowsian et al., 2010; Fontana et al., 2007; Govil et al., 2009; Marshall et al., 2009; Ornish et al., 1999; & Stevens, Glasgow, Toobert, Karanja, & Smith, 2003). As for this particular study, the majority of participants demonstrated dramatic improvements in nutrition by the end of the 60 day intervention (see Table 6).

At the beginning of the study, 43 (68.3%) of participants had two or more risk factors for cardiovascular disease with being overweight, having high cholesterol and high blood pressure as the most prevalent. At the post-intervention health screen, 17 participants (29.31%) lowered their LDL-C cholesterol by 20%, all participants (100%) lost weight with the mean overall weight loss being 12.31 lbs, and the group's mean SBP dropped 14.98 mm Hg allowing for 18 participants (31.03%) to move from a hypertensive blood pressure reading (>140/90 mm Hg) at the first health screen to a normotensive reading at the final health screen. On average, the net reduction in LDL-C for all participants was 18.5 mg/dL (14.10%). Total cholesterol dropped 28.6 mg/dL (0.21%) on average for participants as well. Participants also reduced their LDL-P counts by 147.6 nmol/L – an 11.3% reduction. While the 2013 AHA/ACC Guideline on the Treatment of Blood Cholesterol does not yet have recommendations regarding LDL-P (Stone et al., 2013), there is emerging evidence that LDL-P is a much more accurate predictor of cardiovascular disease than either LDL or total cholesterol (Cromwell et al., 2007; Garshick,

Mochari-Greenberger, & Mosca, 2013; Prado, Shugg, & Backstrand, 2011). However, more research is needed in this area.

Lower blood pressure, improved blood lipids, and improved cardiac function are directly linked to reduced risk of cardiovascular disease. For every 1% drop in total cholesterol, the coronary risk drops by 2% to 3%; and for every 1 mm Hg drop in elevated diastolic blood pressure, there is another 2% to 3% drop in coronary risk (Manson et al., 1992). Interventions with high cholesterol patients using the National Cholesterol Education Program's step 1 and step 2 dietary interventions reported, on average, total cholesterol reductions of 10% and 13%, respectively (Yu-Poth et al., 1999). The PREMIER Clinical trial used a 6-month comprehensive lifestyle modification trial to reduce blood pressure (Appel et al., 2003). Hypertension prevalence at baseline and 6 months in this study was 38% and 12%, respectively, providing further support that change in nutrition and physical activity can directly impact blood pressure, especially among those who are hypertensive. Medication monitoring revealed that three program participants reduced their blood pressure medication during the intervention, suggesting that the program could have produced reductions in blood pressure greater than what was measured.

Dietary Changes

The shift from the typical rich American diet of animal products and refined, processed foods to a more whole-food, plant-centered diet intake of fruits, vegetables, whole grain products and legumes was the major focus of this intervention study. The prescribed diet that participants were asked to adhere to was a low-fat WFPB diet that derived less than 10% of its calories from fat. Participants were instructed to avoid all oils, meat, fish, fowl, all processed foods, and dairy products. Grains, legumes, lentils, vegetables, and fruit comprised the major portion of the diet.

In order to increase adherence, patients were given the option to slowly transition to the diet over a period of four weeks (Appendix D). The majority of participants (82.54%, n = 52) elected to dive right into the diet as opposed to slowly transitioning.

Group Setting

The group setting for each of the sessions provided strong social support and may have contributed to the low drop-out rate of 7.9%. It cannot be specified to what extent social support may have played a role in effecting the outcomes of the intervention. However, this assumption was supported by two research articles that assert that togetherness, peer reinforcement and encouragement strengthen the adherence of interventional trials (Boutin-Foster, 2005; Williamson & Stewart, 2005). This social support was evident in the interactive portion of the educational curriculum. Even though small in number, participants became a critical mass in the community that began to look for healthier food items in the supermarkets and for healthier menus in the restaurants.

Bandura suggested that the development of new behavior is a result of exposure to significant role models and is sustained over time through reinforcement at both the individual and societal level (Bandura, 2004). He emphasized the importance of a favorable social setting for learning and of key opinion leaders in shaping new attitudes and behaviors that can be introduced into a community (Bandura, 2004). Hopefully by providing the participants with a social environment conducive to the sharing of information as well as an advanced-practice nurse leader to initiate and guide discussions, the healthy lifestyle modifications that occurred during this study will be sustained beyond the study end.

Unexpected Results

Despite the positive benefits associated with a low-at WFPB diet, much clinical debate exists of how far dietary change should be pushed to provide effective public health and clinical benefit (Connor et al., 1997). Previous reports by the Nutrition Committee of the American Heart Association acknowledged the value of very low fat diets for the reduction of cardiovascular risk and the regression of CAD. The authors concluded, however, that ‘‘numerous unanswered questions remain that make population-wide recommendations of such diets premature’’ (Lichtenstein & VanHorn, 1998). Two major concerns cited focused on the triglyceride-raising and HDL-lowering effect of a very low fat/high complex carbohydrate diet, especially in the short-term.

The fact that carbohydrate-rich diets often increase plasma triglycerides has led some to question the wisdom of such diets. There is growing reason to suspect that the increased coronary risk associated with elevated triglycerides in Western epidemiology reflects the fact that high triglycerides are a marker for insulin resistance syndrome, rather than any inherent pathogenic role of triglycerides (McCarty, 2004). Triglyceride levels are relatively high in certain Third World societies which are virtually immune to coronary disease so long as they persist in their traditional very-low-fat diets (McCarty, 2004). In Ornish's low-fat plant-based diet study (Chainani-Wu et al., 2011), a moderate rise in triglycerides coincided with a marked reduction in coronary events. Although the particle size of both LDL and HDL tends to decrease when triglyceride levels are high, it is questionable whether this effect has a major pathogenic impact (McCarty, 2004). The one clear drawback of high-carbohydrate diets is a decrease in HDL particle number. This effect is seen whether or not triglycerides increase. Since exercise training has been associated with increased concentrations of HDL-C (Lloyd-Jones et al., 2010),

it is important to note that there were no significant differences in reported exercise frequency and/or exercise intensity before and after the intervention (Table 5).

The favorable effects of a low-fat, WFPB diet on LDL cholesterol, insulin sensitivity, and body weight appear to more than compensate for this decrease in HDL (Barnard, Cohen, et al., 2009; Bloomer et al., 2010; Chainani-Wu et al., 2011, Ferdowsian et al., 2010; Fontana et al., 2007; Govil et al., 2009; and Marshall et al., 2009). It is also worth noting that HDL levels tend to be quite low in Third World cultures at minimal risk for coronary disease (McCarty, 2004). The tendency of high-carbohydrate diets to boost triglycerides can be minimized by exercise training, supplemental fish oil, an emphasis on fiber-rich, low-glycemic-index whole foods, as well as the weight loss that is often seen with the consumption of such diets (McCarty, 2004).

Study Strengths and Limitations

Ideally, individuals who participate in lifestyle interventions would adopt and maintain healthful behaviors for life. In reality, once the lifestyle interventions are completed, many individuals eventually fail to completely embrace new lifestyle habits and revert to pretreatment behavior (Ornish, 2009). The short-term nature of this study sheds little light on long-term adherence, but it does allow for an accurate assessment of the acute benefit of the intervention. The main improvements in nutrition and cardiovascular risk reported in this study are not completely unexpected. The participants were mostly white and sufficiently self-motivated to volunteer to participate in the intervention. On average, participants were also slightly more educated than the Hampton Roads community at large. Participants had lifestyles that permitted them to attend most, if not all, of the classes. This is evident in the high rate of attendance to this time-intensive program. These limitations threaten the generalizability of these findings and make application of the intervention to other populations problematic.

Other factors may explain the impact of this program. In the intervention, participants attended highly interactive weekly group meetings that included an educational lecture on a different topic each week by the advanced practice nurse as well as ample time for social interaction and group discussions. Testimonials, role playing, short presentations from physicians, social support strategies, food selection and planning activities, and other behavior-change-driven activities all helped to encourage participants to willingly evaluate personal behaviors and commit to make the recommended dietary changes.

Another limitation of the study was the small sample size. An *a priori* power analysis estimated that a sample size of 34 would provide a minimum 80% power to detect a difference between the pre-test and post-test results using a two-tailed *t* test with significance level of 0.05. Even though the sample size after attrition was greater than 34 (n=58), it cannot be inferred that the effect size in the sample would be equal to the effect size in the population at large.

Other limitations include the lack of control group and the short-term of the intervention period. Although these improvements in the cardiovascular risk factors of participants were significant, causality and long-term effectiveness cannot be demonstrated without evaluating the program in a randomized controlled trial.

Nursing Practice Implications

The outcomes of this intervention have added to the body of knowledge on the potential impact of a WFPB diet on cardiovascular disease risk factors. This study also demonstrated that an APN–led intervention can effectively achieve cardiovascular disease risk reduction for participants through intensive dietary education and support. APNs, especially DNP-prepared nurses, are able to use strategies of risk reduction, illness prevention, health promotion, and health maintenance to improve the care of individuals, families, and populations. Carefully

planned group-based lifestyle modification programs may represent an important effort to help reduce the economic burden of chronic disease. The potential success of group-based lifestyle modification programs and their emphasis on lifestyle changes through education, understanding, skill acquisition and mutual support could be potentially important in effecting health in the community at large. Consistent with national calls for action and with the longstanding focus on health promotion and disease prevention in nursing curricula and roles, APNs have a foundation in clinical prevention and population health that prepares them for their role of managing chronic illnesses and teaching people how to stay well (AACN, 2006). Inherent in the practice of nursing is a commitment to the prevention of illness among the patients and families served across the continuum of care through inpatient, ambulatory and public health settings. Therefore, nurses are perfectly positioned to improve adherence to guidelines by leading patients to make more comprehensive lifestyle changes, including following a WFPB diet.

Due to the increased complexity of health care, doctoral-prepared nurses with a focus on the practice setting are needed. A primary goal of the DNP-prepared nurse is to translate evidence into practice in ways that improve the quality and safety of patient care and enhance positive patient outcomes. (AACN, 2006). The changing demands of the nation's complex healthcare environment require the highest level of scientific knowledge and practice expertise to assure high quality patient outcomes. As the terminal practice degree for nurses, the DNP-prepared nurse has both the knowledge and skill necessary to provide innovative leadership to the profession through the dissemination of evidence-based practice initiatives to patients, families, communities and populations. These DNP leaders are perfectly positioned to implement community-based lifestyle modification programs, such as the one investigated in this study, with the hope of lowering participants' risk factors and disease burden. Through the

development and implementation of evidence-based, lifestyle modification programs that focus on disease prevention and long-term health maintenance, DNP leaders will be able to make a positive impact on the health of communities by lowering the incidence and the devastating effects of chronic disease.

As an APN looking to integrate a lifestyle modification program into clinical practice, one way to accomplish this is via the group medical care model or shared-medical appointment model. The group medical care model (or group visit) is an important inter-disciplinary care delivery innovation to complement the individual medical visit that has become increasingly popular (Bauer Bartley & Haney, 2010). A group visit brings together a group of patients with similar medical needs or conditions for medical care in an extended appointment with a health care provider. Groups have been used for patients with a range of medical conditions such as asthma, diabetes, ulcerative colitis, multiple sclerosis, cancer, HIV and even menopause, insomnia, and stress (Bronson & Maxwell, 2004). Group medical appointments often incorporate education, counseling, and group discussion around management of patients' medical conditions (Bauer Bartley & Haney, 2010). In a group visit, patients have the added benefit of learning from one another and building self-management skills. As health care moves toward more integrated models for care delivery, the group visit model can provide a validated means for practices to improve efficiency, access, patient satisfaction, provider satisfaction and possibly health outcomes. APNs, especially DNP-prepared nurses, are perfectly positioned to initiate and lead group medical care programs in clinical practice through their clinical background and focus on evidence-based practice.

Implications for Further Research

Further study needs to be done to determine if individuals are able to maintain a WFPB diet beyond the 60 day intervention period and thus maintain the significant reduction in risk factors for cardiovascular disease. However, until long-term, randomized evaluations are completed, it remains to be seen if these improvements and the shift in cardiovascular risk can be maintained over time. Plans are in place to follow-up with this study sample at 6 months and at one year post-intervention to determine if participants were able to maintain lifestyle changes.

Further research is also needed to examine the effects of the program on other populations. Since the diversity of our study sample failed to mimic that of the larger Hampton Roads area, more research is needed to determine the effect of the program on other populations. One way investigators could accomplish this is to partner with community health workers (CHWs). CHWs are frontline public health workers who have a close understanding of the community they serve. This trusting relationship enables them to serve as a liaison between health services and the community to facilitate access to services and improve the quality and cultural competence of service delivery (Landers & Stover, 2011). Another option to increase diversity is to partner with local churches as well as community key opinion leaders. By partnering with CHWs and key opinion leaders in more remote areas, investigators could hopefully gain access to minority communities that might otherwise not participate in research.

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Tables

Table 1

Sample Characteristics at Baseline (N = 58)

Variable	Participant Data
Age (years)	
Mean (SD)	55.12 (6.29)
Range	41 – 75
	n (%)
Gender,	
Male	11(18.97)
Female	47 (81.03)
Race	
African American	7 (12.07)
Asian	1 (1.72)
Caucasian	48 (82.76)
Hispanic	2 (3.45)
Household Income (USD)	
<$25,000	2 (3.45)
$25,000 - $50,000	11 (18.97)
$50,000 - $75,000	20 (34.48)
%75,000 - $100,000	15 (31.25)
>$100,000	7 (12.07)
Did Not Respond	3 (5.17)
Education (highest degree completed)	
Graduated high school	5 (8.62)
Graduated college	47 (81.03)
Post-college degree	7 (12.07)
Marital Status	
Single	4 (6.90)
Married/Living with significant other	43 (74.14)
Divorced	8 (13.79)
Widowed	3 (5.17)
Risk Factors for CVD	
Known CVD	6 (10.34)
High blood cholesterol	33 (56.90)
High blood pressure	29 (50.00)
Diabetes	3 (5.17)
Tobacco abuse	

Yes	1 (17.24)
No	42 (72.41)
Quit	15 (25.86)

*CVD = cardiovascular disease

Table 2

Participants' BMI Classification as Defined by the CDC Before and After the Intervention

BMI Classification*	**Before the Intervention n (%) N = 58**	**After the Intervention n (% N = 58**
Healthy Weight (18.5-24.9)	5 (8.62)	12 (20.69)
Overweight (25.0-29.9)	15 (25.86)	18 (31.03)
Obesity, Class 1 (30.0-34.9)	20 (34.48)	16 (27.59)
Obesity, Class 2 (35.0-39.9)	11 (18.97)	7 (12.07)
Obesity, Class 3 (≥40.0)	7 (12.07)	5 (8.62)

*BMI = body mass index

CDC (2011)

Table 3

Change in Body Weight and Blood Pressure Before and After the Intervention (N = 58)

	Paired Differences					**T**	**df**	**Sig. (2-tailed)**
	Mean	**Standard Deviation**	**Standard Error Mean**	**95% Confidence Interval of the Difference**				
				Lower	**Upper**			***p***
Change in Body Weight	12.3103	6.2306	.8181	10.6721	13.9486	15.047	57	.000*
Change in BMI	2.0586	1.0616	.1394	1.7795	2.3378	14.768	57	.000*
Change in Systolic Blood Pressure	14.9811	16.7854	2.3057	10.3545	19.6078	6.498	52	.000*
Change in Diastolic Blood Pressure	8.4259	10.2379	1.3932	5.6315	11.2203	6.048	53	.000*

*Significant at $p < 0.05$

BMI = Body Mass Index

Table 4

Paired Samples t-test Comparing Change in Blood Cholesterol and Blood Glucose Before and After the Intervention (N = 58)

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Standard Deviation	Standard Error Mean	95% Confidence Interval				
				Lower	Upper			*p*
Change in Total Cholesterol	29.1930	24.5913	3.2572	22.6680	35.7179	8.963	56	.000*
Change in Triglycerides	-10.1579	49.3898	6.5418	-23.2628	2.9470	-1.553	56	.126*
Change in HDL	8.0877	9.0164	1.1943	5.6953	10.4801	6.772	56	.000*
Change in HDL-P	3.1614	3.6908	.4889	2.1821	4.1407	6.467	56	.000*
Change in LDL-C	17.8772	19.0170	2.5189	12.8313	22.9231	7.097	56	.000*
Change in LDL-P	139.6491	220.8122	29.2473	81.0598	198.2385	4.775	56	.000*
Change in Fasting Blood Glucose	-4.6316	9.6021	1.2718	-7.1794	-2.0838	-3.642	56	.001*
Change in HbA1c	-.0151	.2324	.0319	-.0791	.0490	-.473	52	.638*

*Significant at $p<0.05$

HDL = High density lipoprotein cholesterol

HDL-P = High density lipoprotein particle number

LDL-C = Low density lipoprotein particle concentration

LDL-P = Low density lipoprotein particle number

HbA1c = Hemoglobin A1c

Table 5

Change in Exercise Frequency and Intensity Before and After the Intervention, as Reported on the Lifestyle Evaluation Form

	Paired Differences					**T**	**df**	**Sig. (2-tailed)**
	Mean	**Std. Deviation**	**Std. Error Mean**	**95% Confidence Interval of the Difference**				
				Lower	**Upper**			
Change in Exercise Frequency	-.0678	.6660	.0867	-.2414	.1058	-.782	58	.437*
Change in Exercise Intensity	.0169	.6563	.0854	-.1541	.1880	.198	58	.843*

*Significant at $p<0.05$

Table 6

Change in Dietary Consumption of Key Nutrients Before and After the Intervention

	US Diet	**WFPB Diet Followed by Participants**
Fats and Oils	37%	<10-15%
Protein	15%	10-15%
Complex carbohydrates	25%	65-70%
Simple carbohydrates	23%	<10%
Cholesterol (mg/day)	35	<10
Sugar (tsp/day)	35	<10
Salt (g/day)	12	<5
Fiber (g/day)	12	>40

Figures

Figure 1

Outcome measures collected pre- and post-intervention.

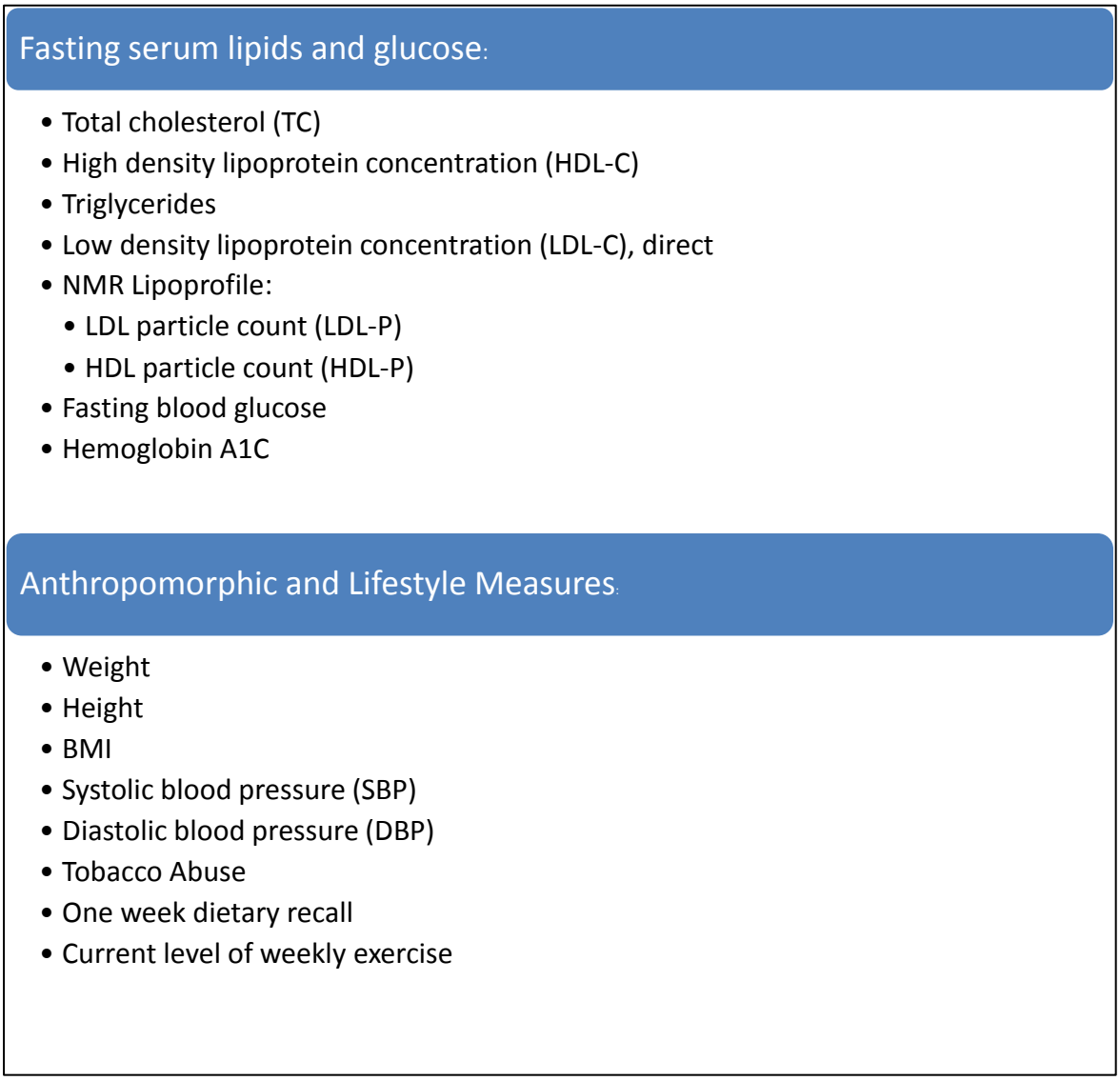
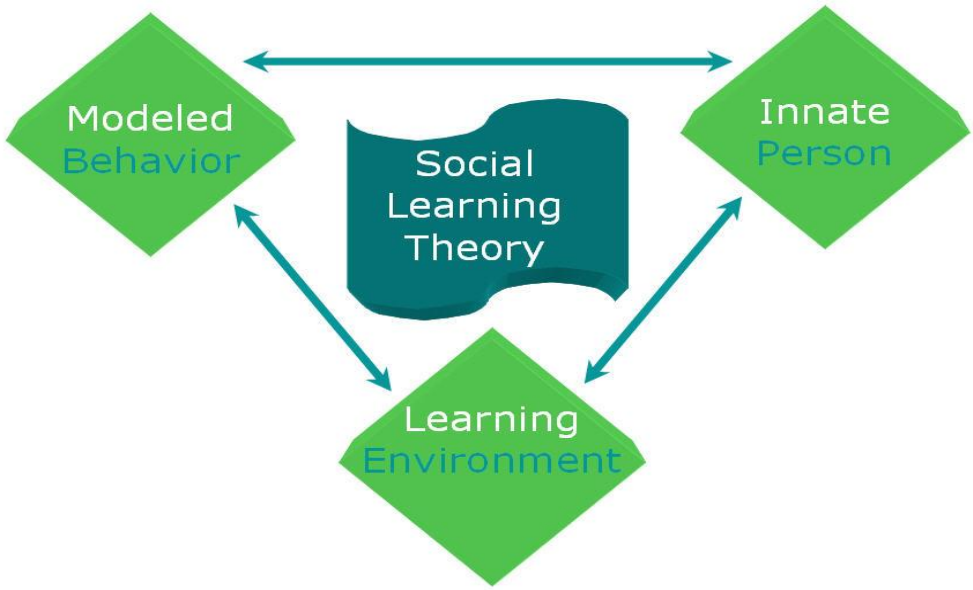


Figure 2

Conceptual Model – Bandura's Social Learning Theory



Barrett (2003)

Appendices

Appendix A – WIRB Approval Letter

Western Institutional Review Board®
3535 7th Avenue SW | Olympia, WA 98502-5010
PO Box 12029 | Olympia, WA 98508-2029
Office: (360) 252-2500 | Toll Free: (800) 562-4789
www.wirb.com

Global Leader | Proven Expert

Certificate of Approval

THE FOLLOWING WERE APPROVED

INVESTIGATOR: Deepak R. Talreja M.D.
1708 Old Donation Parkway
Virginia Beach, Virginia 23454

BOARD ACTION DATE: 08/15/2013
PANEL: 4
STUDY APPROVAL EXPIRES: 08/15/2014
STUDY NUM: 1140888
WIRB PRO NUM: 20131319
INVEST NUM: 153578
WO NUM: 1-793596-1
CONTINUING REVIEW: Annually
SITE STATUS REPORTING: Annually

SPONSOR: Cardiovascular Associates, Ltd and the University of Virginia
PROTOCOL NUM: None
AMD. PRO. NUM:
TITLE:
An InVestigAtion of Plant-BasEd, MediterrAnean, PaleolithiC, and DASH DIETs

APPROVAL INCLUDES:
Investigator
Advertisement - The VA Beach Diet Study #11131007.0 - As Submitted
Appendix B - Lifestyle Evaluation Form #11138564.0 - As Submitted
Protocol (05-06-2013)
Consent Form [S0]
Authorization to Use and Disclose PHI [S0]

WIRB APPROVAL IS GRANTED SUBJECT TO:
The Board requires that all subjects must be able to consent for themselves to be enrolled in this study. This means that you cannot enroll incapable subjects who require enrollment by consent of a legally authorized representative.

The Board directed that persons who are unable to read are not allowed to consent for themselves or others to participate in this study.

WIRB HAS APPROVED THE FOLLOWING LOCATIONS TO BE USED IN THE RESEARCH:
Cardiovascular Associates, Ltd, 1708 Old Donation Parkway, Virginia Beach, Virginia 23454
Cardiovascular Associates, Ltd, 2075 Glenn Mitchell Dr., Virginia Beach, Virginia 23456

If the PI has an obligation to use another IRB for any site listed above and has not submitted a written statement from the other IRB acknowledging WIRB's review of this research, please contact WIRB's Client Services department.

ALL WIRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

1. Conduct the research in accordance with the protocol, applicable laws and regulations, and the principles of research ethics as set forth in the Belmont Report.

2. Although a participant is not obliged to give his or her reasons for withdrawing prematurely from the clinical trial, the investigator should make a reasonable effort to ascertain the reason, while fully respecting the participant's rights.

IF YOU HAVE ANY QUESTIONS, CONTACT WIRB AT 1-800-562-4789
This is to certify that the information contained herein is true and correct as reflected in the records of the Western Institutional Review Board (WIRB), OHRP/FDA parent organization number IORG 0000432, IRB registration number IRB00000533. WE CERTIFY THAT WIRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) REGULATIONS, AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.

Full AAHRPP Accreditation

Appendix B – UVA IRB-HSR Determination of Agent Form

DETERMINATION OF UVa AGENT FORM

INFORMATION ABOUT THIS FORM

- This form is to determine if UVa personnel are or are not considered to be working as an Agent* for UVa on this project.
- If it is determined that UVa personnel are considered to be working as an Agent* for UVa the study team will be required to submit an additional submission to the IRB-HSR, unless the project is determined to not involve human subject research. See Determination of Human Subject Research Form

***Agent**- all individuals (including students) performing institutionally designated activities or exercising institutionally delegated authority or responsibility.*

Enter responses electronically. Email the completed form to IRBHSR@virginia.edu for pre-review.

An IRB staff member will reply with any changes to be made.

Name of Individual to be Working on Project:	Holly Buchanan
Email:	hab9zz@virginia.edu
Phone:	757-350-0386
UVa Messenger Mail Box #	
Project/Protocol Title if Known:	☐ Unknown or Title: The Impact of a Sixty Day Nurse-Led Lifestyle Modification Program Emphasizing a Whole Food, Plant-Based Diet on the Cardiovascular Risk Factors of Adult Volunteers. This is Arm A of a larger study entitled: An InVestigation of Plant-Based, Mediterranean, Paleolithic, and DASH DIETS.
Explain your role in the project: (200 words or less)	I am a doctoral student and the study coordinator for this project as part of my Capstone project for the Doctor of Nursing Practice degree.

Explain the reason for traveling to the outside institution.	I am recruiting participants through and working with a medical practice outside of UVA for my capstone project.

1. Answer the following questions:

☒**Yes** ☐**No** I was involved in the design of this research project.

☐**Yes** ☒**No** A UVa IRB has approved this research. IRB-HSR #

☐**Yes** ☒**No** Funding to conduct this research will come from UVa.

☒**Yes** ☐**No** The only reason I am traveling to this outside institution is to work on this research.

☒**Yes** ☐**No** Working on this research is required for my degree program.

2. I confirm that

☒**Yes** ☐**No** I am a student, employee and/or faculty member of the University of Virginia.

☒**Yes** ☐**No** My work on this project will be overseen by the Principal Investigator and the IRB at the outside institution. This includes completing any training in human subject research protection as required by the outside IRB.

☒**Yes** ☐**No** I will communicate with the IRB and the Contracts Office, to determine what approvals may be needed, prior to receiving any data from the outside institution.

OR

3. **I confirm that :**

☒Yes ☐No I designed this research **(Arm A)**

☐Yes ☒No I am a student at UVa but am employed by another institution **(No, but doing clinical rotation at Cardiovascular Associates, LTD, in Va Beach. Dr. Talreja is listed as the PI of the study as he is affiliated with Cardiovascular Associates Ltd. He is also responsible for the others arms of the study.)**

☒Yes ☐No All subjects will be enrolled at this outside institution.

☒Yes ☐No The research will be overseen by their IRB and, if applicable, their HIPAA Privacy Board. This includes completing any training in human subject research protections as required by the outside IRB.

☒Yes ☐No There is no funding for this study coming through UVa. **The practice of Cardiovascular Associates, LTD has obtained funding.**

☒Yes ☐No I have notified the outside IRB that a UVa IRB will not be overseeing my work.

ATTACH COPY OF OUTSIDE IRB APPROVAL.

FOR IRB-HSR OFFICE USE ONLY

☐ UVa personnel are not considered to be working as an Agent for UVa on this project.

No approvals from the UVa IRB-HSR are required.

☐ UVa personnel are considered to be working as an Agent for UVa on this project.

Submit a research application to the UVa IRB-HSR.

_____ _____

Signature of IRB Chair, Director or Designee Date

Appendix C – Advertising Flyer

The VA Beach Diet Study:

Researchers from Cardiovascular Associates, Ltd. and the University of Virginia are investigating a nutritional approach to managing heart disease risk.

1. Study Involvement:

Participants will be assigned to one of four diet groups:

- Whole food, plant-based diet group
- Paleolithic (hunter/gatherer) diet group
- Mediterranean diet group
- DASH Diet group

2. To participate, you should:

- Be between 35 and 85 years old
- Have one or more risk factors for heart disease:
  - High blood pressure
  - High cholesterol
  - Diabetes
  - Overweight
  - Abuse tobacco

3. All participants will receive:

- Free health screen
- Free laboratory screen
- Group support

If interested, please e-mail WFPBdietstudy@gmail.com for more information!

UNIVERSITY of VIRGINIA

CVA CARDIOVASCULAR ASSOCIATES, LTD.

Virginia Beach Office
1708 Old Donation Pkwy
Virginia Beach, VA 23454
phone: 757-419-3000
fax: 757-213-9377
WFPBdietstudy@gmail.com

Appendix D – Informed Consent Form

Protocol: DASH	**Page 55 of 75**
	APPROVED Aug 15, 2013 WIRB®

TITLE: An InVestigAtion of Plant-BasEd, MediterrAnean, PaleolithiC, and DASH DIETs

PROTOCOL NO.: None
WIRB® Protocol #20131319

SPONSOR: Cardiovascular Associates, Ltd and the University of Virginia

INVESTIGATOR: Deepak R. Talreja, M.D.
1708 Old Donation Parkway
Virginia Beach, Virginia 23454
United States

SITE(S): Cardiovascular Associates, Ltd
1708 Old Donation Parkway
Virginia Beach, Virginia 23454
United States

Cardiovascular Associates, Ltd
2075 Glenn Mitchell Dr.
Virginia Beach, Virginia 23456
United States

STUDY RELATED:

PHONE NUMBER(S): Deepak R. Talreja, M.D.
757-419-2892
757-419-3000 (24 hours)

INTRODUCTION

You are invited to participate in a clinical research study. The study doctor has determined that you meet the initial requirements for participation in this study. Before agreeing to participate in this research study, it is important that you read and understand the following information describing the purpose, procedures, benefits, risks, discomforts and precautions of the study as well as your

responsibilities as a study participant. This informed consent form also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. No guarantees or assurances can be made as to the results of the study.

You must be completely truthful with your study doctor regarding your health history, including past and present usage of both prescription and over-the-counter medications, including vitamins and herbals. If you are not completely truthful with your study doctor you may harm yourself by participating in this study.

The study is being conducted by Cardiovascular Associates, Ltd and the University of Virginia. Your study doctor's institution is being paid by the sponsor for the services it provides in conducting this clinical study.

NATURE AND PURPOSE OF THE STUDY

You are being asked to take part in this study because you have 1 or more risk factors for Cardiovascular Disease and/or you have been previously diagnosed with Cardiovascular Disease by a Cardiologist.

The purpose of this study is to determine whether Cardiovascular Disease is preventable through life style changes and diet therapy. The study will examine the effects of 4 nutritional/diet programs on participants' risk factors for heart disease. If you agree to take part in this study and meet all the requirements, you will be allowed to choose 1 of the 4 diet programs.

- **Whole-Food, Plant Based (WFPB) Diet** - Plant-based diet is a general term that refers to an eating pattern dominated by fresh or minimally processed plant foods and no consumption of meat, eggs and dairy products.
- **Mediterranean Diet** - The principal aspects of this diet include proportionally high consumption of olive oil, legumes, unrefined cereals, fruits, and vegetables, moderate to high consumption of fish, moderate consumption of dairy products (mostly as cheese and yogurt), moderate wine consumption, and low consumption of meat and meat products.
- **Paleolithic Diet** - Centered on commonly available modern foods, the "contemporary" Paleolithic diet consists mainly of fish, grass-fed pasture raised meats, eggs, vegetables, fruit, fungi, roots, and nuts. The diet excludes grains, legumes, dairy products, potatoes, refined salt, refined sugar, and processed oils.
- **DASH Diet** - The Dietary Approaches to Stop Hypertension (DASH) diet. The DASH diet emphasizes fruits, vegetables, whole grains, and low-fat dairy food as well as meat, fish, poultry, nuts and beans. The diet is limited in sugar-sweetened foods and beverages, red meat, and added fats. In addition to its effect on blood pressure.

Multiple research studies have shown that all four of the above diets are associated with reduced body weight, increased insulin sensitivity, and reduced risk for heart disease by lowering blood pressure and cholesterol. The potential benefits of these diets may be especially important for people who already have heart disease as they might slow down the progression of heart disease. Research studies have also shown that these diets are safe and that the benefits of following the diet are greater than any risks that might be involved.

EXPECTED LENGTH OF THE STUDY AND NUMBER OF PARTICIPANTS

This study will take place in Virginia Beach, VA and will include Four Parallel, Non-Randomized groups of about 100 Participants over one year.

Your participation in this study will last approximately 12 months and include a maximum of 10 office visits and approximately 9 telephone calls.

The study consists of 3 periods: Screening, Intervention and Follow up.

- Screening Period – Study Investigators will make an assessment to determine if you are eligible for participation in the study.

- Intervention Period – This is the period of the study where you will return to the clinic to meet as a group weekly for 60 days. Your food diary will be reviewed by the research staff, your questions and concerns will be addressed and you will receive moral support during your weekly visits.

- Follow-Up Period – Your study doctor will conduct another health assessment at the 60 day and 6 Month Follow-up, including a Life style Evaluation Form.

Participating in a research study can be an inconvenience in your daily life. It is very important to this type of study that your study doctor can report on your health condition at the end of the study. If you withdraw, you will be asked to allow medical information to be collected about your health at the end of the study. Please think about the study time commitments and responsibilities that will be required of you when you are deciding whether or not to participate in this study. If you are not willing to keep the planned study visits for the entire length of the study, you should not participate.

STUDY PROCEDURES

<u>Screening Period</u>

You will be asked to read and sign this consent document before any study-specific tests or procedures are performed, if you wish to participate in this study. The following tests and procedures will be performed:

- You will have a health screening to determine risk factor levels. You will be questioned about your age, gender, race, ethnicity, medical and surgical history with attention to your cardiovascular risk, your food, smoking and alcohol habits, menopausal history (females only), and your physical activity as well as previous and current medications.

- A review of instruction to follow for the diet program (Whole-Food, Plant Based Diet, Mediterranean Diet, Paleolithic Diet or DASH Diet) that you have chosen, as well as the nature and causes of Cardiovascular Disease, its risk factors, and the potential for prevention and improving through lifestyle changes. Your diet will be discussed with you, and you will have an opportunity to ask questions. **You are in the _____ Diet Program.**
- You will be given a notebook containing a food diary, guidelines for the diet program that you have chosen, along with sample meal plans, menus, recipes and additional supporting information.
- You will complete a Lifestyle Evaluation Form.
- You will be expected to keep a food diary every day for the first 2 weeks.
- Your vital signs (blood pressure and heart rate), and height, body weight and body mass index will be measured.
- Blood samples will be collected for laboratory testing after you have been fasting for at least 12 hours. Fasting blood samples are taken to measure cholesterol (total, HDL, LDL & ratios), triglycerides, fasting blood sugar as well as other risk factors and advanced metabolic testing for heart disease and diabetes mellitus.
- You should maintain the specific diet you are assigned to throughout the entire study.
- You will be encouraged and should continue to use all your routine medications during the entire study, unless otherwise directed by your own personal primary physician.
- You will be reminded of your weekly group meetings for dietary log review and moral support.

Intervention Period

The Intervention Period will begin on the Monday following your Screening Visit. During the Intervention Period, you will follow the instructions for the diet program that you have chosen. You will return to the study doctor's office every week for the entire 60 day Intervention Period. The following procedures will be performed:

- You will attend a group meeting once a week for the entire 60 day intervention period. In order to help you stick with your diet, you will be given the option to slowly transition to the diet over a period of 4 weeks.
- You will be expected to attend at least 7 out of 9 weekly meetings in order to be included in the study's data analysis. Even if you do not attend at least 7 of the group meetings, your results may still be included in the data analysis.
- At the end of each week, you will be expected to e-mail your food diary to the study physicians for review. If you do not have e-mail access, you will be expected to bring your food diary to the weekly group meeting for study doctors to review.
- After 2 two weeks, you will only have to complete a food diary 3 days a week.
- You may choose which 3 days you would like to record your food intake. In order for your data to be included in the study, you need to complete your food diaries for at least 49 of the 60 day intervention period. Even if you do not complete the food diaries for 49 days, your results may still be used in the data analysis for this study.

- At the end of the 60 Day Intervention Period, you will have another health screen. You will be questioned about your changes in your lifestyle; have your height, weight and blood pressure measured again; have your blood drawn again to check your cholesterol; and be asked about your previous and current medications as well.
- You will also complete a Lifestyle Evaluation Form.

Follow-Up Period

You will return to the study doctor's office within 6 months after you complete the 60 day intervention period. The following procedures will be performed:

- You will complete a Lifestyle Evaluation Form.
- You will be asked about your current medications.
- You will have your height, weight, and blood pressure taken by your study doctor.
- You will also have your blood drawn to recheck your cholesterol.

You will receive a telephone call within 1 year of your completion of the 60 day intervention period. The following procedures will be performed:

- You will complete a Lifestyle Evaluation Form.

Telephone Follow-Up

During the study, you will receive either a phone call or an e-mail from the study doctor's office to remind you to submit your food diary at the end of each week.

Multivitamins, Caffeine & Walnuts

During the Intervention Period of the study, you will need to do the following:

Multivitamins - You will be asked to take a daily multi-vitamin (including vitamin B-12 for participants in the Whole-Food, Plant Based (WFPB) Diet). The daily multi-vitamin will not be provided by your study doctor.

Caffeine Use - You agree to moderate your consumption of alcohol and caffeine.

Walnuts - If you are in the WFPB diet group, you will also be encouraged to include in your daily intake 1 serving of walnuts, 2 tablespoons of flaxseed meal, or 2 tablespoons of chia seeds to ensure sufficient intake of Omega 3 fatty acids. Again, this will not be provided by investigators. This is for the WFPB diet group only.

RISKS AND DISCOMFORTS

Sometimes things happen to people in research studies that may hurt them or make them feel bad. These are called risks.

Blood Draws

Since blood samples will be taken as part of this study, there are some risks involved with drawing a sample of blood. You may have pain and or bruising at the place where blood is taken. Blood clots may form and infections may occur, but these events are rare. When the needle is inserted,you may have a bruise where the blood is taken or get an infection where the blood is taken. An infection does not happen very often. If you feel faint, you should lie down right away to avoid falling down. Then, you should notify the study staff. More than 1 tube of blood may be taken at each blood draw. The amount of blood to be drawn will be approximately 45 ml throughout the study duration (about 3 tablespoons).

ALLERGIC REACTION RISKS

I agree to take full responsibility for any food allergies or intolerances I may have and understand that this involves my personal inquiry about the ingredients of any food served.

PREGNANCY

If, during this study, you become pregnant, you should notify the study doctor as soon as possible.

NEW FINDINGS

You will be told of any significant new findings with regard to your safety that may be relevant to your willingness to continue your participation in the study. If this occurs, you may be asked to sign a new consent form.

POTENTIAL BENEFITS

During this study, you may benefit from closer medical observation, reductions in elevated blood sugar levels, reduction in elevated blood pressure, lowering of total cholesterol, LDL-cholesterol, and triglycerides and an improved total cholesterol/HDL, loss of excessive weight during the 60 day program and possible reduction of medications taken for high blood pressure, blood sugar & cholesterol, and angina pain. There is no guarantee that you will experience these potential benefits.

You will be informed of any relevant findings or information found from the conduct of this study that is important to your personal medical care or situation.

UNFORESEEN RISKS

There may be other risks that are unknown at this time.

ALTERNATIVES TO PARTICIPATING IN THIS STUDY

You do not have to participate in this study to receive management for your condition. Your study doctor will discuss the risks and benefits of other treatments with you before you decide whether or not you want to participate in this study.

COMPENSATION FOR INJURY

In the event you become ill or injured as a direct result of being in this study in a way that is not described in this document, the research team will not pay for your treatment/care to treat the injury. You will not receive pay for lost wages, disability, or discomfort. You should discuss this important issue with the research staff before you sign this document. You still have the right to bring a law suit if you think you were harmed and deserve compensation.

COSTS

There will be no charge to you for your participation in this study. The study visits and study procedures will be supplied at no charge to you or your insurance company during the course of the study.

WILL I BE PAID OR COMPENSATED FOR PARTICIPATING?

You will not be paid for participating in this study.

CONFIDENTIALITY

Records of your participation in this study will be held confidential to the extent permitted by the applicable laws and regulations, and consistent with the Health Insurance Portability and Accountability Act ("HIPAA") Authorization that you will be asked to sign. Study records that identify you will be kept confidential as required by United States privacy regulations. You agree to allow Deepak Talreja, M.D., Holly Buchanan, and the study staff of Cardiovascular Associates LTD or the University of Virginia to use and disclose health information about you to conduct this study. These individuals, Cardiovascular Associates LTD, and the University of Virginia on their behalf, may also release your medical records, the consent form associated with this study, this authorization and the information about you created by this study to any of the above or their designates. In addition, the information created about you may be shared with other institutions doing this study. Other persons who may have access to your records include groups such as data and safety monitoring boards which oversee the safety of a study including accrediting agencies, and United States federal, state and local agencies having oversight over this research, for example, the United States Department of Health and Human Services (DHHS) and the University of Virginia Research Compliance staff and Institutional Review Board (IRB) members or designates. The Western Institutional Review Board® (WIRB®) is a special committee that reviews all medical research studies involving human participants.

If you sign this form, you have given us permission to release information to these other people. There is no expiration date to this permission. If you decided to withdraw your

permission and end this agreement to release the information collected about you, please contact Holly Buchanan at WFPBdietstudy@gmail.com. She will help you document in writing your decision to withdraw this permission. Please note that any information already obtained will continue to be used.

Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. There is potential that information released to Cardiovascular Associates LTD, the University of Virginia, or governmental agencies may be released again and would no longer be protected by privacy laws.

EMERGENCY CONTACT/IRB CONTACT

Your study doctor and study staff will answer any questions you may have regarding the study or the study procedures. At any time, if you have any questions, concerns or complaints regarding this research study, or in the event of a research-related injury, you may contact the study doctor at:

Deepak R. Talreja, M.D., FACC
Cardiovascular Associates, LTD
1708 Old Donation Parkway
Virginia Beach, VA 23454
757-419-2892 (office hours)
757-419-3000 (24 hours)

Holly Buchanan, DNP(c), MS, RN, ANP-BC
WFPBdietstudy@gmail.com
757-350-0386

If you have any questions about your rights as a research subject, or questions, concerns or complaints regarding this research study, you should call or write:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789 or 360-252-2500
Email: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

SUBJECT'S RESPONSIBILITIES

During the entire study, you will be asked to maintain compliance with the scheduling of the study visits, complete your diary, and undergo all study-related procedures.

I accept full responsibility for informing my physician of my participation in this nutrition program and of my test results. I will consult with my physician before making any changes in my medications. To the best of my knowledge, I have no physical or medical conditions that would be adversely affected by participating in this nutritional program. I will inform my physician should I experience any medical problems while participating in the program.

I agree to take full responsibility for any food allergies or intolerances I may have and understand that this involves my personal inquiry about the ingredients of any food served.

I understand that my test results are confidential but may be used for statistical analysis and group summaries.

If you are pregnant or think you might be pregnant, please tell us so we can talk about this with you.

If you are hurt by being in this study in a way that is not described in this document, the research team will not be able to pay for your treatment/care to treat the injury. We also have no plans to pay you for lost wages, disability, or discomfort. You should discuss this important issue with the research staff before you sign this document.

Additional testing such as blood samples may require additional unscheduled visits.

You will be asked to provide additional contact information, such as an alternate phone number, family and/or friends' contact information. These contacts will be used only in the event that the study doctor loses touch with you during the course of the study and needs to locate you to determine your health status.

At the conclusion of the study you are responsible for arranging follow-up care with your personal physician.

You may contact the local study coordinator, Holly Buchanan, at WFPBdietstudy@gmail.com.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Your participation in this study is strictly voluntary. You can also stop participating in this study at any time. Any information gathered about you before you decide to stop this study will continue to be used. If you decide to stop, no one will be angry or upset with you. No one will treat you differently if you decide not to be in this study. This means that there will be no penalty or loss of medical benefits to which you are entitled. If you choose to end your participation in this study, you must first tell the study doctor right away. This is so that a plan can be provided for your continued medical care (if needed).

It is also possible that your participation in this study may be ended at any time by the study doctor or sponsor without your consent for any reason. This might happen if:

- You do not follow the study procedures.
- You do not consent to continue in the study after being told of changes in the research that may affect you.
- In the opinion of the study doctor, it is in your best interest to stop participating in the study.
- If it is discovered that you do not meet the study requirements.
- The study doctor ends the study for any reason.

At the time of the discontinuation, before the end of the study, you will be asked to return as soon as possible to return all study related materials.

AGREEMENT/CONSENT TO PARTICIPATE IN STUDY

I have read all of the information given to me in this informed consent document. The information in this document has been explained to me and I have had the opportunity to ask questions. I have had ample of time to understand the purpose and procedures, the possible risks and benefits of the study, and the other treatments available for my condition. My signature below indicates that I voluntarily agree to participate in the study described in this document.

I have personally printed my name and personally signed and dated this form. I will receive a copy of this signed consent.

_____

Subject's Name (printed)

_____ _____

Subject's Signature Date

To the best of my knowledge, the subject signing this consent form has had the study fully and carefully explained by me and/or a qualified member of the study staff and the subject has been given the opportunity to ask questions regarding the contents of this consent form and his/her participation in this research study.

_____

Printed Name of Person Conducting Informed Consent Discussion

Signature of Person Obtaining Consent Date Time

Printed Name of Witness

Signature of Witness Date

Printed Name of Study Doctor *(if different from above)*

Signature of Person Study Doctor Date

CONSENT FOR SUBJECTS WHO CANNOT READ

The study subject has indicated that he/she is unable to read. The consent document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

Signature of Impartial Witness

Printed Name of Impartial Witness Date

Appendix E – Lifestyle Evaluation Form

LIFESTYLE EVALUATION FORM

Please Print Carefully

_____ _____

Last Name *First Name* *Middle Initial* *Today's Date*

_____

Street Address *City* *ZIP*

_____

Daytime phone# *Evening phone#* *Physician*

Age:_____ □ Male □ Female MARITAL STATUS: □ Single □Married □Divorced □Widowed

Occupation: _____ Highest Education Level:_____

Race: _____ Annual Income: □ <$25,000 □ $25,000 - $50,000
□ $50,000-$75,000 □ $75,000 - $100,000
□ >$100,000

Did you eat or drink anything (but water) during the last 10 hours? ❑ Yes ❑ No

One or both parents died before age 60: of Heart Disease? ❑ Yes ❑ No of Diabetes? ❑ Yes ❑ No

Check (X) if you have ever been told by a physician that you have any of the following:

❑ Angina (yr?___)	❑ Abnormal EKG (last 3 yrs)	❑ Gallbladder disease	❑ Osteoporosis
❑ Heart attack (yr?_____)	❑ Irregular heartbeats	❑ Gout	❑ Osteoarthritis
❑ Angioplasty (yr?_____)	❑ Stroke (yr?_____)	❑ Kidney disease	❑ Rheum. arthritis
❑ Bypass (yr?___)	❑ High blood pressure	❑ Heart failure (yr?____)	❑ High cholesterol
❑ Blood clotting problem	❑ High triglycerides	❑ Diabetes	❑ Overweight
❑ Ulcers	❑ Bronchitis/Emphysema	❑ Thyroid disorder	❑ Cancer: Type ___

List all Medications and Supplements you are presently taking on separate **Medication Form**.
❑ **I take none**

Please fill in the number of servings you eat or drink WEEKLY. If you don't use, then mark "0." Fill in every space, please.

MEAT OR SHELLFISH _____
FOWL OR FISH _____
WHOLE MILK OR 2% _____
COTTAGE CHEESE _____
BUTTER OR CREAM _____
CHEESE _____
SOUR CREAM _____
ICE CREAM _____
YOGURT _____
LIVER/ORGAN MEATS _____

SAUSAGE/HOTDOGS _____
EGGS _____
FRIED FOODS _____
SALTY SNACKS _____
SALAD DRESSINGS _____
MAYONNAISE _____
MARGARINE _____
GRAVIES _____
SOYMEAT/GLUTEN _____
SOY MILK _____

WATER _____
ALCOHOL _____
COFFEE/TEA _____
SOFT DRINKS _____
CANDY OR SUGAR _____
SUGARY DESSERTS _____
HONEY OR SYRUPS
JAM/JELLY _____

EXERCISE

- ❑ None
- ❑ 2-3 days/week
- ❑ 3-5 days/week
- ❑ 4-6 days/week

Type of Exercise:

□ Mild □ Moderate □ Virgorous

SMOKING STATUS

- ❑ Non-smoker
- ❑ Ex-smoker
  Year Quit_____# Years Smoked____
  # Packs per Day_____
- ❑ Smoker:
  Years smoked:_____ # Packs per Day_____

FOR OFFICE USE ONLY:

Height:_____ Weight:_____ BMI:_____kg/m^2 Blood pressure___/_____mmHg

BMI: ❑ Underweight (<18.50) ❑ Normal Weight (18.5-24.99) ❑ Overweight (≥25.00) ❑ Obese (≥30.00)

RESULTS of blood test

_____Glucose, Fasting (mg/dL)

_____Total Cholesterol (mg/dL)
_____LDL Cholesterol (mg/dL)
_____LDL Particle (nmole/L)
_____HDL Cholesterol (mg/dL)
_____Triglycerides (mg/dL)
_____Cholesterol ratio

TOTAL CHOLESTEROL

- ❑ Ideal (<200 mg/dL)
- ❑ Borderline high (200-239 mg/dL)
- ❑ High (>240 mg/dL)

LDL CHOLESTEROL

- ❑ Optimal (<100 mg/dL)
- ❑ Near optimal/Above optimal (100-129 mg/dL)
- ❑ Borderline High (130-159 mg/dL)
- ❑ High (160-189 mg/dL)
- ❑ Very High (>190 mg/dL)

TRIGLYCERIDES

- ❑ Normal (<150 mg/dL)
- ❑ Borderline High (150-199 mg/dL)
- ❑ High (200-499 mg/dL)
- ❑ Very High (>500 mg/dL)

LIFESTYLE EVALUATION FORM

MEDICATION FORM

Please list: first, the prescription drugs, then, the over-the-counter drugs

		Health Screen #1 Date:				*Health Screen* #2 Date:		
#	Name of Medication	Dose mg/gm	Times a day	Daily dose	Reason for Taking	Dose mg/gm	Times a day	Daily dose
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								

Appendix F – Diet Transition Instructions

Week 1 – Eat as many colors from the rainbow as you can on a daily basis: greens, reds, oranges, yellows, and blues. This first week focus on trying to eliminate all dairy products (milk, cheese, yogurt, butter, etc.) as well as processed and refined foods (white bread/pasta/rice/flour, chips, sodas, etc.).

Week 2 – Continue to eat from the rainbow on a daily basis and include whole, unprocessed grains. This week focus on eliminating all meat (anything that flaps a wing, wiggles a fin, paws a hoof, and closes a clam). If it has a face and/or a mother, then it's not on the table!

Week 3 – Continue to eat from the rainbow on a daily basis and include whole, unprocessed grains. This week focus on eliminating all added cooking oils (even olive oil), nuts/seeds (except for one serving daily of walnuts, flax seed meal, or chia seeds), and nut butters.

Week 4 – Continue to follow a low-fat, plant-based, whole food diet and remember to eat as many colors from the rainbow as you can on a daily basis: greens, reds, oranges, yellows, and blues. Include whole, unprocessed grains in your meal plan as well.

Appendix G – Capstone Manuscript for Publication

The Impact of a Sixty Day Nurse-Led Lifestyle Modification Program Emphasizing a Whole Food, Plant-Based Diet on the Cardiovascular Risk Factors of Adult Volunteers

*Holly Buchanan, Ishan Williams, Dorothy Tullmann, Viola Holmes, and Deepak Talreja

Author Note:

*Holly Buchanan, DNP, MS, RN, ANP-BC, DNP Student, University of Virginia School of Nursing, Charlottesville, VA.

Ishan Williams, PhD, Assistant Professor of Nursing, University of Virginia School of Nursing, Charlottesville, VA; Roberts Scholar, Department of Family, Community & Mental Health Systems

Dorothy Tullmann, PhD, RN, Assistant Professor of Nursing, University of Virginia School of Nursing, Charlottesville, VA; Director of the Master of Science in Nursing and Doctor of Nursing Practice Programs, Department of Acute & Specialty Care

Viola Holmes, MS, RD, CDE, University of Virginia Health Systems, Charlottesville, VA.

Deepak Talreja, MD, FACC, Cardiovascular Associates, Ltd., Virginia Beach, VA

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Correspondence concerning this article should be addressed to Holly Buchanan, 527 Hampton Place, Portsmouth, VA 23704. Email: hab9zz@virginia.edu. Phone: (757) 350-0386

Word Count: 4626 Tables: 6

Abstract

Background: Cardiovascular disease (CVD) is the leading cause of death in the United States for middle-aged (45-64 years) men and women. Fortunately, CVD is largely preventable by modifying risk factors through lifestyle change. One such lifestyle change is the adoption of a whole foods plant-based (WFPB) diet.

Objective: The purpose of this study was to examine the effects of a nurse-led, sixty day dietary program emphasizing a low fat, WFPB diet on the cardiovascular risk factors of adult participants in the Hampton Roads area of VA.

Methods: A quasi-experimental pre/post-test, single group design, was used to examine the effect of a weekly nurse-led lifestyle intervention program emphasizing a whole food, plant-based diet on the CVD risk factors of adult participants.

Results: Participants significantly reduced body weight, total cholesterol, LDL-C cholesterol, LDL-P count, and systolic and diastolic blood pressures ($p<0.001$). There was a significant ($p<0.001$) *increase* in fasting blood glucose before and after the 60 day intervention period and a non-significant ($p = 0.126$) increase in triglycerides. As for HbA1C, there was no significant change before and after the intervention.

Conclusions: Well-designed, nurse-led WFPB intervention programs can improve lifestyle choices and health habits. They can also markedly and rather quickly reduce the level of cardiovascular risk factors in a non-randomized population.

Key words: vegetarian diet, vegan diet, cholesterol, diet

Introduction

One of the greatest health threats that Americans face today is cardiovascular disease (CVD). According to the American Heart Association (AHA), heart disease is the leading cause of death in the United States for both men and women (Roger et al., 2012). In 2007, one-quarter of all deaths (616,000) were from diseases of the heart (National Center for Health Statistics [NCHS], 2011). The majority (81%) of heart disease deaths were among people 65 years of age and over; however, disease prevalence can be found among people of all ages and backgrounds (NCHS, 2011). In fact, approximately 150,000 Americans killed by CVD in 2008 were less than 65 years of age.

Not only is heart disease a threat to America's health, it is also a threat to the economy. In 2010, heart disease will have cost the United States $316.4 billion, including the cost of health care services, medications, and lost productivity (Roger et al., 2012). The aging population, obesity epidemic, underuse of prevention strategies, and suboptimal control of risk factors will most likely exacerbate the economic burden of CVD on future generations of Americans (Roger et al., 2012). One of the best ways to combat the economic threat of CVD is to increase adherence to national and community-level guidelines and renew an emphasis on the policy, environmental, and lifestyle changes necessary for its effective prevention and control (Mensah & Brown, 2007).

Unfortunately, Americans as a whole are continuing to experience deteriorating quality of life and a rising incidence of risk factors for CVD. According to a report from the U. S. Department of Health and Human Services (USDHHS) on health statistics from the 2009 National Health Interview Survey (NHIS), 55% of adults had never participated in any type of vigorous leisure-time physical activity, and 17% of adults did not have a usual place of health

care (Pleis, Ward, & Lucas, 2010). Twelve percent of adults had been told by a doctor or health professional that they had heart disease, 24% had been told on two or more visits that they had hypertension, and 3% had been told they had experienced a stroke. Twenty-one percent of all adults were current smokers, and 21% were former smokers. Based on estimates of body mass index, 35% of adults were overweight, and 27% were obese (Pleis, Ward, & Lucas, 2010).

Fortunately, prevention and control of heart disease is largely achievable by modifying risk factors. The leading risk factors for heart disease include high blood pressure, high blood cholesterol, diabetes, diet high in saturated fat, physical inactivity, obesity, and tobacco abuse (Roger et al., 2012). It is critical to address all these risk factors early in life to prevent the potentially devastating complications of chronic CVD (USDHHS, 2011). All of these risk factors can be reversed and even prevented by making lifestyle changes that improve health habits. One such lifestyle change is the adoption of a low-fat, whole food, plant-based (WFPB) diet. This one lifestyle change alone can prevent the majority of the risk factors that lead to heart disease (Barnard et al., 2006; Ornish, 2009; Hooper et al., 2011).

Methods

The purpose of this study was to examine the effects of a nurse-led, sixty day dietary program emphasizing a low fat, WFPB diet on the cardiovascular risk factors of adult participants in the Hampton Roads area of VA. This study used a non-randomized quasi-experimental pre/post-test, single group design, to examine the effect of the dietary program on the CVD risk factors of adult participants. Risk factors for CVD are defined as those listed by the NHLBI: high total blood cholesterol, high LDL cholesterol, high blood pressure, diabetes, smoking, and being overweight (NHLBI, 2012). To establish the risk factor profile for study participants, U.S. reference values were used for all variables.

Description of the Sample

The sample size sought for this study was calculated a priori using G*Power (Faul, 2013) and was based on anticipated LDL reductions of 20% and standard deviations provided in the literature (Faul et al., 2007; Ferdowsian et al., 2010; Barnard et al., 2006). Using these parameters, it was calculated that a sample size of 34 would provide a minimum 80% power to detect a difference between the pre-test and post-test results using a two-tailed *t* test with significance level of 0.05.

Inclusion criteria. Eligible participants were defined as:

- adults, between 35 and 85 years of age,
- having one or more risk factors for CVD as defined by the NHLBI, and/or previously diagnosed with CVD by a cardiologist,
- able to read and fill out questionnaires in English,
- and able to speak English.

Because social support is critical in achieving and adhering to the recommended lifestyle, investigators encouraged spouses and family members to attend the plant-based diet educational session and the weekly group meetings with participants.

Exclusion criteria. Participants were excluded if they:

- were younger than 35 years of age or older than 85 years of age,
- were non-English speaking,
- had plans to join another organized weight loss or exercise program,
- were pregnant,
- were medically unstable, defined as adults whose health impairment was severe enough to require prolonged dependency on medical care or technology and required intense

nursing services at home in order to maintain health and well-being; the health impairment was characterized by periods of acute exacerbation or potentially life-threatening episodes that required frequent hospitalizations or prolonged recuperation periods at home (American Hospital Association, 2003),

- were currently taking prescription medications for Type 1 or Type 2 diabetes mellitus,
- or already followed a low-fat vegetarian diet.

Procedures and Intervention

Following IRB approval, participants were recruited directly from Cardiovascular Associates, Ltd. (CVAL), through promotional flyers posted in the office as well by direct recruitment by CVAL providers. Also, during the recruitment period the principal investigator spoke weekly at healthy eating seminars conducted at the Whole Foods Market grocery store in Virginia Beach, VA, allowing for direct recruitment of participants through these seminars. These healthy eating seminars were co-sponsored by CVAL and Whole Foods Market. Participants were also recruited through promotional flyers that were posted on bulletin boards in restaurants, coffee shops, and YMCA's in the cities of Portsmouth and Norfolk, VA. Newspaper and television advertising was used as well. A study e-mail address was also created so that interested health care providers and potential participants could directly contact study investigators with questions or concerns and obtain more information about the study.

Following the recruitment period, interested participants underwent an initial screening via e-mail or telephone by the APN in order to confirm eligibility. Once eligible, participants were invited to attend a one day health screen and information session in order to be enrolled in the study. This initial health screen consisted of a comprehensive health screen to establish risk factors and collect outcome measures for each participant as well as an educational session

outlining study details and providing information on how to follow a low-fat WFPB diet. This health screen also included a review of current medications and a fasting laboratory evaluation. The educational session emphasized the nature and etiology of CVD, its epidemiology and its risk factors, and the potential for prevention, arrest, and reversal through the adoption of a plant-based diet. Participants were instructed to have nothing to eat or drink, except water, for at least 12 hours prior to the start of the health screen.

Upon arrival at the health screen, participants were provided with their participant notebook and asked to read and sign the Informed Consent. Participants then completed the lifestyle evaluation and met with one of the investigators to have height, weight, and blood pressure measured as well as for review of their lifestyle form and current medications. Participants then had blood drawn and collected by a licensed phlebotomist via venipuncture. Once all participants had completed the health screen portion, the nutritional lecture was given by the advanced practice nurse (APN).

The nutritional lecture instructed participants on the rules and expectations of the study as well as provided information on how to follow a low-fat WFPB diet and how a WFPB diet can prevent, arrest, and reverse heart disease. Participants were also reminded that they were required to take a daily multivitamin to ensure adequate intake of vitamin B-12 since a low-fat WFPB diet is typically deficient in vitamin B-12. Participants were informed that a daily multi-vitamin would not be provided by investigators and adherence would only be measured by participant report. They were also asked, but not required, to moderate their consumption of alcohol and caffeine. Participants were also encouraged to include in their daily diet one serving of walnuts, two tablespoons of flaxseed meal, or two tablespoons of chia seeds to ensure sufficient intake of Omega 3 fatty acids. Again, participants were reminded that this would not be provided by

investigators and adherence would only be measured by patient report in food diaries. Following the lecture, participants were given the opportunity to have any questions or concerns answered and addressed.

The prescribed diet that participants were asked to adhere to was a low-fat WFPB diet that derived less than 10% of its calories from fat. Participants were instructed to avoid all oils, meat, fish, fowl, all processed foods, and dairy products. Grains, legumes, lentils, vegetables, and fruit comprised the major portion of the diet. In order to increase adherence, patients were given the option to slowly transition to the diet over a period of four weeks. The Transition Instruction form was provided to participants in the study notebook given to each participant at the initial health screen. The notebook also contained a section to record their food diaries, a list of fat-free recipes taken from cookbooks and other resources that focus on plant-based nutrition, a sample 30 day meal plan, and additional resources on how to successfully follow a low-fat, WFPB diet including strategies for eating out and celebrating with friends and family.

Once the intervention period began, participants kept daily food diaries for the first two weeks. After the initial two weeks, participants then completed food diaries only three days per week (participants were able to choose which days) for the remaining six weeks. As part of the intervention, participants were also expected to meet as a group once weekly for eight weeks for an educational lecture, to review food diaries with the APN, have any questions answered, and receive moral support from the APN and fellow group members.

At the end of the sixty day intervention, a second comprehensive health screen was conducted to measure the changes in lifestyle, clinical outcomes, and medications over the sixty day intervention period. Study outcome measures were again collected and the lifestyle evaluation and current medications form was again completed by participants. This data was then

compared and analyzed to determine the effect of the program on clinical outcome measures and lifestyle measures.

Data Analysis

All data were entered and analyzed using Microsoft Excel 2010 and IBM SPSS Statistics (version 22, 2013, IBM, Chicago, IL). Demographic data, including race, education level, and income level, were reported as percentages with the exception of age. Age was reported as range and mean age by gender plus or minus one standard deviation. Changes in the outcome measures (fasting lipids, fasting glucose, and anthropometric measures) from baseline to 60 days were analyzed using a paired-samples *t* test. Participants were considered completers if they attended at least 75% (six of eight) of the weekly group meetings and submitted food diaries for at least 75% (six of eight weeks) of the intervention period. Significance was accepted at $p<0.05$.

Results

During the recruitment period, a total of 78 participants were screened and cleared for participation in the first health screen. Of those 78 potential participants, 63 (80.8%) actually enrolled and completed the initial health screen and were enrolled in the study. Recidivism for this study was low: of the 63 participants who were initially enrolled, only five (7.9%) participants failed to complete the study. The final number of program participants who were considered "completers" (attended at least six of eight [75%] of weekly group meetings, completed food diaries for at least six of eight weeks, and attended the second health screen) was 58. Of the five participants who did not complete the study, three failed to attend at least six of eight weekly group meetings and two failed to attend the second health screen. The following data were collected from September 2013 to January 2014 for the 58 study participants who were considered "completers".

Demographics

The following results reported relate to data collected from the 58 participants considered "completers". The participants' ages ranged from 41 to 75 years, with a mean of 55.12 ± 6.29 (Table 1). Forty-seven participants were female (81.03%) and 11 were male (18.97%). The majority of the participants were Caucasian (82.76%, n = 48) and married (74.14%, n = 43). Most participants had attended college (81.03%, n = 47) and had an annual household income greater than $50,000 (72.41%, n = 42). Complete sample characteristics can be found in Table 1.

Disease Categories and Risk Factor Changes

The primary outcome variables for this study included the following cardiovascular disease risk factors: being overweight, elevated blood cholesterol, elevated blood pressure, diabetes, and tobacco abuse. The risk factor of current tobacco abuse will not be further discussed, since tobacco abuse was not a focus of this study. Participants were strongly encouraged to cease and/or avoid the abuse of tobacco; however, no further testing or intervention was applied to this risk factor.

Initial Cardiovascular Risk Factor Presentation

At the start of the study, comorbidities of the participants included one (17.24%) with current tobacco abuse, 29 (50.0%) with high blood pressure, 33 (56.90%) with high cholesterol and 53 with being overweight (91.38%). Since participants currently taking medication for diabetes were excluded from the study, this risk factor was absent in this sample with one exception: three participants reported having a medical diagnosis of diabetes, but were not taking any prescription medication for diabetes during the time of the study. According to each participants' BMI as measured at the initial health screen, 53 (91.38%) were overweight and/or obese. All of the participants in the study fell under the following classifications, according to

the CDC's definition and classification of obesity (NHLBI, 2012): 15 (25.86%) participants were classified as being overweight, 20 (34.48%) were categorized as having class 1 obesity, 11 (18.97%) fell under class II, and seven (12.07%) fell under class III (Table 2).

Changes in Bodyweight

A paired samples *t*-test was conducted to compare changes in body weight before and after the 60 day intervention period (Table 3). There was a significant ($p<0.001$) difference in body weight before (M = 196.1 lbs) and after (M = 183.8 lbs) the 60 day intervention period. On average, the 58 participants who completed the 60 day intervention period lost 12.31 pounds, for an average individual percent weight loss of 6.47%.

As far as each participants' BMI classification as defined by the CDC, four (6.90%) participants moved from the overweight to the healthy weight category; eight (13.79%) participants moved from class I obesity to overweight; six (10.34%) participants dropped from class II obesity to class I obesity; and two (3.45%) participants dropped from class III (severe obesity) to class II obesity (Table 2).

Blood Cholesterol and Triglycerides

A paired samples *t* test was conducted to evaluate whether a WFPB diet could lower participants' cholesterol and thus lower their risk for cardiovascular disease. The test was run on the following variables: total cholesterol, triglycerides, direct HDL-C, direct LDL-C, and LDL particle count (LDL-P).

For total cholesterol, there was a significant ($p<0.01$) difference before and after the 60 day intervention period. Triglycerides, however, did not decrease significantly over the 60 day intervention period as expected. On the contrary, triglyceride levels actually increased. The mean triglyceride level for participants at the start of the study was 113.95 mg/dL and the mean level

after the intervention period was 124.11 mg/dL However, this upward change in triglycerides was not found to be significant ($p = 0.126$). Also contrary to what was predicted in the study hypothesis, HDL-C levels *decreased* over the course of the intervention period. Unlike the change in triglycerides, this decrease was statistically significant ($p<0.01$). The HDL particle count (HDL-P) also decreased significantly during the intervention period (Table 4).

As the cholesterol marker most associated with cardiovascular disease, investigators were highly interested in mean change in LDL-C before and after the intervention. For direct LDL-C, there was indeed a significant ($p<0.01$) decrease in LDL-C before (M = 123.28 mg/dL,) and after (M = 105.40 mg/dL,) the participants initiated a WFPB diet. The average drop in LDL-C for participants after the intervention was 18.5 mg/dL, representing a 14.10% reduction in LDL-C. Another LDL marker tested was the LDL particle count (LDL-P). For this study sample, there was a significant ($p>0.01$) decrease in LDL-P after the 60 day intervention with a WFPB diet. The mean LDL-P count prior to the intervention was 1301.19 nmol/L. Following the intervention, the mean LDL-P count dropped to 1161.54 nmol/L.

Systolic and Diastolic Blood Pressures

At the start of the study, 32 (50.8%) of the participants indicated a history of high blood pressure on their Lifestyle Evaluation Form. The mean systolic blood pressure (SPB) for participants at the start of the study was 137.74 mm Hg . The mean diastolic blood pressure (DBP) was 79.52. Both SBP and DBP decreased significantly ($p<0.001$) after the 60 day intervention period. The mean SBP dropped to 122.76 mm Hg and the mean DBP dropped to 71.09 mm Hg. This represents a mean decrease in SDP and DBP of 14.98 and 9.50 mm of Hg, respectively. The most recent Joint National Committee (JNC) guidelines released in 2014

recommend lowering blood pressure to less than 140/90 mm Hg, which was achieved for 18 participants (31.03%) during the 60 day intervention period (James, et al., 2014).

Diabetes

Results from the initial health screen revealed that 10 (15.87%) of the 63 study participants had a fasting blood glucose greater than 100 mg/dL, while two of those 10 participants had a fasting blood glucose of greater than 126 mg/dL, meeting the criteria for a diagnosis of diabetes (ADA, 2012). There was a significant ($p<0.01$) *increase* in fasting blood glucose (M = 92.21 mg/dL) before and after (M = 96.84 mg/dL) the 60 day intervention period. Similarly to triglycerides, this change was not expected as indicated by the study hypothesis. As for HbA1C, there was no significant change before and after the intervention (Table 4).

Exercise Frequency and Intensity

While exercise was not promoted by investigators, exercise frequency and intensity was self-reported by participants on the lifestyle evaluation form completed before and after the 60 day intervention. It is important to note that there were no significant differences in reported exercise frequency ($p=0. .437$) and/or exercise intensity ($p=0. .843$) before and after the intervention (Table 5).

Discussion

Therapeutic lifestyle change can result in significant improvements in nutrition as well as in reductions in many cardiovascular disease risk factors. This has been well demonstrated in the literature in both short and long-term interventions (Artinian et al., 2010; Barnard, Cohen, et al., 2009; Bloomer et al., 2010; Chainani-Wu et al., 2011, Ferdowsian et al., 2010; Fontana et al., 2007; Govil et al., 2009; Marshall, Walizer, & Vernalis, 2009; Ornish et al., 1999; & Stevens, Glasgow, Toobert, Karanja, & Smith, 2003). As for this particular study, the majority of

participants demonstrated dramatic improvements in nutrition by the end of the 60 day intervention (see Table 6).

At the beginning of the study, 43 (68.3%) of participants had two or more risk factors for cardiovascular disease with being overweight, having high cholesterol and high blood pressure as the most prevalent. At the post-intervention health screen, 17 participants (29.31%) lowered their LDL-C cholesterol by 20%, all participants (100%) lost weight with the mean overall weight loss being 12.31 lbs, and the group's mean SBP dropped 14.98 mm Hg allowing for 18 participants (31.03%) to move from a hypertensive blood pressure reading (>140/90 mm Hg) at the first health screen to a normotensive reading at the final health screen. On average, the net reduction in LDL-C for all participants was 18.5 mg/dL (14.10%). Total cholesterol dropped 28.6 mg/dL (0.21%) on average for participants as well. Participants also reduced their LDL-P counts by 147.6 nmol/L – an 11.3% reduction. While the 2013 AHA/ACC Guideline on the Treatment of Blood Cholesterol does not yet have recommendations regarding LDL-P (Stone et al., 2013), there is emerging evidence that LDL-P is a much more accurate predictor of cardiovascular disease than either LDL or total cholesterol (Cromwell et al., 2007; Garshick, Mochari-Greenberger, & Mosca, 2013; Prado, Shugg, & Backstrand, 2011). However, more research is needed in this area.

Lower blood pressure, improved blood lipids, and improved cardiac function are directly linked to reduced risk of cardiovascular disease. For every 1% drop in total cholesterol, the coronary risk drops by 2% to 3%; and for every 1 mm Hg drop in elevated diastolic blood pressure, there is another 2% to 3% drop in coronary risk (Manson et al., 1992). Interventions with high cholesterol patients using the National Cholesterol Education Program's step 1 and step 2 dietary interventions reported, on average, total cholesterol reductions of 10% and

13%, respectively (Yu-Poth et al., 1999). The PREMIER Clinical trial used a 6-month comprehensive lifestyle modification trial to reduce blood pressure (Appel et al., 2003). Hypertension prevalence at baseline and 6 months in this study was 38% and 12%, respectively, providing further support that change in nutrition and physical activity can directly impact blood pressure, especially among those who are hypertensive. Medication monitoring revealed that three program participants reduced their blood pressure medication during the intervention, suggesting that the program could have produced reductions in blood pressure greater than what was measured.

Group Setting

The group setting for each of the sessions provided strong social support and may have contributed to the low drop-out rate of 7.9%. It cannot be specified to what extent social support may have played a role in effecting the outcomes of the intervention. However, this assumption was supported by two research articles that assert that togetherness, peer reinforcement and encouragement strengthen the adherence of interventional trials (Boutin-Foster, 2005; Williamson & Stewart, 2005). This social support was evident in the interactive portion of the educational curriculum. Even though small in number, participants became a critical mass in the community that began to look for healthier food items in the supermarkets and for healthier menus in the restaurants.

Unexpected Results

Despite the positive benefits associated with a low-at WFPB diet, much clinical debate exists of how far dietary change should be pushed to provide effective public health and clinical benefit (Connor et al., 1997). Previous reports by the Nutrition Committee of the American Heart Association acknowledged the value of very low fat diets for the reduction of cardiovascular risk

and the regression of CAD. The authors concluded, however, that ‘‘numerous unanswered questions remain that make population-wide recommendations of such diets premature’’ (Lichtenstein & VanHorn, 1998). Two major concerns cited focused on the triglyceride-raising and HDL-lowering effect of a very low fat/high complex carbohydrate diet, especially in the short-term.

The fact that carbohydrate-rich diets often increase plasma triglycerides has led some to question the wisdom of such diets. There is growing reason to suspect that the increased coronary risk associated with elevated triglycerides in Western epidemiology reflects the fact that high triglycerides are a marker for insulin resistance syndrome, rather than any inherent pathogenic role of triglycerides (McCarty, 2004). Triglyceride levels are relatively high in certain Third World societies which are virtually immune to coronary disease so long as they persist in their traditional very-low-fat diets (McCarty, 2004). In Ornish's low-fat plant-based diet study (Chainani-Wu et al., 2011), a moderate rise in triglycerides coincided with a marked reduction in coronary events. Although the particle size of both LDL and HDL tends to decrease when triglyceride levels are high, it is questionable whether this effect has a major pathogenic impact (McCarty, 2004). The one clear drawback of high-carbohydrate diets is a decrease in HDL particle number. This effect is seen whether or not triglycerides increase. Since exercise training has been associated with increased concentrations of HDL-C (Lloyd-Jones et al., 2010), it is important to note that there were no significant differences in reported exercise frequency and/or exercise intensity before and after the intervention (Table 5).

The favorable effects of a low-fat, WFPB diet on LDL cholesterol, insulin sensitivity, and body weight appear to more than compensate for this decrease in HDL (Barnard, Cohen, et al., 2009; Bloomer et al., 2010; Chainani-Wu et al., 2011, Ferdowsian et al., 2010; Fontana et al.,

2007; Govil et al., 2009; and Marshall, Walizer, & Vernalis, 2009). It is also worth noting that HDL levels tend to be quite low in Third World cultures at minimal risk for coronary disease (McCarty, 2004). The tendency of high-carbohydrate diets to boost triglycerides can be minimized by exercise training, supplemental fish oil, an emphasis on fiber-rich, low-glycemic-index whole foods, as well as the weight loss that is often seen with the consumption of such diets (McCarty, 2004).

Study Strengths and Limitations

Ideally, individuals who participate in lifestyle interventions would adopt and maintain healthful behaviors for life. In reality, once the lifestyle interventions are completed, many individuals eventually fail to completely embrace new lifestyle habits and revert to pretreatment behavior (Ornish, 2009). The short-term nature of this study sheds little light on long-term adherence, but it does allow for an accurate assessment of the acute benefit of the intervention. The main improvements in nutrition and cardiovascular risk reported in this study are not completely unexpected. The participants were mostly white and sufficiently self-motivated to volunteer to participate in the intervention. On average, participants were also slightly more educated than the Hampton Roads community at large. Participants had lifestyles that permitted them to attend most, if not all, of the classes. This is evident in the high rate of attendance to this time-intensive program. These limitations threaten the generalizability of these findings and make application of the intervention to other populations problematic.

Other factors may explain the impact of this program. In the intervention, participants attended highly interactive weekly group meetings that included an educational lecture on a different topic each week by the APN as well as ample time for social interaction and group discussions. Testimonials, role playing, short presentations from physicians, social support

strategies, food selection and planning activities, and other behavior-change-driven activities all helped to encourage participants to willingly evaluate personal behaviors and commit to make the recommended dietary changes.

Another limitation of the study was the small sample size. An *a priori* power analysis estimated that a sample size of 34 would provide a minimum 80% power to detect a difference between the pre-test and post-test results using a two-tailed *t* test with significance level of 0.05. Even though the sample size after attrition was greater than 34 (n=58), it cannot be inferred that the effect size in the sample would be equal to the effect size in the population at large.

Other limitations include the lack of control group and the short-term of the intervention period. Although these improvements in the cardiovascular risk factors of participants were significant, causality and long-term effectiveness cannot be demonstrated without evaluating the program in a randomized controlled trial.

Conclusion

The outcomes of this intervention have added to the body of knowledge on the potential impact of a WFPB diet on cardiovascular disease risk factors. This study also demonstrated that an APN–led intervention can effectively achieve cardiovascular disease risk reduction for participants through intensive dietary education and support. APNs are able to use strategies of risk reduction, illness prevention, health promotion, and health maintenance to improve the care of individuals, families, and populations. Carefully planned group-based lifestyle modification programs may represent an important effort to help reduce the economic burden of chronic disease. The potential success of group-based lifestyle modification programs and their emphasis on lifestyle changes through education, understanding, skill acquisition and mutual support could be potentially important in effecting health in the community at large. APNs are perfectly

positioned to improve adherence to guidelines by leading patients to make more comprehensive lifestyle changes, including following a WFPB diet.

Implications for Further Research

Further study needs to be done to determine if individuals are able to maintain a WFPB diet beyond the 60 day intervention period and thus maintain the significant reduction in risk factors for cardiovascular disease. However, until long-term, randomized evaluations are completed, it remains to be seen if these improvements and the shift in cardiovascular risk can be maintained over time. Plans are in place to follow-up with this study sample at 6 months and at one year post-intervention to determine if participants were able to maintain lifestyle changes. Further research is also needed to examine the effects of the program on other populations. Since the diversity of our study sample failed to mimic that of the larger Hampton Roads area, more research is needed to determine the effect of the program on other populations.

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Tables

Table 1

Sample Characteristics at Baseline (N = 58)

Variable	Participant Data
Age (years)	
Mean (SD)	55.12 (6.29)
Range	41 – 75
	n (%)
Gender,	
Male	11(18.97)
Female	47 (81.03)
Race	
African American	7 (12.07)
Asian	1 (1.72)
Caucasian	48 (82.76)
Hispanic	2 (3.45)
Household Income (USD)	
<$25,000	2 (3.45)
$25,000 - $50,000	11 (18.97)
$50,000 - $75,000	20 (34.48)
%75,000 - $100,000	15 (31.25)
>$100,000	7 (12.07)
Did Not Respond	3 (5.17)
Education (highest degree completed)	
Graduated high school	5 (8.62)
Graduated college	47 (81.03)
Post-college degree	7 (12.07)
Marital Status	
Single	4 (6.90)
Married/Living with significant other	43 (74.14)
Divorced	8 (13.79)
Widowed	3 (5.17)
Risk Factors for CVD	
Known CVD	6 (10.34)
High blood cholesterol	33 (56.90)
High blood pressure	29 (50.00)
Diabetes	3 (5.17)
Tobacco abuse	

Yes	1 (17.24)
No	42 (72.41)
Quit	15 (25.86)

*CVD = cardiovascular disease

Table 2

Participants' BMI Classification as Defined by the CDC Before and After the Intervention

BMI Classification*	**Before the Intervention n (%) N = 58**	**After the Intervention n (% N = 58**
Healthy Weight (18.5-24.9)	5 (8.62)	12 (20.69)
Overweight (25.0-29.9)	15 (25.86)	18 (31.03)
Obesity, Class 1 (30.0-34.9)	20 (34.48)	16 (27.59)
Obesity, Class 2 (35.0-39.9)	11 (18.97)	7 (12.07)
Obesity, Class 3 (≥40.0)	7 (12.07)	5 (8.62)

*BMI = body mass index

CDC (2011)

Table 3

Change in Body Weight and Blood Pressure Before and After the Intervention (N = 58)

	Paired Differences					**t**	**df**	**Sig. (2-tailed)**
	Mean	**Standard Deviation**	**Standard Error Mean**	**95% Confidence Interval of the Difference**				
				Lower	**Upper**			***p***
Change in Body Weight	12.3103	6.2306	.8181	10.6721	13.9486	15.047	57	.000*
Change in BMI	2.0586	1.0616	.1394	1.7795	2.3378	14.768	57	.000*
Change in Systolic Blood Pressure	14.9811	16.7854	2.3057	10.3545	19.6078	6.498	52	.000*
Change in Diastolic Blood Pressure	8.4259	10.2379	1.3932	5.6315	11.2203	6.048	53	.000*

*Significant at $p < 0.05$

BMI = Body Mass Index

Table 4

Paired Samples t-test Comparing Change in Blood Cholesterol and Blood Glucose Before and After the Intervention (N = 58)

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Standard Deviation	Standard Error Mean	95% Confidence Interval				
				Lower	Upper			*p*
Change in Total Cholesterol	29.1930	24.5913	3.2572	22.6680	35.7179	8.963	56	.000*
Change in Triglycerides	-10.1579	49.3898	6.5418	-23.2628	2.9470	-1.553	56	.126*
Change in HDL	8.0877	9.0164	1.1943	5.6953	10.4801	6.772	56	.000*
Change in HDL-P	3.1614	3.6908	.4889	2.1821	4.1407	6.467	56	.000*
Change in LDL-C	17.8772	19.0170	2.5189	12.8313	22.9231	7.097	56	.000*
Change in LDL-P	139.6491	220.8122	29.2473	81.0598	198.2385	4.775	56	.000*
Change in Fasting Blood Glucose	-4.6316	9.6021	1.2718	-7.1794	-2.0838	-3.642	56	.001*
Change in HbA1c	-.0151	.2324	.0319	-.0791	.0490	-.473	52	.638*

*Significant at $p<0.05$

HDL = High density lipoprotein cholesterol

HDL-P = High density lipoprotein particle number

LDL-C = Low density lipoprotein particle concentration

LDL-P = Low density lipoprotein particle number

HbA1c = Hemoglobin A1c

Table 5

Change in Exercise Frequency and Intensity Before and After the Intervention, as Reported on the Lifestyle Evaluation Form

	Paired Differences					**T**	**df**	**Sig. (2-tailed)**
	Mean	**Std. Deviation**	**Std. Error Mean**	**95% Confidence Interval of the Difference**				
				Lower	**Upper**			
Change in Exercise Frequency	-.0678	.6660	.0867	-.2414	.1058	-.782	58	.437*
Change in Exercise Intensity	.0169	.6563	.0854	-.1541	.1880	.198	58	.843*

*Significant at $p<0.05$

Table 6

Change in Dietary Consumption of Key Nutrients Before and After the Intervention

	US Diet	**WFPB Diet Followed by Participants**
Fats and Oils	37%	<10-15%
Protein	15%	10-15%
Complex carbohydrates	25%	65-70%
Simple carbohydrates	23%	<10%
Cholesterol (mg/day)	35	<10
Sugar (tsp/day)	35	<10
Salt (g/day)	12	<5
Fiber (g/day)	12	>40

Appendix H

Author Guidelines for Submission in the *Journal of Cardiovascular Nursing*

Journal of Cardiovascular Nursing

Author Guide

Author Resources

Author Guide (this page)

Copyright Transfer (PDF)

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Journal of Cardiovascular Author Resources

Nursing

Author Guide

Purpose of the Journal

The primary objective of *The Journal of Cardiovascular Nursing* (JCN) is to foster expert, evidence-based clinical practice of cardiovascular nurses by publishing outstanding clinically relevant cardiovascular research, and state-of-the art, systematic reviews of the cardiovascular research literature. Issues address the physiological, psychological, and social responses of cardiovascular patients and families in a variety of environments.

Publication Policy

JCN publishes both unsolicited articles (research reports, brief reports, systematic reviews of the literature, instrument development papers, and articles on innovations in practice) on any cardiovascular topic, and invited articles on planned topics. We publish Brief Reports, which are shorter versions of research articles and which can include pilot or preliminary results, negative findings, descriptions of study designs (and which can include baseline participant characteristics), and descriptions of unique clinical trial or intervention study methods.

Authors are encouraged to submit (1) original research articles and brief reports; (2) analytical, systematic reviews that codify existing knowledge; (3) instrument development papers and testing of the psychometric properties of new or existing instruments; (4) clinical articles that synthesize information in a specific area or guide the practice of specialists in the field; and (5) articles describing innovations in practice. The decision to accept or reject an article will be based on the judgment of peer reviewers and the editors.

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For six or fewer authors, list all authors.
Doe JS, Lister FG, Lise JK, Kellert JL. Allied medical education. *JAMA*. 1975; 23(3):170–184.

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Doe JS, Justin MN, Gum KL, et al. Drug use during high school. *Am J Public Health*. 1976;64(1):12–22.

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Farber SD, Ball WD. *Neurorehabilitation: A Multisensory Approach.* Philadelphia, Pa: Saunders; 1982.

Chapter in an Edited Book:
Winawar S, Lipkin M. Proliferative abnormalities in the gastrointestinal tract. In: Card WI, Creamer B, eds. *Modern Trends in Gastroenterology*. 4th ed. London, England: Butterworth & Co; 1970.

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