

**A PILOT QUALITY IMPROVEMENT PROJECT: IMPLEMENTING A PLANT-BASED NUTRITION PROGRAM
IN PATIENTS WITH CARDIOVASCULAR DISEASE**

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Abstract

Coronary artery disease is the leading cause of death in the United States. More than two-thirds of Americans suffer from chronic health conditions which can lead to coronary artery disease including obesity, diabetes, hypertension, and dyslipidemia. Proper nutrition and more specifically plant-based nutrition plays a very important role in overall health and well-being. It can effectively combat chronic conditions and assist in weight loss. Extensive research has demonstrated repeatedly that plant-based nutrition cannot only work as a management strategy, but even reverse these chronic diseases. It is a seemingly simple and effective preventative health strategy, but unfortunately many patients do not know the full health benefits of following a plant-based nutrition program, nor do most people consume plant-based diets. The purpose of this project is to evaluate if there is evidence to support plant-based nutrition educational program as a recommended program to promote benefits in the prevention of cardiovascular disease on the basis of implementing a plant-based nutrition program in a cardiology practice over an eight week period. This is a single group interrupted time-series non-experimental descriptive research study design with convenience sampling.

Key words: plant-based, nutrition, health, vegetarian, vegan, diet, cardiovascular

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A Pilot Quality Improvement Project: Implementing a Plant-Based Nutrition Program in Patients with Cardiovascular Disease

Chapter 1

Introduction

Cardiovascular disease is the leading cause of death in the United States. Various risk factors contribute to the development of coronary disease. Research has shown that plant-based nutrition can help prevent, treat, and even reverse coronary artery disease as well as treat the risk factors which contribute to coronary artery disease including obesity, hypertension, diabetes, and hyperlipidemia; however, most Americans do not follow plant-based diets (Graca et al., 2019). A plant-based diet is a diet which is derived predominantly from vegetables and other plant-based sources with reduction or cessation of meat products.

Background

Coronary artery disease (CAD) is defined as the buildup of plaque in the coronary arteries which can cause narrowing and obstruct the blood flow to the epicardial heart vessels (ACC, 2017). It is noted that coronary disease affects about 18.2 million Americans and accounts for 647,000 deaths yearly, making it the leading cause of death in the United States (Kahleova et al., 2017). It is also estimated that coronary artery disease costs the U.S. approximately 219 billion dollars annually between medications, hospitalizations, diagnostic testing, procedures, and care from specialists (CDC, 2019). Those most at risk for the development of coronary artery disease are people who have been diagnosed with diabetes, hypertension, hyperlipidemia, and obesity in addition to people with risk factors including physically inactivity, excessive alcohol consumption, and unhealthy eating habits (Madigan, 2016). Hypertension affects 45% of the United States population and is defined as a blood pressure recording in excess of 140/90 millimeters of mercury measured by a sphygmomanometer, which can lead to shear stress on

the walls of blood vessels causing micro abrasions (ACC, 2017). Platelets can adhere to these micro abrasions collecting cholesterol and fatty deposits eventually leading to hardening of the vessel walls and further increasing pressure given the loss of elasticity. This perpetuates higher blood pressure readings and the potential for cardiovascular events or myocardial infarction if one of these lesions ruptured (AHA, 2016). Dyslipidemia is defined as elevated low-density lipoprotein (LDL) levels, low high-density lipoprotein (HDL) levels, and elevated triglyceride levels. Dyslipidemia is a primary risk factor for cardiovascular disease because of the development of atherosclerotic lesions seen with elevated LDL and triglyceride levels (Jaske et al., 2020). One of the most common methods of quantifying body measurements in healthcare is called a body mass index (BMI) with BMI greater than 25 being considered overweight and a BMI exceeding 30 is considered obese. The prevalence of obesity in the United States is 42.4% (CDC, 2020).

Research has shown that plant-based nutrition (PBN) can help prevent, treat, and even reverse coronary artery disease as well as decrease the risk factors which contribute to CAD (Jaske et al., 2017). Plant-based nutrition is defined as a diet without the consumption of meat, derived predominantly from plants instead. A plant-based diet is rich in vegetables, fruits, nuts, seeds, whole grains, and legumes. This does not necessarily mean that all animal products must be eliminated from the diet entirely, but rather that the emphasis for nutrition is placed on plant-based sources of proteins, fats, carbohydrates, fiber, vitamins, and minerals (Nutrition Facts, 2020). A healthy plant-based diet should predominantly include a variety of vegetables and fruits in addition to whole grains and healthy oils, such as olive or canola oils. Animal products including eggs, cheese, milk, and other dairy products can be consumed, but should be reduced. The American Heart Association 2015-2020 Dietary Guidelines for Americans now recommend vegetarian diets for lowering cardiovascular risk factors as several studies have

identified improved cardiovascular outcomes in patients following plant-based diets (Satija & Hu, 2018).

Problem Statement

In an outpatient cardiology practice, how does implementing a plant-based nutrition educational program for patients with cardiovascular disease affect their knowledge base after an eight week time period? The goal of this Doctor of Nursing Practice (DNP) project is to increase awareness about plant-based diets and thus increase the consumption of plant-based nutrition as a foundation for overall health and reduction of cardiac risk factors in one outpatient cardiology clinic. The purpose of this study is to determine the effect of incorporating a plant-based nutrition program on cardiac patients' knowledge after an eight week time period. Following implementation of the plant-based diet, participants will also be asked to complete a post-study evaluation questioning about any barriers experienced by the participants while on a plant-based diet. The dependent variable for this project is the patient's knowledge about PBN. The independent variable is the plant-based education over an eight week time period. This is a single-group interrupted time-series non-experimental descriptive research study design with convenience sampling.

Chapter 2

Review of the Literature

The study seeks to evaluate the effect of implementing a plant-based nutrition educational program on participants' knowledge and adherence to plant-based diets over an eight week time period. Research regarding plant-based nutrition was obtained from several databases for review.

A quantitative cohort study was performed by Evans et al. (2017), evaluating the impacts of plant-based nutrition on cholesterol and weight for nineteen nurses in Fairfax, Virginia after 21 days of a plant-based diet. The study revealed that the participants had an average weight loss of 4.4 pounds and had a decrease in total cholesterol levels from 203 mg/dL initially to a post-program level of 185mg/dL (Evans et al., 2017). The participants were surveyed at the conclusion of the study demonstrating that more than half "felt better overall" and had increased energy levels (Evans et al., 2017). A quantitative cross-sectional study with 325 subjects found benefits to following PBN by means of weight loss. The purpose of this non-randomized study was to document the effect of body composition indices following a low-fat, plant-based diet over ten weeks (Jaske et al., 2017). There was an average of 4.3% body fat reduction and weight loss of an average of 5.6 kilograms with plant-based nutrition concluding that following a plant-based diet assists with weight loss (Jaske et al., 2017).

Harland & Garton (2016) conducted a quantitative systematic review and meta-analysis of 269 references including randomized control trials, observational studies, and cohort studies to evaluate the relationship between plant-based nutrition and the incidence of coronary artery disease, diabetes mellitus, and obesity. This review demonstrated that there is a 20% risk reduction for cardiovascular disease amongst vegetarians when compared to carnivores (Harland & Garton, 2016). These risks included obesity, hyperlipidemia, and type II diabetes,

with plant-based nutrition showing favorable outcomes and reduction of weight, low-density lipoprotein levels, incidence of coronary artery disease, and improved glycemic control (Harland & Garton, 2016).

A quantitative cross-sectional study was performed, seeking to evaluate the cardiovascular outcomes of 151 people following plant-based diets. This study demonstrated that plant-based nutrition proves to be favorable on cardiovascular profiles by documenting lower body mass indexes, improved lipid panel findings, and improved blood pressure recordings (Jaske et al., 2020). Following a plant-based diet, low-density lipoprotein (LDL) levels, triglycerides, and systolic and diastolic blood pressures were within targets for the majority of the participants (Jaske et al., 2020). Females had higher total and high-density lipoprotein cholesterol levels, the systolic blood pressure was lower, and there was no difference in diastolic blood pressure (Jaske, et al., 2020). More females reached target triglycerides and systolic blood pressure goals and both females and males reached target LDL-cholesterol and diastolic blood pressures (Jaske et al., 2020).

Furthermore, a quantitative systematic review of 90 cross-sectional studies noted an overall lowered risk for cardiovascular disease in adulthood when a plant-based diet is followed starting from childhood and continuing throughout adult life (Desmond et al., 2018). In the cross-sectional analysis of a subset of 592 participants (25% vegetarian; 75% nonvegetarian), the risk of hypertension among dietary groups was lower for vegetarians and higher for omnivores (Desmond, et al., 2018). In a matched cohort study of 4109 participants, vegetarians had a 28% lower risk for hypertension and another systematic review of 32 observational studies and meta-analysis of seven controlled clinical trials with 311 participants demonstrated a significant reduction in mean systolic blood pressure and diastolic blood pressure after implementing a vegetarian diet when compared with the omnivorous diets (Desmond et al., 2018).

A quantitative randomized control trial with 60 participants including a child and his/her adult parent found that plant-based nutrition in both children and adults demonstrated potential beneficial changes from baseline in risk factors for cardiovascular disease (Macknin et al., 2015). Children on plant-based diets for four weeks had nine statistically significant ($p < .05$) beneficial changes from baseline as evidenced by decreases in body mass indices, a mean reduction of 6.43mmHg in systolic blood pressure measurements, a 22.5mg/dL reduction in total cholesterol levels, a decrease of 13.13mg/dL in low-density lipoprotein, a loss of 2 centimeters in mid-arm circumference, an average weight loss of 3.05 kilograms, and waist circumference loss of 2.96 centimeters (Macknin et al., 2015).

Additionally, Mingyang and colleagues (2016) performed a quantitative prospective cohort study ($n=131,342$). The purpose of this study was to examine the association of animal and plant protein intake with mortality risk. The study demonstrated that animal protein intake was not associated with higher all-cause mortality, but was associated with higher cardiovascular mortality whereas plant protein was associated with lower all-cause mortality and lower cardiovascular mortality (Mingyang et al., 2016). Another integrative systematic review of 104 studies was conducted by Kahleova and colleagues (2017) to evaluate the effects of PBN on heart disease and stroke. This study concluded that plant-based nutrition demonstrated a reduction in heart disease risk by up to 40% and a decrease in cerebrovascular events by up to 29% by effectively treating or eliminating the populations' risk factors with plant-based diets (Kahleova et al., 2017). A systematic review demonstrated that plant-based diets protect against chronic conditions including heart disease and that vegetarian diets offer protection from chronic diseases such as hypertension, obesity, diabetes mellitus, and cancers. Most data, however, until now has come from large prospective cohort studies and thus,

randomized control trials are needed for more information including preventative and management strategies (Madigan, 2017).

A quantitative cross-sectional study including 41 healthcare professionals in New Zealand was performed to assess their knowledge and understanding of a nutritious diet amongst healthcare workers. This study concluded that more than half of the participants did not recommend plant-based diets to their patients for various reasons. These reasons mentioned as barriers included the cost of following a plant-based diet, access to foods, and difficulty preparing meals without meat as the main source of protein (McHugh et al., 2019). Cramer et al. (2017) conducted a quantitative cross-sectional study (n=34,525) in an effort to determine the characteristics of Americans choosing vegetarian diets for health reasons. The variables measured were the prevalence of ever use and twelve month use of vegetarian diets for health reasons, pattern of use, demographics and socioeconomics of users, and health related factors including obesity or smoking associated with use of vegetarian diets (Cramer et al., 2017). The study concluded that the prevalence of vegetarian diets solely for health reasons was 4% and twelve month use was 1.9% (Cramer et al., 2017). Accordingly, it was recommended that more emphasis on plant-based nutrition and the improved health outcomes associated are needed to improve knowledge and overall health given that less than 2% of the participants reported actually using a vegetarian diet for the health benefits alone (Cramer et al., 2017). Other reasons for following plant-based diets aside from the health benefits were ethical animal concerns, the desire to improve memory, and to improve athletic performance (Cramer et al., 2017).

Bukambu et al. (2020) conducted a study with 2,731 fifth grade students to evaluate the association between cost and quality of nutrition. The study calculated the cost of food items and utilized the Diet Quality Index-International food guide to determine that high quality diets

including the recommendations for vegetable and fruit intake were significantly more costly leading to a barrier to health eating with lower income families (Bukambu et al., 2020). Furthermore, a study with 1,600 participants was conducted by Graca and colleagues (2019) to examine factors that would support or hinder the transition to plant-based diets. This study demonstrated that putting plant-based nutrition at the center of diets poses a challenge for various reasons including the social prejudice against plant-based nutrition, the presence of marketing and media displaying animal based proteins as the center of meals, convenience given that many carnivorous meals are ready to eat whereas plant-based meals are not as easily accessible, and some consumers feel it is important to experience joy and pleasure in their meals, which is centered around meat consumption (Graca et al., 2019). The study recommended that in order to facilitate increased adherence to plant-based diets in communities, more emphasis would have to be placed on the positive health and environmental outcomes in addition to marketing transitions to display attractive representations of plant-based nutrition to make it more appealing to consumers (Graca et al., 2019).

This literature is peer-reviewed and balanced between both primary and secondary research. Articles prior to the year 2015 were excluded from database searches. There is an abundance of evidence to support transitioning to plant-based diets; however, it is underutilized in daily life and practice for most adults (Cramer et al., 2017). Therefore, an identified gap is how to incorporate current evidence-based knowledge with methods to promote plant-based diets. The population is not following plant-based diets despite much research showing the benefits of PBN and there may several reasons for this, which may include a lack of education about plant-based nutrition, the stigma that accompanies vegetarian or vegan diets, cost, access to food, difficulty preparing plant-based meals, and lack of interest despite the proper education (McHugh et al., 2019). This DNP project aims to incorporate education about plant-based

nutrition including the health benefits, while also providing guidance with regards to nutritional information including what to increase and what to avoid in a plant-based diet, resources for plant-based recipes and cookbooks, and to then evaluate the effect that PBN has on cardiovascular risk factors in an effort to bridge the gap between evidence based research and encouraging more people to transition to plant-based diets. To address the gap in research literature and everyday life, the project will ask participants to complete a survey at the conclusion of their eight week period to determine if they were able to follow the plant-based diet and if not, identify what the barriers to adhering to plant-based nutrition were.

Chapter 3

Project Design

This study's purpose was to investigate how implementing a plant-based educational program affects participants' knowledge and adherence to plant-based diets. This is a single-group interrupted time-series quasi-experimental research study design with convenience sampling. At the conclusion of the study, an exit survey was required asking the participants if they were able to adhere to the plant-based diet and if not, what were the barriers they experienced with adhering to plant-based nutrition. There was also a pre and post plant-based nutrition test to evaluate the knowledge base of the participants before and after following a plant-based diet for eight weeks.

Aims, Outcomes, and Measures are attached in the appendix. The first aim is to educate the clinic staff about plant-based diets. The second aim is to educate the participants about plant-based nutrition. The third aim is to evaluate the participants' experiences on plant-based diets including any barriers that were noted during their time following plant-based nutrition. Further details and measurements for these aims are outlined in the attached appendix attachment (L).

Project Site and Population

The clinical agency is a well respected cardiology office in West Central Florida. This is a busy outpatient cardiology office offering cardiac care for patients with various cardiovascular disease processes. The group has over twenty physicians with different specialties to provide specialized care to patients with all kinds of heart problems, including arrhythmias, coronary artery disease, structural heart disease, and peripheral vascular disease. As an advanced practice nurse in the clinic, I interact with all of the physicians, other advanced practice providers, and office managerial staff on a daily basis.

The population of patients includes adult men and woman of all ages with various cardiac conditions. The patients in the clinic vary in socioeconomic status and education level. This study will recruit adult patients between ages 18 and 75 years old who are willing to implement an eight week plant-based nutrition diet. These patients will be recruited from one outpatient cardiology clinic in Safety Harbor, Florida. This will be a convenience sampling. The inclusion criteria include adult patients between ages 18 and 75. The exclusion criteria would include pregnant or breastfeeding mothers, patients with unstable iron deficiency or pernicious anemia, patients being anticoagulated with a Vitamin K antagonist, or those with a BMI < 18.5. This study will enroll a minimum of 30 and maximum of 50 participants. Patients who are uninsured or underinsured will also be excluded unless they sign a waiver accepting financial responsibility for office visit costs.

The medical assistants will query the patients when rooming them and if there is any interest in participating in the project, their information will be sent to the nurse practitioner to discuss further. The patients will be contacted, either by phone or in person, to discuss the project and determine if they are interested in addition to determining their candidacy.

A SWOT analysis has been performed (attached in appendix C). Some strengths include an abundance of current evidence based research available showing positive data with plant-based diets, the fact that the project is to be carried out in my workplace, which is a very supportive environment with internal resources (the DNP mentor other MDs in the practice), and that there are no significant expenses to carry out the project. A few weaknesses identified are that the advanced practice registered nurse is solely responsible for all education which will be quite time consuming, there is no funding available, and there is no reputation for plant-based diets within the practice thus far, which could lead to skepticism. There are several opportunities which include the opportunity to generate revenue by billing for visits, and

increasing patient satisfaction by promoting education and potentially having the patients on less medications. Threats include the stigma associated with plant-based diets, the cost of plant-based nutrition, and difficulty adhering to the diet due to availability.

Methods

The patient will spend 30 minutes with the provider following the administration of a knowledge based quiz discussing the benefit(s) of plant-based nutrition including dietary choices to replace meat in diets. The enrollee will also be given written information regarding diet recommendations, educational resources including websites, books, & applications, and information for recipes.

Measurement

There will be a pre and post test (attached in appendix J) administered to evaluate knowledge about plant-based nutrition to the participants which should not take longer than thirty minutes to complete. Following the conclusion of an eight week time period, the patients will also take a survey which should not take longer than thirty minutes to complete to evaluate the amount of meat they consumed on a daily basis to see if there is indeed an increase in plant-based nutrition adherence following implementation of an educational program. The survey will also ask the participants to describe what aspects of following a plant-based diet were found to be difficult, if any.

Data Collection Procedures

The patient will spend 30 minutes with the provider discussing the benefit(s) of plant-based nutrition, including dietary choices to replace meat in diets. During the initial educational session, the participants will be given a knowledge base questionnaire to assess the participants' baseline knowledge regarding plant-based nutrition (attached in appendix J). The enrollee will also be given written information regarding diet recommendations, educational resources

including websites, books, & applications, and information for recipes. Attached in appendix D, E, and F are copies of handouts to be given to the participants including resources and nutrition guidance. Following the conclusion of an eight week time period, the patients will take the same knowledge based questionnaire, which should not take longer than thirty minutes to complete to evaluate if there is indeed an increase in the participants' knowledge. The survey will also ask the participants to describe what aspects of following a plant-based diet were found to be difficult, if any. This survey is attached in appendix I.

Data Analysis

The test question answers will be assigned with a number zero (0), for example, for what should be a false question and one (1) for what should be true to evaluate the answers. These numbers will then be summarized for each participant's survey to obtain a total knowledge score. The same will be totaled for the post-project knowledge based scores. The data will be then entered into an Excel spreadsheet and compare the pre-project data to the post-project data using statistics. A paired sample T test will be used to provide statistical analysis support.

Budget

Attached in appendix B is a table to summarize the project's budget. The total estimated cost is \$222.82 to account for the costs of the printer, the ink, the paper, and the folders which will be provided to the participants with the educational packet. The cost for using Intellectus Statistics for one month to analyze the data at the conclusion of the project is \$99.99. Additionally, the ARNP's salary needs to be accounted for given that the education will be provided to the participants during working hours. If there are 30 participants and each participant has 30 minutes of education that equates to 15 hours of work. The hourly salary for the ARNP is \$52/hour, which equals \$780 in total. This number will be adjusted based on the

actual number of participants who enroll in the project. It should be noted that the education will not take place in a setting which would be utilized for any other revenue generating activities.

Timeline

Attached in Appendix A is the GANTT chart. This demonstrates the months on the top axis and the steps of the problem on the vertical axis. The project started in August 2019, at which time emphasis was placed on picking a project topic. After the project topic was picked and finalized, I began working on the protocol and plan for the research. This started in the spring of 2020 and was completed in the end of 2020. The literature review began in Spring of 2020 and took three full months of research and compiling data and research. I finalized all of the protocol planning and project planning by November of 2020 and submitted for IRB approval. The project was approved through the University of Tampa's IRB committee in November 2020. Project implementation occurred from May through September of 2021. All data collection and dissemination were completed from September through November 2021. Dissemination of the project data was carried out in December of 2021.

Ethical Considerations/Protection of Human Subjects

The University of Tampa, Internal Review Board (IRB) approval was obtained prior to initiating the DNP Project, which is attached in appendix G. Also attached is a copy of the Informed Consent in appendix H. All participants were protected by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) which, among other guarantees, protects the privacy of patients' health information. Additionally, the DNP student and practice personnel who carefully conducted this project followed the *Standards of Care* for practice in the cardiology clinic.

There are no physical risks known with this study. There is a potential for psychologic risk as patients could potentially feel anxious about adhering to a plant-based diet in addition to possible feelings of guilt if they are unable to follow through with plant-based nutrition. A potential social risk is that in many social settings or group gatherings, emphasis is placed on food or meals as a mainstay of a social event and those on a plant-based diet may feel excluded from social events if they cannot consume meat. In an attempt to minimize this risk, participants will be advised in their initial counseling session to ask if there will be meat free options at social events and if not, bring their own form of sustenance.

All patient information will remain anonymous. Data collected for this study will be confidential and only the primary investigator will have access to data files. The participants will be identified by number in these files without any personal information shared. The participants will sign the consent form identifying them as participants and these forms will be stored in a locked filing system apart from the data files. No attempts will be made to contact participants once the study has ended. The data will be disposed of after a period of one year. The participants will likely benefit by reflecting on their daily food choices and gain knowledge about dietary choices. Another benefit is the reduction in the incidence of cardiovascular risk factors by means of following a plant-based diet.

Chapter 4

Outcomes

Implementation of the project was carried out in the summer of 2021 dating from May 25th through September 8th. Participants were identified in the clinic by their primary cardiologist and then referred for the plant-based nutrition education/DNP project. There were a total of thirty (30) enrollees. All 30 participants were enrolled within a nine week period. Initially enrollment was slow. The first week there were less than five enrollees. To remedy this and combat the slow enrollment process, this DNP project plan was revisited with all of the medical assistants, physicians, and physician extenders. At that time, a \$25 reward was offered for whichever individual in the practice referred the most patients that were successfully enrolled in the study. This intervention proved to be successful, as the medical assistants began screening more patients in the practice, suggesting to the primary cardiologist a referral to the PBN educational program, and then subsequently the physicians referring them for the study.

The hypothesis was that the participants would have an increase in knowledge base about plant-based nutrition following their educational session and eight week period following the diet. After analyzing the data, the hypothesis is proven to be correct as the participants did indeed show an increase in their overall knowledge base following the project and educational session. Surprisingly however, despite the participants showing an increase in knowledge, very few enrollees noted that they planned to stick with the diet and only one participant completed eight full weeks of a plant-based diet, by their report. The post-surveys were reviewed and analyzed; There were many barriers faced by the participants. The results are outlined further as below:

Table 1: Paired Sample t-test

	M	SD	Mean Diff.	SD	95% Confidence Interval of the Difference		t	df	p
					Upper	Lower			
Pre-Knowledge	6.67	1.54	1.83	1.66	2.45	1.21	6.04	29	<0.001
Post-Knowledge	8.5	1.36							

A paired-sample t-test was conducted to compare the knowledge base score of patients with cardiovascular disease before and after an eight-week time period of plant-based nutrition educational program. The participants' knowledge scores were compared before and after a plant-based nutrition educational program after an eight-week time period. On an average, the participants' knowledge scores were lower before (M = 6.67, SD = 1.54) than after the eight-week time period plant-based nutrition educational program (M = 8.5, SD 1.36). This improvement, 1.83, 95% CI[1.21, 2.45], was statistically significant, $t(24) = -6.04$, $p < 0.001$. There was a large effect of the plant-based nutrition educational program on the patient's knowledge, $d = 1.10$. Table 2 below outlines the data from the paired sample statistics and correlations:

Paired Samples Statistics

	Mean	N	Std. Deviation	Std. Error Mean
Pair 1 Post Knowledge	8.5000	30	1.35824	.24798
Pre Knowledge	6.6667	30	1.53877	.28094

Paired Samples Correlations

	N	Correlation	Sig.
Pair 1 Post Knowledge & Pre Knowledge	30	.346	.061

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	Post Knowledge - Pre Knowledge	1.83333	1.66264	.30355	1.21249	2.45417	6.040	29	.000

The histogram plot below shows the distribution of the knowledge base score before and after the eight-week time period of plant-based nutrition educational program. For the pre knowledge score, we observe that the histogram is skewed to the right i.e., positively skewed, as most of the participants scores fall between 5 and 7. For the post knowledge score, we observe that the histogram is skewed to the left i.e. negatively skewed as most of the participants scores fall between 8 and 10.

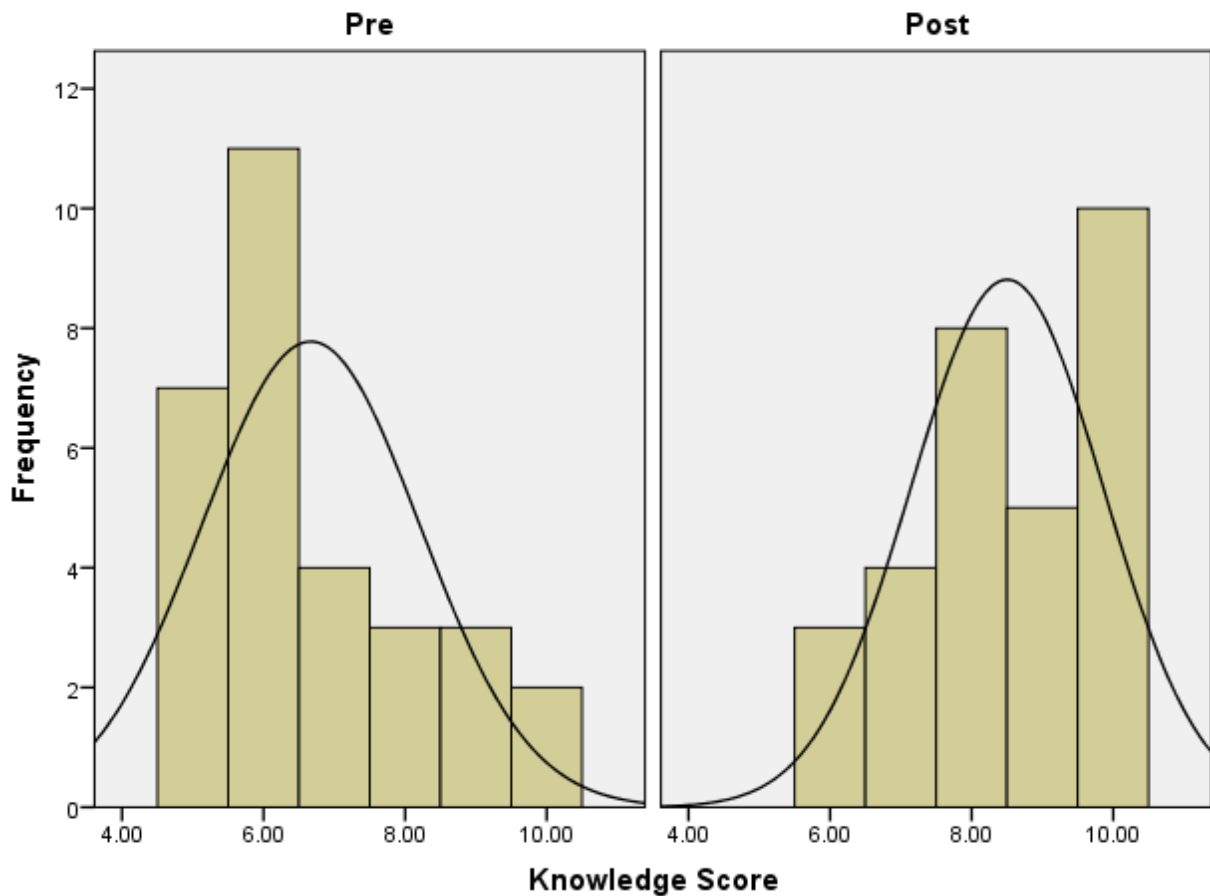


Table 3: Frequency table for the barriers experienced while on plant-based diet

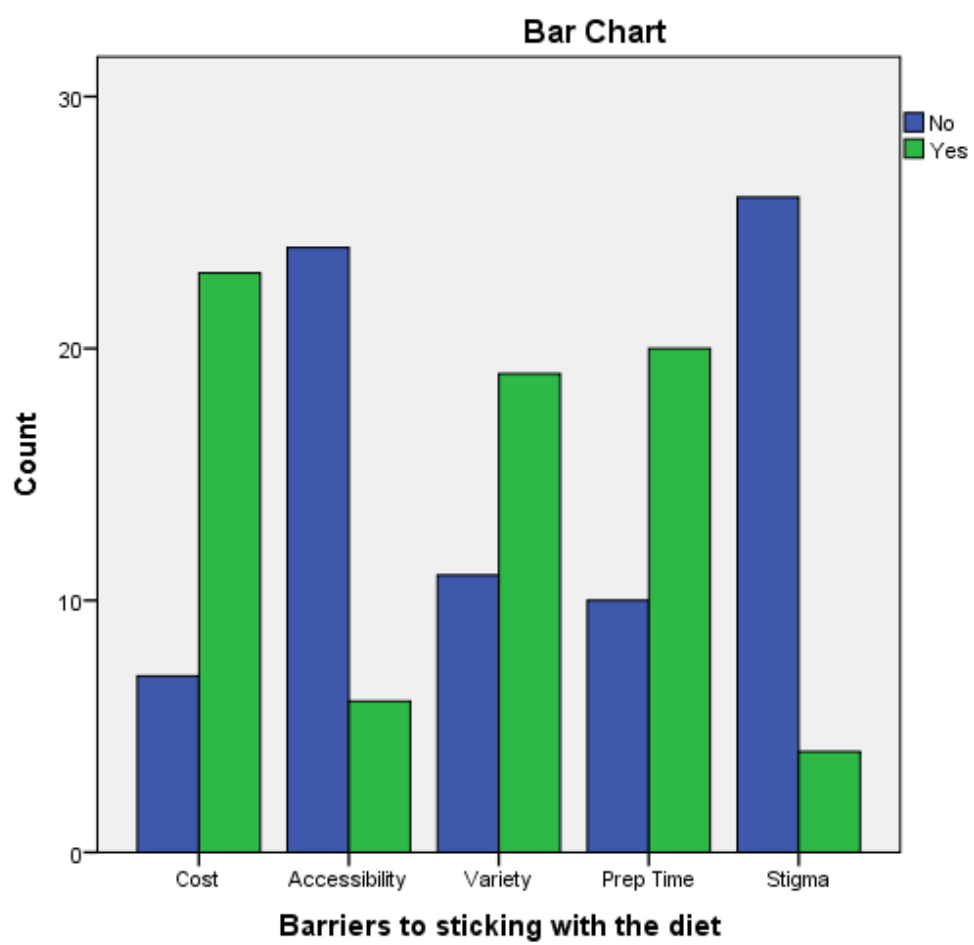
		Frequency	Percentage
Were you able to adhere to a plant-based diet for 8 weeks?	No	29	96.7
	Yes	1	3.3
Were you able to easily find recipes and meal ideas for plant-based meals?	No	19	63.3
	Yes	11	36.7
Were you able to find plant-based meals in restaurants?	No	14	46.7
	Yes	16	53.3
Was cost an issue with plant-based nutrition?	No	6	20.0
	Yes	24	80.0
Did you notice improvement in energy levels or other positives while following plant-based nutrition	No	14	46.7
	Yes	16	53.3
Do you plan to stick with the plant-based diet	No	26	86.7
	Yes	4	13.3

Table 3 above shows the frequency table for the post-study evaluation questionnaire about any barrier(s) encountered by the participants while on a plant-based diet. A total of 29 (96.7%) of the participants indicated that they were unable to adhere to a plant-based diet for 8 weeks, while only one person adhered to the plant-based diet. More than half of the participants (63.3%) were not able to easily find recipes and meal ideas for a plant-based diet while 11 (36.7%) reported they were able to find recipe and meal ideas. A little more than half of the participants (53.3%) indicated they were able to find a plant-based meals in the restaurants while 14 (46.7%) could not find plant-based meals in restaurants. 80% responded to cost being an issue with plant-based nutrition while 6 (20%) indicated cost was not an issue. 53.3% noticed an improvement in their energy level while following the plant-based nutrition while 46.7% did not notice any improvement. 13.3% indicated they plan to stick with the plant-based diet while 86.7% do not plan to stick with this diet.

Table 4 below shows the frequency and percentage for the barriers faced by participants to adhering with the plant-based diet represented by both the table and the bar chart for visual representation. Twenty-three participants, accounting for 76.7% of the participants, indicated cost as a barrier. Another six enrollees (20%) indicated accessibility was a barrier they experienced. Additionally, nineteen of the participants which accounts for 63.3% of all enrollees indicated variety was a barrier whereas twenty participants (66.7%) indicated preparation time was a barrier with adhering to a plant-based diet. Only four of the participants which accounts for 13.3% indicated that stigma is a barrier to sticking with diet.

Table 4: Other barriers to sticking with the diet

		No	Yes
Cost	Count	7	23
	% Within Barriers to sticking with the diet	23.3%	76.7%
Accessibility	Count	24	6
	% Within Barriers to sticking with the diet	80.0%	20.0%
Variety	Count	11	19
	% Within Barriers to sticking with the diet	36.7%	63.3%
Prep Time	Count	10	20
	% Within Barriers to sticking with the diet	33.3%	66.7%
Stigma	Count	26	4
	% Within Barriers to sticking with the diet	86.7%	13.3%



Chapter 5

Strengths and Limitations

One of the project strengths was the ability to enroll patients straight from the clinic setting into the study. Most of the patients being seen in a cardiology clinic benefit from learning about plant-based nutrition as a basis for improved health and given that the patients were already diagnosed with some form of cardiovascular disease, it was apparent they were interested in learning about PBN to improve their overall heart health. Being able to educate and subsequently enroll the participants in a study to reinforce the education that was provided was helpful.

Another strength of the project is the degree of valuable data that was obtained from the post survey questionnaire, including the barriers the participants experienced. This information proves to be incredibly helpful for the future. For example, since 80% of the participants indicated that cost was an issue while on a plant-based diet, in the future ideally more emphasis can be placed on ensuring healthy food choices are available and accessible to everyone at reasonable costs. Furthermore, when providing education in the future, information for local produce shops that tend to be less cost prohibitive can be provided to the patients.

One limitation of the project was the small sample size. The project goal was to enroll 30 to 50 participants. The study successfully enrolled the minimum number of 30 participants, and therefore given the small sample size, the data was limited. Also, the enrollees were all from the same cardiology clinic and thus most participants were in the same localized region. This proves to be quite a limited sampling of the patient

population. Another limitation of the project was the length of time for the participants to follow plant-based diets. The study asked enrollees to follow a plant-based diet for an eight week period, and only one out of thirty participants indicated that they were able to adhere to the diet for that period of time. It is also suspected that had the diet implementation period been shortened to only six weeks, perhaps more participants would have enrolled in the study.

The other limitation of the project was the time constraint for the advanced practice registered nurse with implementation of the project and providing the educational session for each participant. The participants were provided individualized education and this proved to be quite time consuming. In fact, it limited the number of enrollees per day for the nurse practitioner to educate due to the time constraints.

Implications

The data obtained from this Doctor of Nursing (DNP) project revealed that there was indeed an increase in overall knowledge base after implanting a plant-based nutrition educational program in a cardiology office. Furthermore, more than half of the participants enrolled noted that they experienced an improvement in their energy levels or other positive outcomes while on the plant-based diet. For these reasons, the education program should be continued for the cardiac patients, and the plan is to continue the program in the cardiology clinic. The data obtained from this study also provided a lot of insight about the barriers that the enrollees experienced and what hindered their ability to adhere to a plant-based diet. This proves to be beneficial as it guides what information can be provided during the educational program sessions in

the clinic. For example, with the data obtained from this study, it has been noted that cost is an issue with plant-based diets. Local produce shops (including their locations and phone numbers) can be recommended for patients who are interested in following plant-based diets as local produce markets tend to be less cost prohibitive than some chain grocery stores. This data should also be published nationally, and emphasis should be placed on making plant-based diets more affordable. Additionally, another example of how the project's data can be applied to improving the future of the plant-based education protocol, is by acknowledging that 63.3% of participants indicated they could not easily find meal ideas or recipes. Accordingly, the educational program can include more recipes and ideas when they information about plant-based nutrition is provided initially.

The plant-based nutrition educational program will continue in the outpatient cardiology clinic. Further, ideally this educational program will continue to grow and begin to educate more patients in our other office locations about plant-based diets.

Recommendations for Future Projects

If the study were to be replicated, the educational session could be changed from an individualized meeting for each participant to a group meeting instead. This could be done in person or as a Zoom meeting and could include many more enrollees. It could also be performed once a week for several weeks in a row until the goal number of participants were enrolled. This would save a lot of time for the sole educational provider and could also allow for open communication amongst participants and encourage discussion that may answer more questions for all enrollees.

Additionally, the study could be shortened to a six week period, ideally to increase adherence to the plant-based diet. An alternative to shortening the duration of the plant-based diet would be to set up a meeting at the halfway point with the participants to obtain the feedback, answer questions, and continue to encourage the enrollees to adhere to the diet. Many participants indicated that finding recipes, meal ideas, or meals in restaurants proved to be difficult while on a plant-based diet. Meeting halfway into the project could help combat participants from abandoning the diet as reinforcement, encouragement, and recommendations for local restaurants as well as more guidance for meal ideas could be provided. This would likely increase the number of enrollees that are able to successfully adhere to the diet, both in the short and long term.

Dissemination Plan

The title of my Doctor of Nursing (DNP) project is A Pilot Quality Improvement Project: Implementing a Plant-based Nutrition Program in Patients with Cardiovascular Disease. The purpose of this project was to implement a plant-based nutrition educational program in a cardiology clinic to promote plant-based nutrition as a foundation for health and to improve knowledge about plant-based diets in cardiac patients over an eight week period. Specifically, the project utilized a ten question true/false test to assess knowledge both before and after an educational program and following a plant-based diet. Furthermore, this study used a post-study questionnaire to assess any barriers experienced by the participants if they could not adhere to the plant-based diet. This Doctor of Nursing Practice project will be presented to the

University of Tampa's progression committee, which will take place in the fall of 2021, with a target date of November 23, 2021. It will also be presented to the University of Tampa's most recent cohort of DNP students.

Primary end users who would benefit from the information gained from this DNP project include all providers in the field of cardiology. This includes physicians, advanced practice nurses, physician assistants, and nurses. Dieticians would also benefit from the information learned in this project. Additionally, providers in primary care would benefit from this information.

Dissemination of this project's findings include sharing the information locally with colleagues, but also ideally on both the state and national level as well. The long term plan for dissemination is to present at meetings and conferences for advanced practice nurses, such as the Tampa Bay Advanced Practice Nurses Council, and more specifically at cardiology conferences either locally or nationally. Communication methods that are beneficial in spreading project findings include poster presentations, PowerPoint presentations, speaking at conferences, submitting an abstract, publishing in journals, drafting letters to state and national officials, and sharing the information on social media. The plan for this project specifically is to create a poster presentation for dissemination. The poster can be used to present to colleagues and at conferences. Additionally, the information obtained from this study will be presented to the clinic staff at the cardiology office where the project took place. Potential obstacles to disseminating the project's findings include the inability to reach end users that are not local and also funding for publishing as it can be costly to publish in journal.

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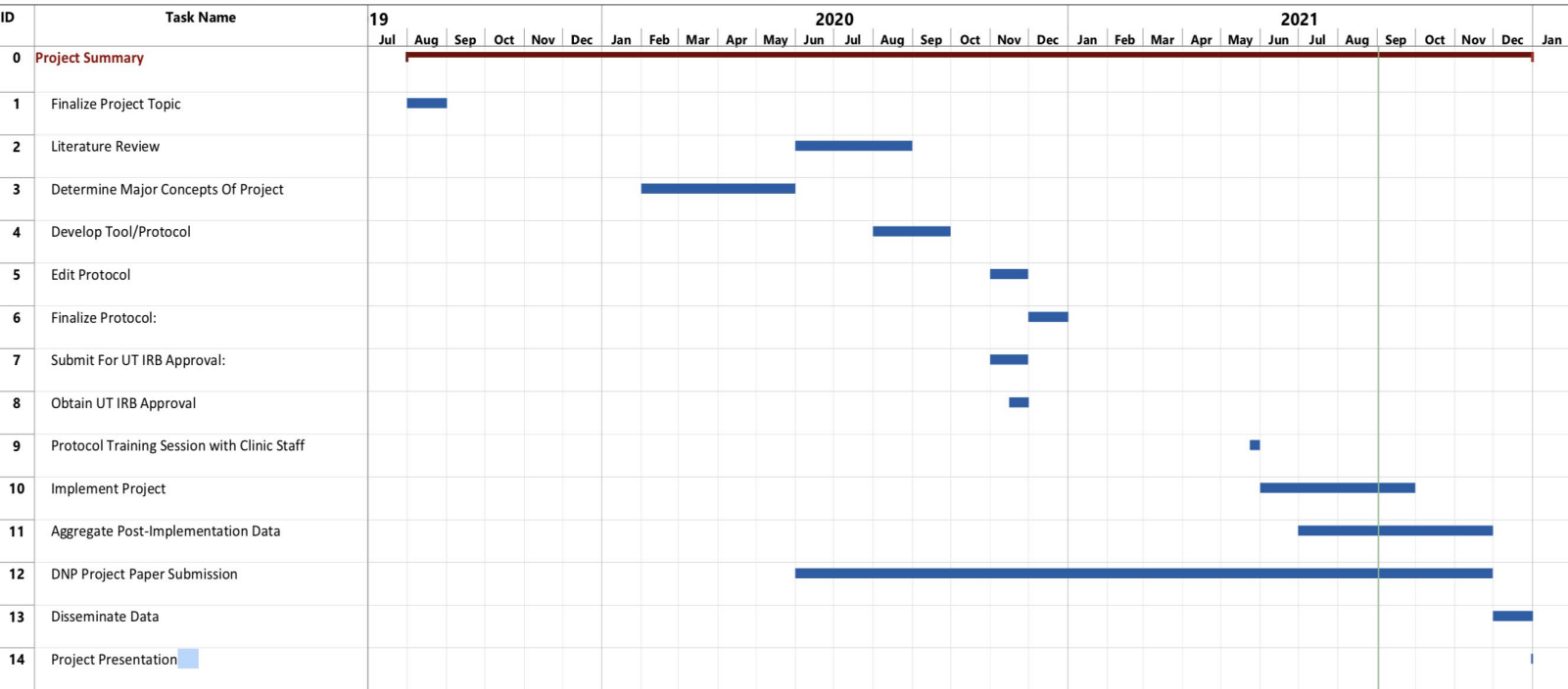
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Appendix

APPENDIX A: GANTT CHART

Project Title: DEVELOP AN EVIDENCE - BASED PROTOCOL FOR PLANT - BASED NUTRITION EDUCATION PROGRAM




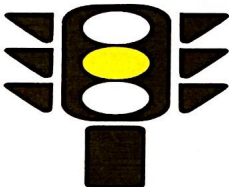

APPENDIX B: BUDGET

ITEM	ESTIMATE	ACTUAL	COMMENTS	VARIANCE
MATERIALS				
Epson Wireless Printer	\$69.99	\$69.99	Purchased at Target	No change
Printer Ink	\$ 37.95/package	\$113.85	Purchased from Target	No change
Multipurpose printer paper (500 sheets)	\$6.99/package	\$13.98	Purchased from Staples	No change
Folders	\$0.50/each	\$25.00	Purchased at Target	No change
Projected Total: \$222.82 / Actual Total: \$222.82				
PERSONNEL				
UT Doctoral Faculty	9-12-month faculty salary position	In kind	Costs would be deferred as additional time outside of regularly scheduled work hours would not be expected	No change
DNP Project Preceptor	salary position	In kind	Costs would be deferred as additional time outside of regularly scheduled work hours would not be expected	
Clinicians	Salary position	In kind	ARNP salary which equates to \$52/hour should be considered as part of the budget for educational purposes during implementation of the project	
Others	Various wages	In kind	Costs would be deferred as the educational in-service would be during regularly scheduled weekly staff meetings.	
Total: \$0.00				
SUPPORT				
Submission of results and research to journal	No costs associated	N/A	N/A	
Total: \$0.00				
GRAND TOTAL: \$222.82				

APPENDIX C: SWOT

S.W.O.T.	
Strengths	Weaknesses
<ul style="list-style-type: none"> - Abundance of current evidence based research available showing positive data with Plant-based diets. - Project to be carried out in my workplace, which is a very supportive environment. - Internal resources (Dr. Zelenka and other MDs in the practice). - No significant expenses to carry out the project 	<ul style="list-style-type: none"> - Education is provided solely by ARNP. - Lack of funding for project - No reputation for plant-based diets within the practice thus far.
Opportunities	Threats
<ul style="list-style-type: none"> - Plant-based diets have shown promising data for reducing cardiovascular disease and if positive outcomes are shown, the practice can recruit more participants. - Billing for educational visits for dietary teaching can increase revenue for the group. - Increase patient satisfaction 	<ul style="list-style-type: none"> - Cost of plant-based diets - Stigma - Difficulty finding plant-based meals in restaurants thus limiting adherence

APPENDIX D: GREEN LIGHT FOODS

Green Light Foods	Yellow Light Foods	Red Light Foods
		
3 SERVINGS per day	1-3 SERVINGS per day	ELIMINATE/REDUCE!!!
<p>Dark Leafy Greens (3+ servings): (Kale, spinach, collard greens, mustard greens, red/green leaf lettuce, romaine lettuce, turnip greens, swiss chard, beet greens, broccoli, cabbage)</p> <p>Fresh or Frozen Vegetables (3+ servings): Brussel sprouts, carrots, peas, celery, okra, tomatoes, zucchini, squash, sweet potatoes, mushrooms</p> <p>Fresh Fruit (up to 3 servings): Blackberries, raspberries, blueberries, strawberries, apples, oranges, bananas, pears, peaches, plums</p>	<p>Legumes, beans, lentils (2-3 servings): Lentils, soybeans, edamame, black beans, garbanzo beans, cannellini beans, kidney beans, Tofu, and Tempeh</p> <p>Whole Grains (1-2 servings): Quinoa, spelt, millet, barley, steel cut/rolled oats</p> <p>Nuts & Seeds (1-2 servings): Raw and unsalted nuts/seeds (8-30 nuts per day), 2 TBSP of ground chia seeds/ ground Flax seeds</p>	<ul style="list-style-type: none"> -Juices -Sodas -Processed/packaged foods -Candy -Sweets, cookies, muffins, pastries, cakes -White bread -White pasta -Red Meat -Processed meat -High-fat dairy -Butter/margarine -Fried foods -Added oils (vegetable oil, peanut oil) -Minimize or eliminate all animal products

APPENDIX E: EDUCATION

What is a Whole Food Plant Based Diet (WFPB)?

The term “whole” in WFPB describes foods which are not at all or minimally processed. This includes a diet rich in fruits, vegetables, and legumes. It also includes nuts, seeds, avocados, soy products, and whole grains, in moderation. Heavily processed foods, highly refined grain products (examples include white rice, white flour), foods with added sugars or artificial sweeteners (example: high fructose corn syrup, Splenda/Sucralose) should be avoided. Also, possibly eliminating or limiting meat, dairy, and animal products is important. If you choose to eat animal products, it would be advised that you stick with low-fat dairy, fish such as salmon, and lean meat.

“Let food be thy medicine, and medicine be thy food.” -
Hippocrates



- **MEAL PLANNING WEBSITES**

- Perm.org
- Planttricianproject.org
- Forksoverknives.com (APP: Forks Over Knives)
- Mealplanner.22daysnutrition.com
- Whole30 Program

- **Find a Registered Dietician**

- Eatright.org

Nutrimeddy.com

Masteringdiabetes.org (Plant-based Health Coach)

Local: BeeWell Nutrition; Liat Golan, R.D. 727-735-4473

- **Books**

- Becoming Vegan – B. Davis, RD
- Kick Diabetes: Essential Diet & Lifestyle Guidelines – B. Davis, RD
- The Alzheimer’s Solution – Ayesha & Dean Sherzai, MD
- Greenprint – Marco Borges
- Your Body in Balance – N. Barnard, MD
- Prevent and Reverse Heart Disease – C. Esselstyn MD
- The Truth About Food – D. Katz, MD
- Trifecta of Health – A. Sadeghi, MD
- The Plant Paradox – S. Gundry, MD
- Obesity Code – J. Fung, MD

Examples of Vegetarian Swaps to Use Instead of Meat

When people think of a vegetarian diet, they tend to assume the diet will be boring, limited, and be made up predominantly salads. This is not true. There are so many substitutions available to eliminate the consumption of meat products. Plant-based diets do not have to be bland or boring. Here are some examples:

-Substitute Jackfruit for Pork or Chicken

-Jackfruit is a fruit loaded with vitamins, potassium, and magnesium, but it holds up really well in meat recipes. Great substitute for pulled pork BBQ sandwiches.

-Instead of steak, use portobello mushrooms

-The large meaty caps of the portobello mushroom are resistant enough to make for a good substitute for steak on a burger, skewers, or fajitas.

-Instead of ground beef or sausage, use beans, legumes, or lentils.

-Beans, legumes, and lentils make for good ground beef substitutes and provide a good amount of protein. Try a chickpea burger or blackbean enchiladas.

-Instead of hot dogs, use carrots

-Instead of Steak or poultry, use cauliflower

-Instead of chicken, use Eggplant

-Eggplant has a meaty texture and there are tons of entrée recipes available.

-Instead of Fish or Chicken, use Tofu

-Tofu is a soy-based meat substitute high in protein that typically comes in a block and can be found in the refrigerated section at grocery stores. For a meat substitute, use the extra-firm tofu as the texture is a bit firmer. Tofu has little flavor on its own, so marinade/seasonings are important.

-Instead of Bacon or Beef, use Tempeh

-Tempeh is similar to tofu, but it's fermented so it's more flavorful. It has a meatier texture than tofu, also, and is nutrient dense.

-Instead of Chicken, use Seitan

-Seitan (also called "wheat meat" or "wheat gluten") is a wheat-based (rather than soy-based such as tofu or tempeh) meat substitute that has meaty texture and can replace many meat products without notice in recipes.

More recently with research showing such strong evidence supporting plant-based diets, several companies have created meat substitutes which are available at local grocery stores. Some examples of these are:

-Beyond Burger/Beyond Sausage

-Impossible Burgers/Sausage

-IncuMeato by MorningStar

APPENDIX G: IRB

University of Tampa IRB: Research Proposal NUR703

Title of Proposal:

A Pilot Quality Improvement Project: Implementing a Plant-Based Nutrition Program in Patients with Cardiovascular Disease

Principal Investigator Name:

Krystene Menzies, ARNP, DNP Student

Department: College of Nursing

E-mail: krystene.menzies@spartans.ut.edu

Role at the University of Tampa: Doctor of Nursing Practice Student

This research involves co-investigators: Yes x No

Co-investigators Name(s): Dr. Cindy Parsons

If the Principal Investigator is a student, a faculty member must be named as a co-investigator

CITI Training *

- X - All investigators named above have completed CITI training

Funding:

- - This project is NOT being funded by a grant or some other source.

Date project will begin: (Date format: MM/DD/YYYY)

 01/01/2021

Date project will end: (Date format: MM/DD/YYYY)

 01/01/2022

What level of review is appropriate for your proposal? The UT IRB has three levels of review: 1) Full, for research the deals with very sensitive topics, special populations,

or involves risk to the participant; 2) Expedited, for research where anonymity cannot be assured, involves deception, or that involves children; and 3) Exempt, for research on normal adult participants, where the anonymity of responses is assured, and there is little risk.

Level of Review Requested

- X - Expedited or Full Review
- ☐ Exempt Review (if selected, you will be prompted to ensure criteria)

1. **Study Description:** Clearly and completely describe your study, using language easily understood by someone who is not familiar with your research. State the purpose for conducting the study, including hypotheses, and describe its design:

Coronary artery disease (CAD) is defined as the buildup of plaque in the coronary arteries which can cause narrowing and obstruct the blood flow to the heart vessels (ACC, 2017). CAD affects about 18.2 million Americans and accounts for 647,000 deaths annually, making it the leading cause of death in the United States (CDC, 2019). Those most at risk for the development of coronary artery disease are people diagnosed with diabetes, hypertension, hyperlipidemia, and obesity, in addition to people with risk factors of physical inactivity, excessive alcohol consumption, and unhealthy eating habits (Madigan, 2016).

Research has shown that plant-based nutrition (PBN) can help prevent, treat, and even reverse coronary artery disease, as well as decrease the risk factors which contribute to CAD (Madigan, 2016). Plant-based nutrition is defined as a diet consumed from plants, which is rich in vegetables, fruits, whole grains and legumes with elimination of meat products (Nutrition Facts, 2020). The American Heart Association Dietary Guidelines now recommend vegetarian diets for lowering cardiovascular risk factors as studies have now identified improved cardiovascular outcomes in those patients who follow plant-based diets (Satija & Hu, 2018).

There is sufficient research available showing the cardiovascular benefit associated with plant-based nutrition; however, there appears to be a gap with implementation (Cramer et al., 2017). Therefore, the identified gap is how to incorporate current evidence-based knowledge of the benefits of plant-based nutrition into the diets of those identified with CAD. The population is not following plant-based diets despite much research showing the benefits of PBN. Reasons may include: a lack of education about plant-based nutrition, the stigma that accompanies vegetarian or vegan diets, cost, access to food, difficulty preparing plant-based meals, and lack of interest despite the proper education (McHugh et al., 2019). A proposed solution to bridge this gap is by means of one on one education with patients in a clinical setting, written handouts, dietary guidance, and follow-up office visits.

The goal of this DNP project is to increase awareness in the patient population to encourage plant-based nutrition as a foundation for overall health and reduction of cardiac risk factors. In one outpatient cardiology practice, the plan is to teach patients about the benefit of eliminating meat intake with emphasis on plant-based nutrition in its place. During the initiation phase of the project, the nurse practitioner will conduct a

thirty minute visit educating the patient about what constitutes a plant-based diet and the participants will be given handouts with resources and dietary recommendations. Outcomes will be evaluated at the conclusion of an eight week time period to reassess the patient's knowledge as well as determine any barriers to adhering to plant-based diets.

This study's purpose is to investigate how implementing a plant-based educational program will affect participants' knowledge and adherence to plant-based diets. This is a single-group interrupted time-series descriptive research study design with convenience sampling. At the conclusion of the study, an exit survey will be required asking the participants if they were able to adhere to the plant-based diet and if not, what were the barriers they experienced with adhering to plant-based nutrition. There will also be a pre and post PBN test to evaluate the knowledge base of the participants before and after following a plant-based diet for eight weeks.

PICOT Question

In an outpatient cardiology practice, how does implementing a plant-based nutrition educational program for patients identified with coronary artery disease affect their knowledge base after an eight week time period?

Research Questions

- 1) How does implementing plant-based nutrition educational program affect participant's knowledge about plant-based diets?
- 2) How does implementing plant-based nutrition program affect attitudes and beliefs about plant-based nutrition?
- 3) What effect does implementing a plant-based educational program have on patients' adherence to plant-based diets?

Hypothesis

Adults who have been diagnosed with cardiovascular disease who participate in a plant-based nutrition education program will have an increase in knowledge about plant-based diets over an eight week time period.

2. **Research Participants:** Describe the participants you plan to recruit and the selection criteria. Indicate age of participants, the approximate number to be recruited, and any special inclusion or exclusion criteria.

This study will recruit adult patients between ages 18 and 75 years old who are willing to implement an eight week plant-based nutrition diet. These patients will be recruited from one outpatient cardiology clinic in Safety Harbor, Florida. This will be a convenience sampling. The inclusion criteria include adult patients between ages 18 and 75. The exclusion criteria would include pregnant or breastfeeding mothers, patients with unstable iron deficiency or pernicious anemia, patients being anticoagulated with a Vitamin K antagonist, or those with a BMI < 18.5. This study will enroll ideally 30-50 participants. Patients who uninsured or underinsured will also be

excluded unless they sign a waiver accepting financial responsibility for office visit costs.

3. **List any expenses or remuneration paid to or in behalf of subjects, if any.**

There will be no expenses to be paid or on behalf of enrollees. Office visit costs will be covered by the participants' insurance or out of pocket cost will be covered by the participant if they are uninsured.

4. **Method of Data Collection:** Describe all procedures participants will do, indicating the time necessary to complete them, the frequency of administration, and the setting in which they will be administered. The surveys, interview questions, and other materials to be administered to the participants will be attached at the end of this form.

The patient will spend 30 minutes with the provider discussing the benefit(s) of plant-based nutrition including dietary choices to replace meat in diets. The enrollee will also be given written information regarding diet recommendations, educational resources including websites, books, & applications, and information for recipes. Attached are copies of handouts to be given to the participants including resources and nutrition guidance. Following the conclusion of an eight week time period, the patients will take a survey which should not take longer than thirty minutes to complete to evaluate the amount of meat they consumed on a daily basis to see if there is indeed an increase in plant-based nutrition adherence following implementation of an educational program. The survey will also ask the participants to describe what aspects of following a plant-based diet were found to be difficult, if any. There will be a pre and post test administered to evaluate knowledge about plant-based nutrition to the participants which should not take longer than thirty minutes to complete.

5. **Risk Level:** Describe any physical, psychological, social risks, if any, and precautions taken to minimize risks. Exempt studies have at most minimal risks (i.e., those encountered in daily life).

There are no physical risks known with this study. There is a potential for psychologic risk as patients could potentially feel anxious about adhering to a plant-based diet in addition to possible feelings of guilt if they are unable to follow through with plant-based nutrition. A potential social risk is that in many social settings or group gatherings, emphasis is placed on food or meals as a mainstay of a social event and those on a plant-based diet may feel excluded from social events if they cannot consume meat. In an attempt to minimize this risk, participants will be advised in their initial counseling session to ask if there will be meat free options at social events and if not, bring their own form of sustenance.

6. **Confidentiality**: Describe the measures you will take to protect the confidentiality of the information obtained. Also indicate if the data will be recorded anonymously (exempt studies must be anonymous. Note that confidentiality (how the data may or may not be shared) is not the same as anonymity (data cannot be traced back to any individual participant). Exempt studies must be anonymous.

All patient information will remain anonymous. Data collected for this study will be confidential and only the primary investigator will have access to data files. The participants will be identified by number in these files without any personal information shared. The participants will sign the consent form identifying them as participants and these forms will be stored in a locked filing system apart from the data files. No attempts will be made to contact participants once the study has ended. The data will be disposed of after a period of one year.

7. **Benefits**: Describe any benefits to the research participants directly or benefits to society.

The participants will likely benefit by reflecting on their daily food choices and gain knowledge about dietary choices. The participants will also be held accountable for improved dietary choices as they will be surveyed at the conclusion of their eight week period to assess whether or not they adhered to a plant-based diet. Participants may also benefit by achieving a reduction in cardiac risk factors.

APPENDIX H: INFORMED CONSENT

INFORMED CONSENT FORM NUR703 THE UNIVERSITY OF TAMPA

Project Title: A Pilot Quality Improvement Project: Implementing a Plant-Based Nutrition Program in Patients with Cardiovascular Disease

Principal Investigator: Krystene Menzies, DNP Student, University of Tampa

Purpose of Project: The goal of this project is to use evidence-based practice to demonstrate how implementing a plant-based nutrition educational program in participants' diet will affect their knowledge base and adherence to plant-based diets over an eight week period.

Procedures: All study procedures will take place at one outpatient cardiology clinic in Safety Harbor, Florida. The participants will receive both verbal education and written material regarding plant-based nutrition, which they are asked to implement for a period of eight weeks. At the introduction and then again at the conclusion of this eight week period of time, they will be given the same knowledge based quiz to evaluate if their knowledge about plant-based nutrition improved after eight weeks of plant-based eating. Furthermore, the participants will be surveyed to determine if they were able to adhere to plant-based diets for eight weeks, and if not, what barriers they experienced.

Risks/Benefits: There are no known potential physical harm issues with this study. The only psychologic or social risks identified are possible feelings of guilt if unable to adhere to plant-based nutrition or feelings of isolation or anxiety if participants feel they cannot consume meat in social settings with others. The participants will likely benefit by reflecting on their daily food choices and gain knowledge about dietary choices. The participants will also be held accountable for improved dietary choices as they will be surveyed at the conclusion of their eight week period to assess whether or not they adhered to a plant-based diet. Participants may also benefit by achieving a reduction in cardiac risk factors.

Confidentiality: Data collected for this study will be confidential and only the primary investigator will have access to data files. The participants will be identified by number in these files without any personal information shared. The participants will sign the consent form identifying them as participants and these forms will be stored in a locked filing system apart from the data files. No attempts will be made to contact participants once the study has ended.

CONDITIONS OF PARTICIPATION

Participating in this project is voluntary, and refusal to participate or withdrawing from participation at any time during the project will involve no penalty or loss of benefits to which the subject is otherwise entitled. The principal investigator may terminate participation of a subject or the project entirely without regard to the subject's consent. In the event of questions or difficulties of any kind during or following participation, the subject may contact the Principal Investigator as indicated above.

I. CONSENT

I have read the above information and my questions and concerns, if any, have been responded to satisfactorily by project staff. I believe I understand the purpose, benefits, and risks, if any, of the study, and give my informed and free consent to be a participant.

PARTICIPANT SIGNATURE

DATE

RESEARCHER SIGNATURE

DATE

THIS RESEARCH PROJECT HAS BEEN APPROVED BY THE INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS OF THE UNIVERSITY OF TAMPA (Phone: 813-253-3333)

Debriefing Statement

Thank you for participating in this study. Its purpose is to investigate how implementing a plant-based nutrition educational program will affect participants' knowledge and adherence to plant-based diets as research has shown that plant-based diets can effectively treat and even reverse heart disease and its risk factors. This study will be conducted over an eight week time period. Education (verbal and written) will be provided during an initial office visit, teaching participants about plant-based nutrition. In addition, participants will be given information with websites, books, cookbooks, and applications for mobile phones or tablets to assist with plant-based recipes and meal ideas.

Furthermore, this project aims to determine what barriers participants experienced (if any) while following a plant-based diet to provide guidance to future patients, which will be determined in a follow-up survey at the conclusion of the project. A pre and post-test will also be given regarding plant-based diets to evaluate if participants have increased knowledge about plant-based nutrition after following a plant-based diet for eight weeks.

This is ongoing research so please do not discuss the materials and research rationale with friends or peers.

If you would like further information about this research or have questions or concerns, please feel free to contact Dr. Cindy Parsons by email at cindy.parsons@ut.edu.

APPENDIX I: SURVEY

Post-Project Plant-based diet Survey

DIRECTIONS: Please answer as accurately as possible in the space provided.

1. Were you able to adhere to a plant-based diet for 8 weeks?

YES

NO

If no, please list what were barriers to sticking with the diet?

Cost	Accessibility	Variety	Prep time	Stigma	Other:
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2. Were you able to easily find recipes and meal ideas for plant-based meals?

YES

NO

3. Were you able to find plant-based meals in restaurants?

YES

NO

4. What are your favorite ingredients for plant-based cooking?
-

5. Was cost an issue with plant-based nutrition?

YES

NO

6. Did you notice improvement in energy levels or other positives while following plant-based nutrition? If yes, please explain.

YES

NO

7. Do you plan to stick with the plant-based diet?

YES

NO

APPENDIX J: KNOWLEDGE SURVEY

Plant-Based Nutrition Knowledge Survey

DIRECTIONS: Please answer these questions to the best of your ability.

1. Plant-based diets are diets which do not include meat products.
True False
2. Plant-based diets include only fruits and vegetables.
True False
3. Plant-based diets are not practical.
True False
4. Plant-based nutrition is only for people who care about animal rights.
True False
5. Plant-based diets do not provide enough protein.
True False
6. I cannot consume alcohol when following a plant-based diet.
True False
7. There are no plant-based restaurants.
True False
8. Plant-based diets are considered heart healthy.
True False
9. Plant-based diets can aid in weight loss.
True False
10. Plant-based diets can manage and even reverse risk factors for heart disease (high blood pressure, high cholesterol).
True False

APPENDIX K: AFFILIATION AGREEMENT

THE UNIVERSITY OF TAMPA

DEPARTMENT OF NURSING BACCALAUREATE AND GRADUATE PROGRAMS

AGREEMENT OF AFFILIATION

THIS AGREEMENT made and entered into between THE UNIVERSITY OF TAMPA, INC., whose office is located at 401 West Kennedy Boulevard, Tampa, FL 33606, hereinafter referred to as the "University" and:

AGENCY Clearwater Cardiovascular Consultants
CONTACT Kathy Healy TITLE office manager
COMPLETE MAILING ADDRESS 1840 Mease Drive Suite 202, Safety Harbor, FL
PHONE: 727-725-6246 E-MAIL: Healeyh@cccheart.com 34695

Hereinafter referred to as the "Agency":

WHEREAS the University is desirous of using the facilities of the Agency to implement a Baccalaureate of Science in Nursing Program and a Masters of Science in Nursing Degree Program and,

WHEREAS, the Agency shall cooperate with the University in implementing the above named programs, NOW, THEREFORE, the parties do hereby agree as follows:

THE RESPONSIBILITIES OF THE UNIVERSITY ARE:

1. To arrange with the facility to provide for a clinical preceptor for all regularly scheduled experiences for students.
2. To provide the agency annually with information as to the number of students for whom clinical experience is being requested during the ensuing year and the times when the Agency is needed for experience. Detailed plans will be submitted prior to each semester. The Agency will be provided course objectives and all other course materials necessary to plan appropriate learning experiences.
3. To observe appropriate Agency channels as designated by the Director of the Nursing Department for planning experiences.
4. To have faculty participate in individual and/or group conferences with appropriate Agency staff for the purpose of discussing objectives and planning for the learning experiences and for evaluating student performance.
5. To assure that faculty and students are oriented to the Agency, including its policies and procedures, and that they comply with the policies and procedures of the Agency. In addition, the faculty will be responsible to nursing service administration for the quality of care given by the students.
6. To provide professional liability insurance coverage for University and staff and students according to the University's professional liability insurance policy.
7. To require that all students have malpractice insurance.
8. To require that students and faculty meet the requisite health requirements.
9. To have its representatives meet with the administrators of the Agency for review when requested by either party.

(SIGNATURE NEEDED ON REVERSE SIDE>>>>>)

THE RESPONSIBILITIES OF THE AGENCY ARE:

1. To make its resources and facilities available for clinical experiences for students enrolled in nursing at the University.
2. To cooperate with the University faculty in planning for the educational program and for evaluating the experiences and student performance.
3. To retain overall responsibility for quality of patient care and assure that faculty and students adhere to Agency standards.
4. To orient faculty and students to the philosophy, policies, and standards of the Agency.
5. To provide documentation of Florida State Licensure type and/or name of accrediting agencies.

THE AGENCY AND UNIVERSITY FURTHER AGREE THAT:

1. The assignment of students and faculty will be made without regard to race, creed, color, sex, or national origins of persons involved.
2. The agency may request the University to withdraw a student whose conduct or nursing practice does not meet standards for continuation in the program.
3. The University may withdraw any student whose progress, conduct, or performance in nursing practice does not meet standards for continuation in the program.
4. Agency personnel may serve as resource persons in the educational program for students in a manner consistent with the maintenance of the standards of patient care and the goals of the educational program.
5. Faculty can be withdrawn from the Agency at the request of the Agency.
6. Any medical care provided to students or faculty will be done so at the expense of the student, faculty or the University of Tampa.
7. This agreement will remain in force until terminated upon the giving of thirty (30) days written notice by either party to the other party. Students already enrolled and participating in the program shall have an opportunity to complete the program at the Agency to meet the course of student requirements for graduation.
8. Contracts will be updated on a biannual basis or at the request of either agency.

SIGNATURES:

Date _____

David Stern, Ph.D.
Provost and Vice President, Academic Affairs
The University of Tampa

Date _____

Carol A. Botwinski, Ed.D., APRN
Director, Department of Nursing
The University of Tampa

Date 7.31.2020

Kathleen Healey
Executive Officer – Affiliating Agency

(rev. 5.2018)

APPENDIX L: AIMS AND OUTCOMES

AIM 1: Educate the clinical staff (physicians, advanced practice providers, medical assistants and nurses) at cardiology office about plant-based diets and its role in overall health and the specific beneficial cardiovascular effects of plant-based nutrition.

OUTCOME 1a: 100% of clinical staff members in the cardiology clinic are to receive education about plant-based nutrition including the cardiovascular benefits during a brief breakfast meeting before clinic one morning to provide verbal education.

MEASURE 1a: Attitudes and beliefs will be measured about the clinical staff's perception and understanding of plant-based nutrition.

Calculation of measure 1a: Attitudes and beliefs will be measured by means of asking the clinical staff their thoughts about plant-based nutrition on an individual basis.

AIM 2: Educate the participants (patients from a pool of every provider's patients in the cardiology practice) about plant-based diets including the evidence-based benefits, resources available to aid in implementing plant-based diets, and recipes. These patients are to be selected from any provider's patient list in the clinic as all providers will receive education about plant-based diets and can then refer potential participants for the study.

OUTCOME 1a: At least 90% of patients will be screened to assess their interest in learning more about plant-based diets and then directed to DNP student.

MEASURE 1a: Pre and post tests would be provided before and after education to evaluate their knowledge about plant-based nutrition

Calculation of measure 1a: Percentage of knowledge would be calculated on pre and post tests; calculation of difference in scores using paired t-test to determine significance.

AIM 3: Evaluate the participants' experience on plant-based diets and what barriers (if any) they found while following a plant-based diet.

OUTCOME 1a: 80% of participants will have made an attempt at transitioning to a plant-based diet.

MEASURE 1a: Post-study survey to determine if the participants were able to adhere to a plant-based diet and if not, what barriers they experienced that hindered their ability to commit to plant-based nutrition.

Calculation of measure 1a: Track information through post study evaluation based on experience following plant-based diet

