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## The Impact of a Heart Healthy Diet on the Development of Heart Disease

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**The Impact of a Heart Healthy Diet on the Development of Heart Disease**

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NURS 4500: Nursing Research and Senior Thesis

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December 10, 2021

## **Abstract**

Heart disease is the leading cause of death in the United States. Both modifiable and non-modifiable risk factors contribute to the development of this disease. One modifiable risk factor is diet. Potentially, the right diet, i.e. one that is deemed heart healthy, can aid in the prevention of heart disease.

This thesis aims to determine what constitutes a heart healthy diet. First, a literature review related to the use of diet and nutrition for the prevention of heart disease will be provided. Next, this thesis will present a research proposal for a longitudinal study that will compare five-year and 10-year outcomes for a group of people who follow a diet defined as heart healthy, compared to a group of people who follow their usual eating patterns. This proposed study will plan to include 200 people, 100 men and 100 women. Participants will be divided into either a control group or an experimental group. The control group will be allowed to continue their usual diet whereas the experimental group will follow a carefully monitored heart healthy diet. A follow-up will be done after one year, five years, and at 10 years to determine how many people from each group develop heart disease.

**Table of Contents**

Introduction	4
Purpose Statement	5
Research Questions	5
Literature Review	5
Theoretical Framework	11
Research Aim	12
Ethical Considerations	12
Methods	13
Discussion	15
Conclusion	16
References	17
Appendix	19

## Introduction

The leading causes of death in the United States (U.S.) have shifted from communicable to non-communicable diseases. This is due to the use of vaccines and antibiotics, which are forms of primary prevention. Primary prevention is the prevention of developing a disease and can be implemented for all types of diseases. Currently, heart disease is the leading cause of death in the U.S. Primary prevention of heart disease focuses on choosing healthy lifestyle habits in order to decrease the risk of the development of heart disease. Among these healthy lifestyle habits, following a healthy diet is reported to be one of the top ways to prevent heart disease.

According to the U.S. Centers for Disease Control (CDC), 659,041 deaths were caused by heart disease in 2019, the #1 cause of death (CDC, 2021). The cost of health care services, medicines, and lost productivity due to death from heart disease costs the U.S. about \$219 billion each year (CDC, 2021). People at high risk for heart disease include those with diabetes as well as those who are overweight, follow an unhealthy diet, are physically inactive, and who drink alcohol excessively. A diet that is full of fruits and vegetables, whole grains, nuts, fish, poultry, and vegetable oils; includes alcohol in moderation; and goes easy on red and processed meats, refined carbohydrates, foods and beverages with added sugar, sodium, and foods with trans-fat is offered as the best hope for the prevention of heart disease.

One segment of the U.S. population that appears to be particularly impacted by heart disease is the South Asian ethnic group. According to Stanford Healthcare (2021), South Asians have a 40% higher chance of mortality from myocardial infarction compared to the rest of the population, and 50% occur in South Asian patients who are younger than 50 years old. Further, in California, people of South Asian descent are hospitalized for coronary artery disease at a rate four times higher than any other ethnic population.

## **Purpose Statement**

The purpose of primary prevention is to prevent disease before it occurs. Focusing on primary prevention for heart disease — as the leading cause of death in the U.S. — may decrease the number of people who experience this disease and lower health care costs. The same can be said for all types of diseases in which causes and risk factors can be identified. Primary prevention can prevent the disease itself, therefore eliminating the need for treatment after a disease develops.

In the case of heart disease, referring primarily to coronary artery disease, also known as coronary heart disease or ischemic heart disease, there are ways to decrease the chances of developing the disease, and therefore reduce other complications often associated with heart disease. Among the modifiable risk factors is diet. Nurses can start promoting good nutrition habits for people at a young age to help reduce the development of heart disease as well as other adverse health conditions. By focusing on modifiable lifestyle changes, nurses potentially also promote an overall greater sense of well-being.

## **Research Question**

How effective is practicing good nutrition habits, using a heart healthy diet, in preventing heart disease in South Asians living in California?

## **Literature Review**

The objective of this literature review is to explore the research, clearly define “healthy nutrition habits” and identify a diet that is "heart healthy," and determine whether there is a correlation between healthy nutrition and the prevention of heart disease.

A number of search terms were used to find articles that are related to the topic. Search terms include: “prevention,” “heart disease,” “nutrition habits,” “coronary artery disease,” “lifestyle changes,” “cardiovascular disease,” and “diet prevention.” Electronic databases and websites were searched to find relevant articles. Online sources include the American Heart Association, Journal of the Academy of Nutrition and Dietetics, the European Heart Journal, the New England Journal of Medicine, and the American Medical Association. Thousands of articles were discovered using the search terms listed above. The search produced secondary reviews as well as primary studies. After eliminating reviews, the number of articles was narrowed down. Only peer-reviewed articles were included. To help ensure that seminal or groundbreaking work was incorporated, there was no restriction for dates in the search. The titles and abstracts were screened to determine which articles were most relevant to the objective. A total of six articles were chosen to be used for this review.

The articles are split into two categories. The first category focuses specifically on diet and nutrition in relation to the prevention of heart disease. The articles within this category take into account what the participants consume and how their consumption relates to the presence of heart disease. The design of these studies supports the objective of this review and the results support the idea that there is a correlation between healthy nutrition and the prevention of heart disease. The second category includes articles that provide evidence on the prevention of heart disease through lifestyle changes. The studies in this category further support the objective from a broader perspective by not focusing only on diet and nutrition, but other factors as well. Diet and nutrition are a part of the lifestyle changes that these articles reflect on, which is why they remain relevant. See Appendix A for a Literature Review Table summarizing each article.

## **Category I: Diet and nutrition in relation to the prevention of heart disease**

Four research articles are chosen for this first category because they focus on specific foods and/or diets and the prevention of heart disease. The diets that the articles focus on are a “heart healthy diet,” fruit and vegetable intake, and a Mediterranean diet. These studies include large sample sizes, which increases generalizability.

The objectives of the first study are to investigate the relationship between a heart-healthy dietary pattern and subclinical heart disease in women and to identify potential opportunities for primary prevention (Millen et al. 2004). This longitudinal, correlational study involved 1,423 women in the Framingham Offspring/Spouse (FOS) Study cohort in Framingham, Massachusetts who did not have cardiovascular disease (CVD) at baseline. Dietary patterns and cardiovascular disease risk factors were assessed at the baseline. At a 12-year follow-up, the presence of sub-clinical heart disease was assessed using carotid atherosclerosis measured by ultrasound. It was found that women who ate a heart-healthy diet had more favorable baseline CVD risk factor profiles. The age-adjusted odds of subclinical heart disease at follow-up was 40% lower for heart-healthy women. This article also included an analysis stratified by smoking status, which showed that women who consumed a heart-healthy diet and who had never smoked had more than 80% less odds for subclinical heart disease compared with smokers whose diets were less heart-healthy (Millen et al. 2004). Although the study is 14 years old, this article was included because the study was among the first to focus on women and sustained a long follow up period (12 years).

The second study by Crowe and Roddam (2011) assessed the relation between fruit and vegetable intake and risk of mortality from ischemic heart disease (IHD) in the European Prospective Investigation into Cancer and Nutrition (EPIC)-Heart study. In the study, 519,978 men and women were recruited by 23 collaborating centers in 10 European countries between 1992 and 2000. This study found that there was a significant association between fruit and veg-

etable intake and lower risk of fatal IHD. Participants who consumed at least eight portions of fruits and vegetables per day had a 22% lower risk ratio (RR) of fatal IHD compared with those consuming fewer than three portions a day. Each portion increment in the consumption of fruits and vegetables was associated with a 4% lower risk of dying from IHD (Crowe & Roddam 2011).

The third study was performed in Spain. Estruch and his research team (2013) tested the efficacy of two Mediterranean diets (one supplemented with extra-virgin olive oil and another with nuts), as compared with a control diet (advice on a low-fat diet), on primary cardiovascular prevention. Eligible participants were men 55 to 80 years of age and women 60 to 80 years of age with no cardiovascular disease at enrollment, but who had either type 2 diabetes mellitus or at least three of the following major risk factors including smoking, hypertension, elevated low-density lipoprotein cholesterol levels, low high-density lipoprotein cholesterol levels, overweight or obesity, or a family history of premature coronary heart disease. The researchers enrolled a large number of participants, 7,447, including 57% women. The major finding of this research was that among persons at high cardiovascular risk, a Mediterranean diet supplemented with extra-virgin olive oil or nuts reduced the incidence of major cardiovascular events (Estruch et al., 2013).

The fourth study by Lorgé et al. (1999) tested whether a Mediterranean-type diet may reduce the rate of recurrence after a first myocardial infarction. Six hundred five survivors of a first myocardial infarction were enrolled. Participants were randomized into either a control or a Mediterranean group. In this study, a specific design was used to recruit and randomize the patients without informing them and their physicians that they were participating in a comparative trial. Results indicated that the protective effect of the Mediterranean dietary pattern was maintained up to four years after the first infarction, supporting previous intermediate analyses (Lorgé et al., 1999).

### ***Summary of Category I Research***

Information obtained from the review of the studies in Category I provided enough data to help narrow down specific nutritional patterns and provide insight in to dietary prevention methods. These articles added to the definition of a “heart healthy diet” and distinguished other risk factors associated to the development of heart disease. The research is applicable to men and women who have risk factors for heart disease as well as those who do not.

### **Category II: Evidence on the prevention of heart disease through lifestyle changes**

The articles of Category II discuss indirectly how nutrition can prevent heart disease. They focus on “lifestyle habits,” which include nutrition. These studies take into account risk factors for heart disease, such as smoking and BMI.

The purpose of the first study in this category, by Canoy et al. (2007) was to examine the prospective relation between fat distribution indices and coronary heart disease using proportional hazards regression. In this study, 24,508 men and women 45 to 79 years of age living in Norfolk, UK were recruited from general practice registers during 1993–1997. At the clinic visit, trained research nurses took anthropometric measurements on individuals using a standard protocol, blood pressure, and measured serum lipid concentration from non-fasting blood samples. Participants completed a health and lifestyle questionnaire indicating any family history of heart disease or physician-diagnosed prevalent diseases such as heart attack or myocardial infarction, stroke, and diabetes mellitus. Cigarette smoking habit, physical activity level, and alcohol intake were assessed. After a mean follow-up of 9.1 years, there were 2,600 coronary heart disease events (662 fatal and 1938 nonfatal) with 1,708 events in men (27.6% fatal) and 892 events in women (21.4% fatal). When categorized into fifths, an increasing risk for coronary heart disease was observed across the whole range of waist-hip ratio with no apparent threshold in both men and women (Canoy et al., 2007).

The objective of the second study in this category was to determine the feasibility of patients to sustain intensive lifestyle changes for a total of five years and the effects of these lifestyle changes (without lipid-lowering drugs) on coronary heart disease. This work by Ornish and his team of researchers was performed in the U.S. and was among the first to closely examine the potential for actual reversal of disease in addition to prevention. Patients who were diagnosed with moderate to severe coronary heart disease were recruited for this study. Experimental group patients made and maintained comprehensive lifestyle changes for five years, whereas control group patients made more moderate changes. The conclusions were that in the experimental group regression of coronary atherosclerosis occurred after one year and continued to occur during the five year study period. In contrast, in the control group, coronary atherosclerosis continued to progress and more than twice as many cardiac events occurred (Ornish et al., 1998).

### ***Summary of Category II Research***

The articles in category II broaden the understanding of what can be done to prevent heart disease from developing or worsening. This is done by using surveys to identify present risk factors and comparing interventions done in groups with and without these risk factors. The interventions performed in these studies go beyond assessment of nutrition and dietary habits. By including assessments with anthropometric measurements, blood pressure, and serum lipid concentration, these studies allow for a more in depth understanding of what can be done to prevent heart disease. In addition, the research provides evidence that patients can maintain a heart healthy diet with proper support.

### **Summary of the Research Literature**

Over all, the literature showed that adherence to a heart healthy diet can help prevent heart disease. The Mediterranean Diet was used as an example of a healthy pattern of eating in two studies (Lorgeril et al., 1999; Estruch et al., 2013) and is worthy of further investigation.

## Theoretical Framework

The Health Promotion Model is a key theory used for this study. The model was initially developed in 1982 and it was revised in 1996. The model was designed by Nola J. Pender to be a “complementary counterpart to models of health protection” and is directed at increasing a patient’s level of well-being (Petiprin, 2020). Health promoting behavior is the desired behavioral outcome, which makes it the end point in the Health Promotion Model. These behaviors should result in improved health, enhanced functional ability and better quality of life at all stages of development. A theoretical statement that comes from the model is “Prior behavior and inherited and acquired characteristics influence beliefs, affect, and enactment of health-promoting behavior” (Petiprin, 2020, para. 4).

This model relates to the study because the study focuses on how behavior can affect one’s health in the future. This study will specifically focus on how behavior relating to nutrition will lead to better quality of life demonstrated by the absence of heart disease. This model can also be used to explain other health benefits that arise from following a certain behavior that promotes health. The model emphasizes that prior behavior can influence actually participating in the health-promoting behavior. People who are likely to engage in a healthy diet are likely to follow other healthy habits such as exercising and limiting the use of alcohol and tobacco.

A borrowed theory is also used to frame this study. Maslow’s Hierarchy of Needs is a motivational theory in psychology. It consists of a five-tier model of human needs. From the bottom of the hierarchy upwards, the needs are: physiological, safety, love and belonging needs, esteem, and self-actualization. Needs lower in the hierarchy must be satisfied before individuals can attend to needs higher up (McLeod, 2020, para. 2). Once that level is fulfilled, the next level up is what motivates us.

This study will blend these two theoretical frameworks to demonstrate how fulfilling the physiological need will bring people up the tiers and attain needs higher up. Physiological needs

are our requirements for survival, and consist of air, food, drink, shelter, clothing, warmth, sex, and sleep. If these needs are not satisfied, the human body cannot function optimally. This relates to the study because when people fulfill the bodily need of food, they can go on to achieve higher levels of health. The development of heart disease is not only associated with a healthy diet but is also influenced by other lifestyle habits as well as stress. Psychological needs are higher up in the model, so in relation to the study, following a heart healthy diet meets the body's basic needs so that higher levels of health promotion can be achieved. When higher needs are attended to, a person's conscious capacity can expand to include the experience of self-actualization.

### **Research Aim**

- To determine the effectiveness of the Mediterranean diet for maintaining a healthy heart in the South Asian population who lives in California.

### **Ethical Considerations**

This study will be reviewed by the Dominican University Institutional Review Board (IRB) and the Kaiser Permanente Healthcare IRB for ethical considerations. IRB approval will be obtained prior to the start of data collection. A study identifier will be assigned to each participant to help ensure that private health information is protected, and that confidentiality is maintained. For people who agree to participate, medical records will be examined to obtain the participants' medical history and background. The longitudinal design of this study could create a burden. The need for records and the time commitment will be fully explained to potential participants. Potential participants also will be notified that they are allowed to withdraw from the study at any time. Informed consent will be needed from potential participants prior to joining the study.

## **Methods**

### **Participants**

The participants of this study will include men and women between the ages of 20 and 55 who belong to a South Asian ethnic group. Exclusion criteria includes having a family history of heart disease.

### **Population**

The sample will represent those belonging to a South Asian ethnic group living in California who receive healthcare through the Kaiser Permanente Healthcare System.

### **Design**

For this study, a quantitative, prospective, longitudinal randomized clinical trial is proposed.

### **Recruitment**

This study will be focused on the development of heart disease in South Asian people who have no family history of heart disease. The recruitment will start by finding adults in California who are not already at risk for developing heart disease or have other factors that contribute to heart disease. Recruitment will continue until 100 males and 100 females are enrolled, or after six months, whichever comes soonest.

The researcher will partner with four hospital centers in the Kaiser Permanente Healthcare System, a state-wide provider of healthcare that promotes healthy living, to screen for candidates for participation at their outpatient clinics. Two of the Kaiser facilities will be located in Northern California and two will be located in Southern California. Primary care providers will be provided with informational flyers about the study, which will be made available to patients in the waiting room or front desk of the offices. The flyers will contain a link to a screening survey that will request information about the potential participant's name, ethnicity, and personal and family heart health history. After sorting out people who do not meet inclusion criteria, and filter-

ing in those who qualify, potential participants will be invited to a face-to-face meeting to explain the research study and obtain informed consent. Participants will be notified of the background of research, the aim of the study, what to expect during the study, and why the study is useful for the greater good.

### **Sample Size**

A total of 200 participants will include 100 men and 100 women; 50 men and 50 women will be in the control group and the remaining will be placed in the intervention group.

### **Method**

The intervention group will receive three two-hour educational sessions that will take place once per week for three weeks. The sessions will teach about the benefits of a heart healthy Mediterranean diet and provide cooking tips and menus to follow. The control group would resume their usual diet habits. Both groups will be asked to keep a diet log. A nutrition history and assessment, a physical exam, an electrocardiogram (ECG) and a lipid panel will be obtained at baseline for all participants. A follow-up that includes checking the diet log and the lipid panel will be performed at three-months and six months. At one-year, the nutritional assessment, physical exam, ECG, and lipid panel will be repeated. For the intervention group, a survey will be provided to gather information on what the participants are experiencing and how well they are adhering to their diet regimes. Questions will ask participants in the intervention group to rank their responses on a five-point Likert scale (1 = complete agreement to 5 = complete disagreement). Example questions are:

- Rate how well:
  - you have adhered to your diet regimen
  - enjoy food offered on the Mediterranean diet
  - you feel about your health overall
  - you feel about your heart health in particular

Follow-up on all measures will be performed annually for an additional nine years (providing 10 years of data) to check adherence, assess lipid profile, cardiovascular status, and examine risk factors associated with the development of heart disease.

### **Data Analysis**

The results of this study will be analyzed using descriptive statistics, mean, median, mode, and frequency distributions. The outcome measures for the two groups will be compared using independent sample t-tests.

### **Discussion**

It is expected that participation in following a heart healthy diet will lead to a lower chance of the development of heart disease. Unhealthy lifestyle factors play a major role in the development of heart disease. Atherosclerosis is the most common cause of coronary artery disease, and risk factors for it include high cholesterol and triglyceride levels, diabetes, obesity, and eating saturated fats. These risk factors all pertain to nutrition. By participating in healthy behaviors to target these risk factors, it is expected that the probability of the development of heart disease can be lowered and perhaps prevented. Data analysis will include using the statistics from the study to determine a correlation between following a heart healthy diet and the development of heart disease. At a 10 year follow up, that significant data will have been collected. The study will find out how many people out of each group developed coronary artery disease. Specific outcome measures will include evaluation of patients' physical assessment, lipid profile (cholesterol levels), and ECG change physical assessment (if any). The medical record will be checked for any new history of atherosclerosis or diagnosis of coronary artery disease. The data for the different groups will then be compared with each other to determine if there is a correlation between nutrition habits and heart disease.

## Conclusion

The research proposal can be used to promote health-promotion behaviors for other diseases as well. This study potentially will show the importance of adherence to a particular behavior to achieve higher levels of health. Education is also an important factor because it can determine whether or not people will adhere to the behavior. As the Health Promotion Model explains, health care providers are important sources of interpersonal influence that can increase or decrease commitment to and engagement in health-promoting behavior. By educating people on how following a heart healthy diet can prevent heart disease and even other diseases, people are more likely to engage in that behavior. This framework can be used to promote other healthy behaviors and prevent more disease.

The evidence in the literature review teaches that following a diet that is considered to be heart healthy can decrease the risk of developing heart disease. Even more importantly, it demonstrates the importance of education and adherence to healthy behaviors. This advances the profession of nursing because teaching is a skill that aligns well with service. The educational strategy that this thesis offers can be applied not only to prevention of heart disease, but to all types of diseases that have modifiable risk factors. Next steps for study might to look even deeper the role of diet as related to other risk factors of heart disease, such as having a high blood pressure, smoking, and exercise. Another area for further research is to examine how adoption of a healthy lifestyle can impact each risk factors on the development of the disease.

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## Appendix

Authors, Citations	Purpose, Objective of Study	Population of interest, Sample (N=Size)	Study Design	Study Methods	Major Finding(s)	Strengths	Limitations
<p>Canoy, D., Boekholdt M., Wareham N., et al. (2007). Body Fat Distribution and Risk of Coronary Heart Disease in Men and Women in the European Prospective Investigation Into Cancer and Nutrition in Norfolk Cohort. <a href="https://doi.org/10.1161/CIRCULATION-AHA.106.673756">https://doi.org/10.1161/CIRCULATION-AHA.106.673756</a></p>	<p>To examine the prospective relation between fat distribution indices and coronary heart disease using proportional hazards regression.</p>	<p>N=24,508 Men and women 45 to 79 years of age living in Norfolk, UK, who were recruited from general practice registers during 1993–1997</p>	<p>Quantitative: prospective, longitudinal and correlational</p>	<p>At the clinic visit, research nurses took anthropometric measurements on individuals using a standard protocol. BP and measured serum lipid concentration from non-fasting blood samples were obtained. Participants completed a health and lifestyle questionnaire indicating any family history of heart disease or physician-diagnosed prevalent diseases such as heart attack or myocardial infarction, stroke, and diabetes mellitus. Cigarette smoking habit, physical activity level, and alcohol intake were assessed.</p>	<p>After a mean follow-up of 9.1 years, there were 2,600 coronary heart disease events (662 fatal and 1938 nonfatal) with 1,708 events in men and 892 events in women. An increasing risk for coronary heart disease was observed across the whole range of waist-hip ratio with no apparent threshold in both men and women. BMI remained predictive of coronary heart disease, but risk estimates were greatly attenuated when fat distribution, biological mediating factors, and prevalent disease were considered.</p>	<ul style="list-style-type: none"> <li>- Large sample size increases generalizability</li> <li>- 9-year study of both men and women</li> <li>- Correlates association between BMI and heart disease</li> <li>- Includes adjustments of covariates.</li> </ul>	<ul style="list-style-type: none"> <li>- More accurate measures of fat distribution may be needed to improve risk assessment in specific subgroups in the population</li> <li>- Further studies are needed to assess to what extent central adiposity measurement can improve disease prediction with the use of existing coronary heart disease risk models.</li> </ul>

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<p>Crowe, F., Roddam, A., Key, T. (2011). Fruit and vegetable intake and mortality from ischaemic heart disease: results from the European Prospective Investigation into Cancer and Nutrition (8)-Heart study. <i>EHJ</i>, 32(11) 1235-1243. <a href="https://doi.org/10.1093/eurheartj/ehq465">https://doi.org/10.1093/eurheartj/ehq465</a></p>	<p>To assess the relation between fruit and vegetable intake and risk of mortality from IHD in the European Prospective Investigation into Cancer and Nutrition (EPIC)-Heart study.</p>	<p>N=519,978 Men and women were recruited by 23 collaborating centers in 10 European countries (Denmark, France, Germany, Greece, Italy, the Netherlands, Norway, Spain, Sweden, and the UK) between 1992 and 2000.</p>	<p>Quantitative, prospective, correlational</p>	<p>Dietary intake during the year before enrollment was measured by country-specific food questionnaires. They were calibrated using a 24 h diet recall method common to all centers. The second dietary measurement was administered via a face-to-face interview using a computerized 24 h diet recall method. Follow-up was analyzed from recruitment until the date of death from IHD or censoring at the date of death from other causes, emigration, other loss to follow-up, or the date at which follow-up was considered complete in each center.</p>	<p>Participants consuming at least eight portions of fruits and vegetables a day had a 22% lower RR of fatal IHD compared with those consuming fewer than three portions a day. Each portion increment in the consumption of fruits and vegetables was associated with a 4% lower risk of dying from IHD after controlling for established risk factors and 5% lower risk after the additional adjustment for other dietary variables hypothesized to be related to the risk of IHD.</p>	<ul style="list-style-type: none"> <li>- Large sample size increases generalizability</li> <li>- Includes assessment of non-dietary variables</li> <li>- Uses a European-wide sample with large dietary heterogeneity</li> <li>- The availability of a large set of known IHD risk factors allowed analyses to be appropriately adjusted, thus minimizing the impact of confounding</li> </ul>	<ul style="list-style-type: none"> <li>- No lipid or apolipoprotein measurements available for the majority of the EPIC cohort, and so results could not be adjusted for these IHD risk factors.</li> <li>- These results are also limited by error in the measurement of fruit and vegetable intake and other confounding variables</li> </ul>

Authors, Citations	Purpose, Objective of Study	Population of interest, Sample (N=Size)	Study Design	Study Methods	Major Finding(s)	Strengths	Limitations
<p>Estruch, R., Ros, E., Salas-Salvadó, J., et al. (2013). Primary Prevention of Cardiovascular Disease with a Mediterranean Diet. DOI: 10.1056/NEJMoa1200303</p>	<p>To test the efficacy of two Mediterranean diets (one supplemented with extra-virgin olive oil and another with nuts), as compared with a control diet (advice on a low-fat diet), on primary cardiovascular prevention.</p>	<p>N=7,447 Eligible participants were men (55 to 80 years of age) and women (60 to 80 years of age) with no cardiovascular disease at enrollment, who had either type 2 diabetes mellitus or at least three of the following major risk factors: smoking, hypertension, elevated low-density lipoprotein cholesterol levels, low high-density lipoprotein cholesterol levels, overweight or obesity, or a family history of premature coronary heart disease.</p>	<p>Quantitative; Longitudinal, Comparative</p>	<p>Participants who were at high cardiovascular risk were randomly assigned to one of three diets: a Mediterranean diet supplemented with extra-virgin olive oil, a Mediterranean diet supplemented with mixed nuts, or a control diet (advice to reduce dietary fat). Participants received quarterly individual and group educational sessions. The primary end point was the rate of major cardiovascular events. The trial was stopped after a median follow-up of 4.8 years.</p>	<p>Among persons at high cardiovascular risk, a Mediterranean diet supplemented with extra-virgin olive oil or nuts reduced the incidence of major cardiovascular events.</p>	<ul style="list-style-type: none"> <li>- Highlights the parts of the diet that lowered the rate of cardiovascular events</li> <li>- Includes the risk of stroke for the groups</li> </ul>	<ul style="list-style-type: none"> <li>- The more infrequent visit schedule and less intense support for the control group might be limitations of the trial</li> <li>- The lower intensity of dietary intervention for the control group during the first few years might have caused a bias toward a benefit in the two Mediterranean-diet groups, since the participants in these two groups received a more intensive intervention during that time.</li> </ul>

Authors, Citations	Purpose, Objective of Study	Population of interest, Sample (N=Size)	Study Design	Study Methods	Major Finding(s)	Strengths	Limitations
<p>Lorgeril, M., Salen, P., Martin, J-L., et al. (1999, February 16). Mediterranean diet, traditional risk factors, and the rate of cardiovascular complications after myocardial infarction. <i>Circulation</i>. <a href="https://www.ahajournals.org/doi/10.1161/01.CIR.99.6.779">https://www.ahajournals.org/doi/10.1161/01.CIR.99.6.779</a></p>	<p>To test whether a Mediterranean-type diet may reduce the rate of recurrence after a first myocardial infarction</p>	<p>N=605 Survivors of a first myocardial infarction</p>	<p>Single-blind, randomized, secondary prevention trial</p>	<p>Participants were randomized into either a control or a Mediterranean group. In this dietary trial, a specific design was used to recruit and randomize the patients without informing them and their physicians that they were participating in a comparative trial. The attending physician bias was evaluated by studying drug usage and the investigator bias by constructing a questionnaire from which specific scores were used to evaluate (1) how the patients appreciated their participation in the study and (2) whether this participation resulted in significant changes in their way of living.</p>	<p>Major traditional risk factors, such as high blood cholesterol and blood pressure, were shown to be independent and joint predictors of recurrence, indicating that the Mediterranean dietary pattern did not alter, at least qualitatively, the usual relationships between major risk factors and recurrence. The protective effect of the Mediterranean dietary pattern was maintained up to 4 years after the first infarction, confirming previous intermediate analyses.</p>	<ul style="list-style-type: none"> <li>- Randomization and the single-blind design provide assist in ensuring the integrity of the findings.</li> <li>- No major bias was detected in the trial</li> <li>- Examines the relationships between traditional risk factors, dietary patterns, and the occurrence of complications</li> </ul>	<p>- A comprehensive strategy to decrease cardiovascular morbidity and mortality should include primarily a cardioprotective diet. It should be associated with other (pharmacological?) means aimed at reducing modifiable risk factors. Further trials combining the 2 approaches are warranted.</p>

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<p>Millen, B., Quatromoni, P., Nam, B., et al. (2004). Dietary patterns, smoking, and subclinical heart disease in women: opportunities for primary prevention from the Framingham nutrition studies. <a href="https://doi.org/10.1016/j.jada.2003.11.007">https://doi.org/10.1016/j.jada.2003.11.007</a></p>	<p>To investigate the relationship between a heart-healthy dietary pattern and subclinical heart disease in women, and to identify potential opportunities for primary prevention.</p>	<p>N=1,423 Women in the population-based Framingham Offspring/Spouse (FOS) Study cohort, Framingham, Massachusetts. Subjects did not have CVD at baseline.</p>	<p>Quantitative: Prospective, longitudinal, correlational</p>	<p>Prospective analysis in which dietary patterns and cardiovascular disease (CVD) risk factors were assessed at baseline. Presence of subclinical heart disease was assessed using carotid atherosclerosis measured by ultrasound at 12-year follow-up.</p>	<p>Women who ate a heart-healthy diet had more favorable baseline CVD risk factor profiles. The age-adjusted odds of subclinical heart disease at follow-up was 40% lower for heart-healthy women. In analyses stratified by smoking status, women who consumed a heart-healthy diet and who had never smoked had more than 80% less odds for subclinical heart disease compared with smokers whose diets were less heart-healthy.</p>	<ul style="list-style-type: none"> <li>- Focuses on a heart healthy diet</li> <li>- Subjects did not have CVD at baseline</li> <li>- Includes smoking as a risk factor</li> <li>- Promotes a public health priority</li> </ul>	<ul style="list-style-type: none"> <li>- Only studies women; cannot be applied to approximately half the population</li> </ul>

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<p>Ornish, D., Scherwitz, L., Billings, J., et al. (1998). Intensive lifestyle changes for reversal of coronary heart disease. <a href="https://www.ornish.com/wp-content/uploads/Intensive-lifestyle-changes-for-reversal-of-coronary-heart-disease1.pdf">https://www.ornish.com/wp-content/uploads/Intensive-lifestyle-changes-for-reversal-of-coronary-heart-disease1.pdf</a></p>	<p>To determine feasibility of patients to sustain intensive lifestyle changes for a total 5 years and the effects of these lifestyle changes (without lipid-lowering drugs) on coronary heart disease</p>	<p>N=93 Patients with moderate to severe coronary heart disease were randomized to an intensive lifestyle change group or to a usual-care control group, and 35 completed the 5-year follow up</p>	<p>Quantitative; Randomized control trial using a randomized invitational design</p>	<p>Intensive lifestyle changes include 10% fat whole foods vegetarian diet, aerobic exercise, stress management training, smoking cessation, group psychosocial support. One group participated in these lifestyle changes for 5 years, and the other group was given usual care.</p>	<p>In the experimental group, the average percent diameter stenosis at baseline decreased 1.75 absolute percentage points after 1 year and by 3.1 absolute percentage points after 5 years. 25 cardiac events occurred in the experimental group whereas 45 events occurred in the control group.</p>	<ul style="list-style-type: none"> <li>- RCT is a strong research design to help inform evidence-based practice</li> <li>- Promotes healthy diet as primary prevention as a public health strategy</li> </ul>	<ul style="list-style-type: none"> <li>- Half of the patients who underwent quantitative coronary arteriography in the participatory hospitals did not meet all of the inclusion and exclusion criteria and were not invited to participate in the study.</li> <li>- There is a possibility of differential loss of lesions in patients in both groups, there were 14 lesions that were lost to follow-up.</li> </ul>