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Analysis of the Feasibility and Validity of the Mediterranean Diet Adherence Screener in a Cohort of Veterans Undergoing a Lifestyle Change Intervention

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Abstract

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By Elizabeth J. Schafer

Introduction: Among veterans enrolled in the Veteran Affairs Healthcare System, cardiovascular disease continues to be the leading cause of death even though it is primarily a preventable disease influenced by numerous modifiable dietary and lifestyle risk factors.^{1,2} The Mediterranean diet has been identified as an evidence-based diet for reducing cardiovascular disease (CVD) risk. The Mediterranean Diet Adherence Screener (MEDAS) has been used to determine adherence to this dietary pattern and is associated with improved CVD outcomes. However, limited validation studies have been conducted in the United States, especially in the context of lifestyle change programs like cardiac rehabilitation.

Methods: We examined MEDAS data in participants undergoing cardiac rehabilitation at the Atlanta VA Healthcare Systems. A paired T-Test was used to evaluate changes in the MEDAS score throughout the 12-week home-based cardiac rehabilitation study and McNamar's tests evaluated whether individual-level questions improved throughout cardiac rehabilitation. Multivariable linear regressions were used to evaluate the association of MEDAS changes with cardiometabolic risk factors, controlling for age, sex, and smoking status.

Results: We examined data on 39 participants for this study: 94% male, 46% black, and the mean (SD) age was 63.7 (6.8) years old. We did not find any statistically significant differences between enrollment and completion MEDAS scores. There was a significant increase in the number of veterans who used olive oil as their main source of fat. Otherwise, in our analysis of individual questions, we found that for 7 of the 14 questions, veterans reported non-adherence at both baseline and follow-up periods (mean score of 0 for both time points). Furthermore, there was no statistically significant association between MEDAS score improvements and cardiometabolic risk factor changes before versus after program completion.

Conclusions: In this cohort of 39 individuals, we did not find a statistically significant association between changes in MEDAS scores and cardiac rehabilitation participants nor correlations between MEDAS changes and cardiometabolic risk factors. This contrasts with previous findings in Spain and does not support our use of MEDAS in a cohort of American veterans.

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Chapter 1: Background and Literature Review

Increasing Prevalence of Cardiovascular Disease, especially amongst Veterans

On average, one person dies from cardiovascular disease every 36 seconds.³ The most common type of heart disease is coronary artery disease, also known as coronary heart disease or ischemic heart disease. In 2017, over 350,000 deaths were a result of coronary heart disease.³ Myocardial infarction, also known as a heart attack, affects roughly 805,000 adults every year. Of these, 200,000 are recurrent myocardial infarctions episodes.³ At the current increasing rate of cardiovascular disease, it is estimated that more than 40% of the United States population will have clinical symptoms of cardiovascular disease by 2030.⁴

The rising prevalence of cardiovascular disease significantly impacts the current U.S. healthcare system. According to the American Heart Association, cardiovascular disease costs roughly \$1 billion a day.⁵ Throughout the last decade, medical costs from cardiovascular disease have increased, on average, by 6% and account for roughly 15% of increased medical spending.⁴ From 2016 to 2017, the total cost of cardiovascular disease was \$363.4 billion, including \$216.0 billion in direct medical costs and \$147.4 billion in indirect costs of disability or mortality.⁶ It is projected that the direct cost of cardiovascular disease will increase almost 3-fold in the next 20 years, and, by 2035, it will cost more than \$1 trillion annually.⁵

Within the United States, certain populations are at higher risk for cardiovascular disease than others. Research has shown that veterans tend to experience higher cardiovascular disease incidence than nonveterans.⁷ In 2018, a cross-sectional epidemiological study was conducted to determine veterans' likelihood of reporting cardiovascular disease and found that veterans aged 35 years old have a greater chance of reporting early-onset cardiovascular disease than nonveterans aged 35 years old.⁸ Furthermore, the Health and Retirement 20-year cohort follow-up found that U.S. veterans were at higher risk to develop cardiovascular disease compared to nonveterans when controlling for baseline

socioeconomic status, chronic medical conditions, health behaviors, body mass index, and depressive symptoms between 1992 to 2012.⁹ These findings are consistent with other studies that show veterans tend to be at a higher risk for cardiovascular disease mortality and morbidity.^{10,11} Though cardiovascular disease continues to rise, it is largely a preventable disease associated with many modifiable risk factors.

Cardiovascular Disease Risk Factors

Even though cardiovascular disease has been the leading cause of death in the United States since the 1940s, it is essentially a preventable disease.^{1,2} The INTERHEART case-control investigated modifiable risk factors associated with myocardial infarction in 52 countries. This study determined nine potentially modifiable risk factors associated with over 90% of an initial myocardial infarction risk across all geographic regions. These nine potentially modifiable risk factors include current smoking status, diabetes, history of hypertension, abdominal obesity, psychological index, daily consumption of fruits and vegetables, regular physical activity, alcohol consumption, and increased abnormal lipids based on raised ApoB/ApoA1.¹² Various lifestyle behaviors such as poor diet, little physical exercise, high alcohol consumption and tobacco use increase one's risk of developing mediators of cardiovascular. These mediators include hypertension, obesity, diabetes, and dyslipidemia.^{13,14} The INTERHEART study found that smoking status and abnormal lipids are the two most important risk factors, resulting in over two-thirds of the population attributable risk. Additionally, regular consumption of fruits and vegetables was associated with a 36% relative risk reduction.¹² Furthermore, higher obesity levels are associated with increased morbidity and mortality from atherosclerosis and heart failure and increased risk for hypertension, dyslipidemia, and insulin resistance.¹⁵

Research has shown that poor diet is a critical component of cardiovascular disease risk due to its association with high blood pressure, diabetes, high cholesterol, raised lipids, and obesity.¹⁶⁻¹⁹ In 2017, the Global Burden of Disease study found that 11 million deaths worldwide were attributable to dietary risk factors. Ten million deaths were from cardiovascular disease, indicating the high association

between cardiovascular mortality and poor nutritional factors.²⁰ Additionally, 69.2% of age-standardized ischemic heart disease deaths worldwide were primarily attributable to poor diet quality.²¹ Therefore, nutrition has been identified as a critical modifiable behavior, with dietary modification being able to decrease the risk for first and recurrent cardiovascular events. Unfortunately, engaging in risky behaviors association is found to be higher among veterans.

Cardiovascular Risk Factors in Veterans

Studies have shown that Veterans tend to experience higher risk factors associated with cardiovascular disease and participate in risky behaviors more than the general population. According to the U.S. Department of Veterans Affairs, approximately 80% of veterans have two or more risk factors for cardiovascular disease.²² In an executive report published by the United States Department of Agriculture in 2020, between 2003 to 2016, veterans had a lower overall diet quality score based on the Healthy Eating Index compared to nonveterans when controlling for demographic characteristics.²³ Furthermore, a cross-sectional study published in 2015 found that veteran men were more likely to be obese than nonveteran men based on data from the 2009 to 2013 National Health and Nutrition Examination Survey.²⁴ Between 2011 and 2012, while the prevalence of obesity did not increase among nonveterans, there was a statistically significant increase among veterans.²⁴

Numerous studies have shown that veterans tend to engage in risky cardiovascular disease behaviors at higher rates than nonveterans. These behaviors include increased alcohol abuse, smoking consumption, and worse diet quality.^{7,23,25} Due to prior life experiences, veterans tend to have higher depression and post-traumatic stress disorder rates associated with poor dietary habits and metabolic diseases.^{9,11,23,26} In a 12-week, randomized controlled exercise trial published in 2021, it was found that veterans with PTSD consume less fiber, calcium, whole grains, dairy, fruit, vegetables, and legumes than recommended by the U.S. Department of Agriculture and the American Heart Association.²⁴ Furthermore, combat veterans have higher rates of smoking, depressive symptoms, chronic stress

levels, and lower life satisfaction than non-combat.⁷ After returning home, combat deployed soldiers are at a higher risk for heavy and binge drinking problems.^{27,28} Finally, Bohnert and colleagues found that veterans aged 61 to 70 were 73% more likely to be heavy drinkers than nonveterans after controlling for demographic differences.²⁹ All of these behaviors increase the risk of developing cardiovascular disease.

The Evolution of a Heart-Healthy Diet and the Mediterranean Diet

Beginning in the middle of the 1940's, the rise in cardiovascular disease sparked an interest in studying the relationship between possible risk factors associated with CVD, including different dietary patterns. Since then, various hypotheses and nutritional recommendations have been developed, including the diet-heart belief encouraging high carbohydrate and low-fat consumption, the USDA 1980 Dietary Guidelines for Americans, the introduction of the food pyramid, and the MyPlate recommendations. The 2015- 2020 Dietary Guidelines for Americans recommend the Dietary Approaches to Stop Hypertension (DASH) diet, the Mediterranean Diet, or a Vegetarian dietary pattern. Beginning in 2019, the American College of Cardiology and American Heart Association recommended a plant-based and Mediterranean diet high in fruits, vegetables, legumes, nuts, whole grains, and fish for cardiovascular health.^{30,31}

The hypothesis that the Mediterranean diet is protective against cardiovascular disease began when geographic differences in cardiovascular disease prevalence were observed in the Southern European population.³² In 1957, the Seven Countries Study started to compare the association between dietary patterns and cardiovascular risk in the United States, Japan, Finland, Netherlands, former Yugoslavia, Greece, and Italy. Ancel Keys found that the risk of coronary heart disease mortality was lower in the Mediterranean population than in the other 15 populations from the seven countries, terming the name the Mediterranean diet.^{14,33} Since then, the Mediterranean diet has become one of the most studied diets for cardiovascular disease protection.^{33,34}

The Mediterranean diet consists of a) a high intake of olive oil as the primary source of dietary fat; b) a high intake of fruits, vegetables, nuts, whole grains, and legumes; c) low to moderate intake of animal sources foods; and d) moderate consumption of wine during meals.^{18,33,34} Multiple studies have found that a higher degree of adherence to the Mediterranean diet is associated with a reduction in total mortality, cardiovascular mortality, and recurrent cardiovascular events.³⁵⁻³⁷ Increased adherence is found to be inversely associated with diabetes risk and metabolic syndrome and beneficial for decreasing blood pressure, triglycerides, low-density lipoprotein cholesterol, and body mass index.³³

The Prevencion con Dieta Mediterranea, PREDIMED, randomized clinical trial assigned three dietary patterns to individuals at high risk for cardiovascular disease with no prior cardiovascular disease at enrollment. The three patterns included a Mediterranean diet supplemented with extra-virgin olive oil, the Mediterranean diet supplemented with mixed nuts and a low-fat control diet. The results found that the incidence of cardiovascular events was lower among participants assigned to either Mediterranean diet intervention group than the control group. The Mediterranean diet with extra virgin olive oil and supplemented mixed nut intake had lower hazard ratios than the control group.³⁷ Furthermore, in patients with a previous myocardial infarction, the Lyon Diet Heart Study found that patients randomized to the Mediterranean diet experienced a lower rate of cardiac death and nonfatal infarction after 46 months (1.24 deaths per hundred patients per year) compared to patients randomized to the prudent Western-type diet (4.07 deaths per hundred patients per year).³⁸

The Mediterranean diet has been studied primarily in European populations. However, in 2016 the Reasons for Geographic and Racial Differences in Stroke (REGARDS) Study conducted in the stroke belt of the United States found that greater adherence to the Mediterranean Diet was inversely associated with the hazard of recurrent coronary heart disease events.³⁹ In a follow-up study conducted in 2021, the REGARDS study compared sudden cardiac death in participants mostly living in southern states of the United States. After ten years of follow-up, the results showed an inverse association

between Mediterranean diet score and risk of sudden cardiac deaths for participants with no prior history of cardiovascular disease at baseline. Following a Southern dietary pattern consisting of added fats, fried food, egg dishes, processed foods, and sugar-sweetened beverages was associated with a higher risk of sudden cardiac death than those who had lower adherence to this dietary pattern.⁴⁰ Improved nutrition, specifically adhering to the Mediterranean diet, has been beneficial for preventing primary and recurrent cardiovascular disease events. One clinical program that promotes the Mediterranean diet through dietary coaching is cardiac rehabilitation.

Cardiac Rehabilitation as Secondary Prevention

Primary and secondary prevention for cardiovascular events has been identified as a public health priority due to the rising prevalence rates and increased medical expenses seen in the United States.¹⁵ Cardiac rehabilitation (C.R.) is a practical, evidence-based secondary prevention strategy that can prevent recurrent cardiovascular events and decrease heart disease mortality by promoting lifestyle modification.⁴¹ Cardiac rehabilitation is recommended for patients after myocardial infarction, coronary artery bypass grafting surgery, coronary stent placement, valve surgery, heart failure, coronary artery disease, or angina.^{42,43} When individuals enroll in cardiac rehabilitation, they will engage in exercise programs, nutritional education, weight management, lipids, and blood pressure control, tobacco cessation, and psychosocial management support designed to decrease and monitor cardiovascular risk factor behaviors and conditions.⁴⁴

Cardiac rehabilitation is shown to reduce mortality and morbidity from cardiovascular disease successfully. Over three years, cardiac rehabilitation participation was shown to reduce cardiac mortality by 26% and reduce cardiac rehospitalizations over 12 months by 31%.⁴⁵ enrollment can improve quality of life, physical activity status, and anxiety levels decrease depression.^{46,47} Unfortunately, even with these well-established benefits of cardiac rehabilitation, it remains underutilized. Roughly 10% to 35% of eligible patients in the United States and Canada actively participated.⁴⁵ Participation is highest among

north and central states and lowest in southern states. In 2015, Georgia had one of the lowest cardiac rehabilitation participation rates at 9.7%.⁴⁵ Among veterans, participation is even lower, with fewer than 10% of eligible veterans enrolling in cardiac rehabilitation.⁴⁸ Furthermore, literature shows that of those enrolled in cardiac rehabilitation, 30% to 60% do not complete the program. Completing cardiac rehabilitation is critical since research shows a dose-response relationship between the number of sessions completed and cardiovascular disease mortality.⁴⁹ Patients encounter many barriers that can make it difficult to enroll and complete cardiac rehabilitation.

Barriers to Cardiac Rehabilitation

Barriers to this underutilization include low physician referral rates, lack of physician endorsement, racial and ethnic differences, comorbidities, socioeconomic factors, psychological factors, patient time constraints, and transportation issues.⁴⁹ A review published in 2021 found that the lack of perceived need, awareness, and clinical encouragement of patients referred to cardiac rehabilitation influenced their decision not to enroll. Other barriers include limited hours, being referred to off-site cardiac rehabilitation, language barriers, and lack of tailoring to meet individual needs.⁵⁰ In 2019, only about 28% of Veterans Health Administrations had an on-site cardiac rehabilitation program. Veterans can be referred to private sector hospitals to receive cardiac rehabilitation. However, off-site referrals can be harder for veterans due to increased distance to travel, possible co-payments for every session, or may require a driver due to possible comorbidity conditions.⁵¹ Therefore, home-based cardiac rehabilitation has been identified as a possible solution.

Home-Based Cardiac Rehabilitation

In 2019, the American Association of Cardiovascular and Pulmonary Rehabilitation, the American Heart Association, and the American College of Cardiology released a scientific statement urging health care practices to incorporate home-based cardiac rehabilitation (HBCR). Home-based cardiac rehabilitation can improve cardiac rehabilitation delivery and increase eligible patients' participation. Currently, home-

based cardiac rehabilitation has been successfully implemented in Australia, Canada, and the United Kingdom; however, few health care facilities have been able to provide a home-based cardiac rehabilitation option.

The same services offered during center-based cardiac rehabilitation are provided via telephone or telehealth during home-based cardiac rehabilitation. Health outcome benefits from home-based cardiac rehabilitation are similar to center-based cardiac rehabilitation; however, few studies have investigated this association in Veteran Affairs facilities.⁵² A quality improvement study conducted between 2015 and 2017 at the Malcolm Randall Department of Veteran Affairs Medical Center found that veterans who completed the 12-week home-based cardiac rehabilitation program reported significant improvements in physical capacity, 6-minute walk test, and functional capacity. Additionally, one-year survival rates and recurrent myocardial infarction were not different for those who completed home-based cardiac rehabilitation or usual center-based care.⁵² Among veterans who enrolled in home-based cardiac rehabilitation after transcatheter aortic valve replacement in a pilot study at North Florida/South Georgia VA Medical Centers between 2015 to 2018 found improved physical function after completion.⁵³ However, few studies have measured changes in diet quality during cardiac rehabilitation.

Measuring Nutrition in Cardiac Rehabilitation

Estimating a patient's diet quality is a critical but challenging component of cardiac rehabilitation. Unfortunately, limited research is available on the best practices for measuring diet quality in cardiac rehabilitation. Typically, 24-hour recalls, food frequency questionnaires, or multiple-day food records measure habitual dietary patterns.⁵⁴ However, these methods are often very time-consuming and burdensome to the patients. They cannot be completed in a cardiac rehabilitation consultation, and immediate dietary improvement cannot be provided. Therefore, brief, valid assessments that measure the frequency of certain food items may be more effective in improving

dietary quality in a clinical setting. The American Heart Association and American College of Cardiology recommend the Rate Your Plate, Mediterranean Diet Score, or the Daily Food Plan to assess and monitor adherence to achieving recommended dietary intake for cardiovascular health.⁵⁵

The Rate Your Plate (RYP) assessment tool is a 24- question assessment designed to determine saturated fat levels in an individual's diet. It is a qualitative assessment designed to understand habitual consumption of fat, animal protein, fruit, vegetables, whole grains, processed foods, and desserts.⁵⁶ The RYP dietary tool is validated against the Willett food frequency questionnaire and is used to understand habitual eating patterns in many cardiac rehabilitation programs.^{57,58} Gans et al. compared the Rate Your Plate survey to the Willett FFQ and found a negative, statistically significant correlation between Rate Your Plate scores and intake of fat, saturated fats, cholesterol.⁵⁹

The 24 questions each have three possible answer choices corresponding to appropriate heart-healthy scores. For instance, responses in the first column are the most heart-healthy. In contrast, responses in the last column are the least heart-healthy. The possible scores range from 24 to 72 points, with higher scores indicating better diet quality. Scores that range between 24 to 40 indicate the individual can make substantial improvements to their diet, scores between 41 to 57 indicate the individual is occasionally making heart-healthy choices, and 58 to 72 indicate the individual is making heart-healthy choices frequently. Therefore, this tool has been effective in cardiac rehabilitation programs as it provides recommendations on improving lower heart-healthy scores.^{56,57} Nevertheless, the rationale for using the RYP is out of date as it focuses mainly on cholesterol and saturated fat intake and not consumption of heart healthy whole foods.

The Mediterranean Diet Adherence Screener is a 14-point questionnaire that consists of 12 food frequency questions and two food intake habit questions. The PREDIMED study validated the 14-question Mediterranean diet questionnaire (MEDAS) against a 137 – item validated food frequency questionnaire. This validation study found that adherence to the Mediterranean diet was determined

only using the 14- question questionnaire instead of the longer, more time demanding, and expensive food frequency questionnaire. Furthermore, this dietary assessment is quick and easy to implement in the clinical setting.⁶⁰

The Mediterranean diet score is designed to determine if food items are beneficial or detrimental to heart health. For beneficial items, 1 point is given if an individual's consumption is higher than the recommendation, and a 0 is given for consumption is below the recommended level. A 1 is given to responses below the recommended level for determinantal food items, and a 0 is given to responses above the recommended level. A total of 14 possible points is possible, with higher scores indicating higher adherence to the Mediterranean diet. Unfortunately, in this assessment, the number of servings and grams are asked, which can make it difficult for participants to accurately estimate portion size.⁵⁶ Furthermore, this dietary assessment tool has yet to be validated in this United States.

Dietary Assessment Gap and Project Aims

Prior studies have shown cardiac rehabilitation can improve overall dietary habits⁶¹⁻⁶⁴, however, limited research is available on the effectiveness of replicating the Mediterranean diet adherence screener (MEDAS) in the United States. The ICAROS Survey conducted in 62 cardiac rehabilitation centers in Italy found that 63.3% of individuals with a low Mediterranean diet score at enrollment improved their score at the one-year follow-up. However, this Mediterranean diet score was based on a 4 point score looking at the frequency of regular consumption of vegetables, fruit, fish, olive oil, cheese, and butter.⁶⁵ Another validation study conducted in Canada validated the PREDIMED Mediterranean Diet Adherence Screener (MEDAS) against a 3-day food record in two cardiac rehabilitation programs. This study found the agreement between the 14-item MEDAS and the 3-day food record based on Pearson correlation coefficients; however, no associations were found between the Mediterranean diet score and abdominal obesity and high lipids.⁶⁶ To our knowledge, there has yet to be a validation study conducted in the United States.

Therefore, the aim of this thesis is three-fold: to evaluate changes in MEDAS scores in veterans enrolled in the 12-week HBCR program at the Atlanta Veteran Affairs Healthcare System; to analyze individual question improvements, and; validate changes in MEDAS scores against anthropometric and laboratory measurements. We hypothesize that the veterans enrolled in the study will experience an increased in overall MEDAS scores while improving anthropometric and biochemical measurements outcomes, making the MEDAS a valid assessment tool for Veterans enrolled in Cardiac Rehabilitation. The results of this thesis will improve the current implementation of cardiac rehabilitation at Veteran Affairs Healthcare System by determining an appropriate and valid dietary assessment to improve current nutrition counseling practices.

Chapter 2: Analysis of the Feasibility and Validity of the Mediterranean Diet Adherence Screener in a Cohort of Veterans Undergoing a Lifestyle Change Intervention

Introduction

Among veterans enrolled in the Veteran Affairs Healthcare System, cardiovascular disease continues to be the leading cause of death even though it is primarily a preventable disease influenced by numerous modifiable dietary and lifestyle risk factors.^{1,2} In 2017, the Global Burden of Disease Study determined that nearly 70% of age-standardized ischemic heart disease mortality worldwide is attributable to poor diet quality, and 10 million deaths from cardiovascular disease were associated with poor dietary risk factors.²⁰ These findings are consistent with prior research that shows improved nutrition may be the most preventative factor for cardiovascular disease (CVD) mortality.¹⁶⁻¹⁸

A leading, evidence-based dietary pattern in nutrition programs designed to reduce CVD is the Mediterranean diet. Prior research has found that increased adherence to the Mediterranean diet reduces total mortality, cardiovascular mortality, and recurrent cardiovascular events.³⁵⁻³⁷ The PREDIMED study found a lower hazard of first cardiovascular events in participants following a Mediterranean diet supplemented with either extra-virgin olive oil or mixed nuts compared to a low-fat control diet.³⁷ Furthermore, in patients with a previous myocardial infarction, the Lyon Diet Heart Study found that patients randomized to the Mediterranean diet experienced a lower rate of cardiac death and nonfatal infarction after 46 months compared to patients randomized to the prudent Western-type diet.³⁸ Due to this increasing evidence, in 2019, the American College for Cardiology recommended the Mediterranean diet pattern to support long term cardiovascular health.^{30,31}

In the clinical setting, measuring adherence to the Mediterranean diet is critical to ensure nutrition programs are tailored to the patient's needs for optimal cardiovascular health improvements. The gold standard for measuring nutrition is the 137 - item food frequency questionnaire. However, this

assessment is time-consuming, expensive, and unfeasible to complete in the clinical setting. Therefore, the Mediterranean Diet Adherence Screener (MEDAS) was developed to rapidly assess compliance with the Mediterranean diet intervention in the PREDIMED study. The PREDIMED study validated this 14-question MEDAS against a 137 – item validated food frequency questionnaire. In this validation study, adherence to the Mediterranean diet was successfully determined using only the 14- question questionnaire instead of a time-intensive food frequency questionnaire.⁶⁰ However, to our knowledge, no validation studies have been completed in the United States.

To address this gap, this study aimed to validate the MEDAS against cardiometabolic risk factors amongst Veterans enrolled in the three-month cardiac rehabilitation program in the United States. We evaluated changes in overall MEDAS scores and individual level questions improvements during the 12-week home-based cardiac rehabilitation program at the Atlanta Veteran Affairs Healthcare System. We hypothesized that veterans would increase overall MEDAS scores after the program, compared to before the program, and that such improvements would associate with cardiometabolic outcomes.

Methods

Setting and subject population

This single arm clinical program consisted of individuals enrolled in a 12-week home-based cardiac rehabilitation program at the Atlanta Veteran Affairs Medical Center in Atlanta Georgia between October 21, 2019, to July 22, 2021. The VA HBCR was designed to model traditional cardiac rehabilitation (CR); it was a multicomponent, holistic program that included patient-individualized nutrition and weight management, exercise and physical activity, tobacco cessation, medication adherence, stress management and psychosocial support counseling.⁶⁷ Nutritional counseling was tailored based on patient's needs, with those with greater needs were referred to a dietitian.⁶⁷ Veterans are referred to home-based cardiac rehabilitation after experiencing a myocardial infarction, coronary artery bypass graft procedure, percutaneous coronary intervention, stable congestive heart failure or

are diagnosed with stable angina. After referral, patients were enrolled and evaluated by a cardiac rehabilitation professional and provided with educational workbooks and exercise equipment.⁶⁷ During the 12-week program patients participated in individuals' weekly CR sessions via synchronous videocalls and/or telephone calls. After completing the program, veterans were reassessed for improvements in exercise capacity, knowledge of CVD, psychosocial health, and nutritional adherence.⁶⁷

Participants were excluded from the study if cardiac rehabilitation enrollment and/or completion of Mediterranean Dietary Adherence Screener (MEDAS) scores were missing or if the scores were implausible (outside the range of possible points). The study team obtained IRB approval and received a waiver for written informed consent to perform chart review and analyze the data.

Mediterranean Diet Assessment Adherence Screener Tool

The primary exposure of interest is a change in the 14-point MEDAS score between enrollment and completion of home-based cardiac rehabilitation. The MEDAS consists of 12 food frequency questions and 2 food intakes habits questions identified as key characteristics of the Spanish Mediterranean Diet. For each characteristic, participants were asked whether or not they consumed certain foods more or less than a pre-established cut point.⁶⁸ Each question is scored 0 or 1, with a total of 14 possible points. Table 1 depicts the scoring criteria for all 14 questions on the screener.

Primary Outcome Variables of Interest

The primary dependent variables of interest are cardiometabolic measurements at the completion of home-based cardiac rehabilitation. A team of experienced clinicians performed chart review and extracted participants' height, weight, and laboratory measurements collected at enrollment in the cardiac rehabilitation program. BMI was calculated as weight in kilograms divided by the square of height in meters. Laboratory measurements collected include high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, triglycerides, systolic blood pressure, triglycerides, A1C levels, diastolic blood pressure, and total cholesterol.

Covariates of Interest

Demographic information and health behaviors extracted in chart review include gender, race, age, rurality, smoking status, and alcohol consumption. Based on a review of prior literature, analyses were controlled for age, smoking status, and sex.

Statistical Analysis

A descriptive analysis was conducted to investigate the demographic characteristics of the cohort. Mean (SD) or count (percentage) for each demographic were calculated. A Paired T-Test was used to evaluate changes in the MEDAS score throughout the 12-week home-based cardiac rehabilitation study. Additionally, McNamar's tests were used to assess improvements of individual level questions on MEDAS.

To assess the effectiveness of the MEDAS, multivariable linear regressions were used to evaluate the association of the MEDAS changes and cardiometabolic risk factors. Dependent variables include BMI, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, triglycerides, systolic blood pressure, triglycerides, A1C levels, diastolic blood pressure, and total cholesterol. Statistical significance was based on an alpha level of 0.05, and analyses were conducted using SAS version 9.4 software.

Results

Participant characteristics

A total of 39 participants met the eligibility criteria and were included in this analysis. The mean (SD) for the 14-item MEDAS score at enrollment was 3.46 ± 1.1 , with a max score of 5 points. The mean age was 63.7 years old, majority of the participants were male (94%), lived in an urban setting (97%), and were previous smokers (54%). Table 2 illustrates the sociodemographic and clinic characteristics of participants.

Mediterranean Diet Adherence Screener

The mean MEDAS score after participating in cardiac rehabilitation was 3.36, ranging from 2 points to 6 points. Based on our paired T-Test analysis, there was no statistically significant difference between mean enrollment and completion MEDAS scores ($p = 0.63$). However, when comparing changes at the individual question level, olive oil as the principal source of fat and red meat consumption were statistically significant (Table 3). At enrollment, only 56.41% of veterans used olive oil as their primary source of fat for cooking while; this increased to 71.79% at follow-up ($p = 0.01$). We found an increase in the percentage of veterans who consumed red meat during cardiac rehabilitation ($p = 0.01$). Additionally, veterans reported non-adherence to 7 of the 14 questions at both baseline and follow-up periods (mean score of 0 for both time points). Finally, the percentage of veterans who consumed butter, margarine, cream, and pastries decreased while those who preferred poultry over red meat increased, however these improvements were not significant.

Cardiovascular Disease Risk Factors

No statistically significant association between MEDAS score improvements and cardiometabolic risk factors based on multivariate linear regressions when controlling for age, sex, and smoking status. (Table 4).

Discussion

In this analysis of veterans undergoing home-based cardiac rehabilitation, we found that overall MEDAS adherence was low, and did not find any changes in the score after participation in HBCR. We also did not find any statistically significant associations between changes in MEDAS question scores and changes in cardiometabolic risk factors that would indicate biological relevance. One particular concern to emphasize is that veterans did not adhere to 7 of the 14 questions at both baseline and follow-up periods. These findings reduce the validity of the MEDAS (when presented with binary categorical choices) in this sample of veterans in the United States.

Cultural variations make it difficult to replicate the MEDAS assessment in the United States efficiently. Many of the food items captured on the MEDAS may not be culturally appropriate, given that the scale was originally validated in Europe. This became apparent after comparing the mean MEDAS scores from the PREDIMED study performed in Spain with our U.S. population at the end of cardiac rehabilitation, 8.6 ± 2.0 and 3.4 ± 1.1 , respectively.⁶⁰ This difference from PREDIMED may reflect cultural differences in consumption of traditional Spanish dietary patterns and lifestyle practices and dietary patterns in the United States.⁶⁰ Based on table 3, almost 50% of the food items collected on the MEDAS are not commonly consumed items in our population, such as sofrito sauce, fish, legumes, and wine.

An additional reason for low adherence scores may be due to the cutoff values. As such, minor dietary improvements may not be captured effectively. We measured a 16% increase in the percentage of veterans using olive oil as the primary source of fat. Despite that, zero participants reported consuming more than 4 tablespoons a day of olive oil – hence, they were still non-adherent to this question. Overall, this underscores how a lower cutoff (any olive oil versus none) may detect dietary changes with more sensitivity.

We also observed other concerns with the MEDAS that may help to explain the lack of changes after HBCR. For example, it does not measure certain dietary patterns recommended by the American Heart Association's *2021 Dietary Guidance to Improve Cardiovascular Health*. This publication highlighted a variety of dietary recommendations to promote cardiometabolic health. These recommendations include whole-grain foods, processed food items, salt consumption, alcohol consumption of drinks other than wine, and low-fat dairy products, which are not captured in the MEDAS.⁶⁹ To provide the best nutrition education possible in a clinical setting, a dietary tool that captures all dietary habits associated with cardiovascular health is needed.

Validity concerns of the MEDAS outside the Mediterranean region have been voiced by the Working Group, which is a group established at the California Walnut Commission Scientific Advisor meeting in July 2016. The Working Group reviewed the PREDIMED study materials and investigated the practicality of this dietary pattern and assessment tool in the United States. Based on the Healthy U.S. Mediterranean style diet promoted in the 2015 – 2020 Dietary Guidelines for Americans, the Working Group estimated that a subpopulation in the U.S. can achieve a MEDAS score between 4 to 7 points. They argue that olive oil, fruit, butter, and legume consumption recommendations provided in the 2015-2020 Dietary Guidelines for Americans do not fulfill the requirements for the 14-item MEDAS. Additionally, the Dietary Guidelines for Americans do not have any recommendations for sofrito sauce or red wine. Perfect adherence to the U.S. Mediterranean style diet recommended in these guidelines will only provide a MEDAS score of 7.⁷⁰ The criteria used in the MEDAS assessment should be reevaluated to capture the recommendations from the Healthy U.S. Mediterranean Style Diet promoted in the Dietary Guidelines for Americans.

Only one validation study was conducted in North America, which was among 150 cardiac rehabilitation patients in Toronto, Canada. Less than half of the population in this study adhered to the recommended consumption of olive oil, fish, and legumes. Only 35% of patients fulfilled the four tablespoons or more of olive oil a day requirement, 43.3% consumed three servings or more of fish each week, and 51.2% met the legume requirement. This low adherence percentage supports our findings that many of the cutoff points are not culturally appropriate. Additionally, this study found no association between closer adherence to the Mediterranean diet and lower prevalence of abdominal obesity or improved lipid profiles, which supports our study's findings.⁶⁶ There are inconsistent findings on association between higher MEDAS adherence and improvements in cardiometabolic risk factors. Some studies have found an association between the 14-item MEDAS adherence and obesity prevalence

and lipid profiles while other have not.^{60,66,71} Other prospective studies show higher adherence to the Mediterranean diet is associated with lower 10-year estimated coronary heart disease risk.^{71,72}

There are many limitations to this study. Firstly, we did not validate the MEDAS against a 3-day food record or food frequency questionnaire. Secondly, our small sample size limits our ability to precisely estimate the true effect of association. Additionally, due to the Covid-19 pandemic, CR assessment surveys were mostly completed on an online format, limiting our study to those with the technical ability to complete the forms. The COVID-19 pandemic also led to a high percentage of missing data due to data management challenges of providing clinical care virtually. Finally, the self-reported nature and relying on participants memory to accurately complete the MEDAS should be considered when interpreting the results of the study.

Some of the findings were counterfactual to our expectations. We found a paradoxical relationship between changes in red meat and butter consumption and participation in cardiac rehabilitation. During cardiac rehabilitation, the percentage of veterans consuming butter, margarine, or cream increased. Though, this was not statistically significant and could be due to chance. However, there was a statistically significant association between participation in cardiac rehabilitation and worse red meat habits. The reason for this association is unknown, however, it could be due to the inherent limitations of dietary tools to accurately assess usual dietary consumptions. This relationship needs to be further explored and addressed in the clinical, dietary setting.

Despite these limitations, this is the first study to assess the validity of the MEDAS in the United States. Even though prior research suggests the Mediterranean diet promotes cardiovascular health, this study highlights the need to reconsider the current MEDAS as a practical dietary assessment tool in the United States. Due to cultural differences and exclusion of key dietary recommendations for cardiovascular health, the current adherence cutoff points and included questions should be reassessed to provide the best dietary coaching support to individuals in a clinical setting. Additional research is

needed to confirm these findings and understand the implications of replicating the MEDAS outside the Mediterranean region.

Conclusion

Overall, the results from this analysis highlight the need to reconsider the current Mediterranean Diet Adherence Screener as a practical dietary assessment tool in a clinical setting. Though the Mediterranean Diet has been identified as a possible nutrition program for cardiovascular health, additional research is needed to determine a practical dietary assessment tool that captures all dietary recommendations associated with cardiovascular disease with culturally appropriate adherence cutoff points. The results from this analysis do not support our original hypothesis; veterans did not improve their dietary scores, and higher MEDAS adherence was not associated with improved cardiometabolic outcomes. Additional studies are warranted, including a repeat assessment of each MEDAS question as a continuous measure to allow for evaluation of smaller incremental changes, which would allow for detection of lifestyle changes in HBCR with greater sensitivity.

Figures and Tables

Table 1: 14-Item Mediterranean Diet Adherence Screening Questions	Criteria for Scoring 1 Point
1. Do you use olive oil as the principal source of fat for cooking?	Yes
2. How much olive oil do you consume per day (including that used in frying, salads, meals eaten away from home, etc.)?	≥ 4 tablespoons per day
3. How many servings of vegetables do you consume per day? (side dishes or accompaniments = 1/2 serving. 1 serving = 1 cup)	≥ 2 servings per day
4. How many pieces of fruit (including fresh-squeezed juice) do you consume per day?	≥ 3 servings per day
5. How many servings of red meat, hamburger, or sausages do you consume per day? A full serving is 3-5 ounces	< 1 serving per day
6. How many servings (1 tablespoon) of butter, margarine, or cream do you consume per day?	< 1 serving per day
7. How many carbonated and/or sugar-sweetened beverages do you consume per day?	< 1 serving per day
8. Do you drink wine? How much do you consume per week?	≥ 7 glasses per week
9. How many servings (1 plate or 5 ounces) of beans/lentils do you consume per week?	≥ 3 servings per week
10. How many servings of fish/seafood do you consume per week? (3-5 oz of fish, 4-5 pieces or 7 oz of seafood)	≥ 3 servings per week
11. How many times do you consume commercial (not homemade) pastry such as cookies or cake per week?	≤ 2 servings per week
12. How many times do you consume nuts per week? (1 serving = 1 ounce)	≥ 3 servings per week
13. Do you prefer to eat chicken, turkey, or rabbit instead of beef, pork, hamburgers, or sausages?	Yes
14. How many times per week do you consume boiled vegetables, pasta, rice, or other dishes with a sauce of tomato, garlic, onion, or leeks sauteed in olive oil?	≥ 2 servings per week

Table 2: Sociodemographic characteristics of Participants (N=39)	
Characteristics	
Age, years (Mean \pm SD)	63.7 \pm 6.8
Sex (n %) (n = 33)	
Male	31 (93.94%)
Female	2 (6.06%)
Race	
White, Non-Hispanic	20 (51.28%)
Black, Non-Hispanic	18 (46.15%)
Other or unknown	1 (2.56%)
Rurality (n = 36)	
Urban	35 (97.22%)
Rural	1 (2.78%)
Current Smoking Status	
Yes	6 (15.38%)
No	12 (30.77%)
No, but smoked in the past	21 (53.85%)
Cardiovascular Risk Factors	
BMI (n = 36)	29.9 \pm 5.08
A1C (n = 31)	6.87 \pm 1.74
HDL (n = 33)	46.24 \pm 17.79
LDL (n = 31)	105.35 \pm 47.22
Systolic Blood Pressure (n = 36)	133.28 \pm 19.87
Triglycerides (n = 33)	130.15 \pm 70.01
Cholesterol (n = 33)	177.55 \pm 52.25
Diastolic blood pressure (n = 36)	80.28 \pm 12.97
Duration in CR, n (%)	
Eight weeks	2 (5.13%)
Nine weeks	4 (10.26%)
Ten weeks	2 (5.13%)
11 weeks	5 (12.82%)
12 weeks	23 (58.97%)

MEDAS Question	Enrollment	Completion	McNemar's Test
1. Olive oil is the main source of fat	56%	72%	0.01
2. Olive oil > 4 tablespoons/ day	0%	0%	-
3. Vegetables \geq 2 servings/ day	0%	0%	-
4. Fruit \geq 3 servings / day	3%	0%	-
5. Red meat < 1 serving / day	49%	26%	0.01
6. Butter, margarine, cream < 1 serving/day	39%	28%	0.29
7. Sugar-sweetened drinks < 1 serving/day	26%	33%	0.44
8. Wine \geq 7 glasses/ week	0%	0%	-
9. Legumes \geq 3 servings/ week	0%	0%	-
10. Fish/Seafood \geq 3 servings/ week	0%	0%	-
11. Pastry \leq 2 servings/week	98%	100%	-
12. Nuts \geq 3 servings/ week	0%	0%	-
13. Prefer poultry more than red meat	75%	77%	0.78
14. Use of tomato, garlic, onion, or leeks sauce sauteed in olive oil \geq 3 servings/ week	0%	0%	-
Total MEDAS Score (Mean)	3.5 \pm 1.1	3.4 \pm 1.1	0.63*

*Paired T-TEST

Table 4: Multiple adjusted regression coefficients between differences in Mediterranean Diet Score and cardiovascular risk factor variables scores between enrollment and completion

Changes in Dependent Variable	Mediterranean Diet Score (1 point)		
	Regression Coefficient	95% CI	P-Value
HDL	0.57	(-5.19 – 6.33)	0.83
LDL	-2.17	(-22.03 – 17.70)	0.81
Cholesterol	-0.31	(24.72 – 24.10)	0.98
Systolic BP	2.07	(- 4.72 – 8.86)	0.55
Triglycerides	6.35	(-28.55 – 41.26)	0.41
A1C	-0.07	(-0.42 – 0.28)	0.68
Diastolic BP	-1.35	(-6.45 – 3.76)	0.59
BMI	-0.22	(-0.57 – 0.12)	0.19

*Controlling for age, sex, and smoking status

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