ABSTRACT

Determining the Relative Validity of a Short Screener for Assessing Adherence to a
Modified Mediterranean Diet in Cardiopulmonary Rehabilitation Patients

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The purpose of the study was to determine the relative validity of a short screener used to assess dietary compliance to a modified Mediterranean diet in a cardiopulmonary rehabilitation program. Thirty-one participants completed a newly developed short screener in the clinic and an at-home seven-day food journal that was used as a reference to explore validity. A survey was designed and completed by five Registered Dietitians to assess face validity of the screener. Descriptive statistics were used to analyze and compare the differences of the reported answer frequencies between both measurement tools. The results of the face validity survey and descriptive statistics determined the screener was not valid. Since the study was a pilot study, the statistical methods used to analyze the data were mainly used as a preliminary way to assess the relative validity. In conclusion, future research should address and implement the necessary changes to improve validation.

Determining the Relative Validity of a Short Screener for Assessing Adherence to a Modified
Mediterranean Diet in Cardiac Rehabilitation Patients

by

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DEDICATION

To my beloved, selfless, and extraordinary parents without whom none of this would exist. Thank you for sacrificing everything so I could have it all. I owe everything to you. And to my indescribably incredible husband. You carried me through when I could go no further. Thank you for supporting me relentlessly and for filling all of my days with abounding love, joy, and silliness.

CHAPTER ONE

Introduction

Assessing overall diet quality and dietary patterns is a necessary component in nutrition epidemiology as well as in educational rehabilitation programs. Adherence to specific diets such as the Mediterranean Diet is an especially helpful indicator of the exact level of educational intervention needed. The Mediterranean Diet has been consistently associated with improved health outcomes along with possessing cardioprotective elements (Schroder et al. 2011 & Martinez-Gonzalez et al. 2004). Thus the Mediterranean Diet has been adopted into many cardiopulmonary rehabilitation programs.

The data collection process of dietary patterns in epidemiological settings is mostly done by full-length food frequency questionnaires. These full-length questionnaires are unfortunately very time consuming (Schroder et al. 2011). Food journals are an additional data collection tool used in clinical settings. However, there are numerous inadequacies produced by the food journals including a lack of detailed dietary patterns, which in turn do not provide a sufficient portrayal of a patient's overall diet (Eysteinsdottir et al. 2012). Short simplified screeners have therefore been developed to reduce data collection time as well as to appropriately assess adherence to the Mediterranean Diet (Schroder et al. 2011 & Martinez-Gonzalez et al. 2004).

A short 14-point Mediterranean Diet Adherence Screener (MEDAS) was developed for rapid control of dietary intervention compliance assessment of the

Prevencion con Dieta Mediterranea study (PREDIMED). The questionnaire was validated and proven to be reliable in estimating adherence to the Mediterranean diet in clinical settings (Schroder et al. 2011). However, questionnaires, screeners, or any other measurement tools validated in one population group may not be easily interpreted to a different population group for many reasons such as language, culture, and education levels. Thus, the development of new questionnaires is continually necessary (Nse et al. 2015). However, based on previous experiences with data collection in patients in a cardiopulmonary rehabilitation program in central Texas, the MEDAS questionnaire and food journals did not provide sufficient information to adequately assess patient compliance to a modified Mediterranean Diet. In an effort to improve data collection content as well as reduce data collection time, a short screener (screener) was developed at the cardiopulmonary rehabilitation program in the Baylor Scott and White Hillcrest, Ted and Sue Getterman Wellness Center to assess patient compliance to the diet as well as to assess the level of educational intervention needed to help the patient better adhere to the modified diet (see Appendix A.1 for timeline of study events). Additionally, the screener was developed based on a modified version of the Mediterranean Diet, meaning the original Mediterranean Diet was adjusted to include a higher intake level of healthy fats (see Appendix B.1 for definition of terms). The primary objective of the study was to determine the relative validity of the newly developed instrument in cardiopulmonary rehabilitation patients. This was done by statistically analyzing the results of the screener with the information collected by an extensive seven-day food journal.

CHAPTER TWO

Literature Review

Adherence to specific diets is an especially helpful indicator of the level of educational intervention needed in cardiopulmonary rehabilitation programs. Evidence supports the direct connection between nutrition and the development of chronic diseases that cause the highest rates of mortality and morbidity in developed populations (Fernandez-Ballart et al. 2009). The leading cause of mortality and disability-adjusted years of life lost worldwide is cardiovascular disease (Martinez-Gonzalez et al. 2009 & Nse et al. 2015).

Mediterranean Diet

The Mediterranean Diet has been consistently associated with improved health outcomes along with possessing cardioprotective elements (Schroder et al & Martinez-Gonzalez et al). It is native to the southern European countries surrounding the Mediterranean Sea such as France, Spain, Greece, and Italy. Scientific studies in these countries have shown a low incidence of coronary artery disease when compared to northern European countries and the United States and their adherence to a Mediterranean food pattern (Lluis Serra-Majem et al. 2006 & Trichopoulou et al. 2003). Decades of research have consistently produced similar results and the Mediterranean Diet has been associated with decreased incidence of cardiovascular diseases since the 1960s (Pangiotakos et al. 2006). One well-known study, the Lyon Diet Heart Study, tested whether a Mediterranean type diet compared with a western type diet, could reduce

the recurrence rate after a first myocardial infarction in patients. The final report represented data over a mean follow-up period of forty-six months per patient where as the intermediate analysis represented data over a twenty-seven month period. The results of the complete study demonstrated impressive protective benefits of the Mediterranean type diet. The rate of cardiac death and nonfatal infarction in the experimental group after forty-six months was 1.24 per one hundred patients per year similar to the observed 1.32 per one hundred patients per year after twenty-seven months. The rate in the control group was 4.07 after forty-six months and 5.55 after twenty-seven months. These impressive results suggested even several years after intervention, patients will adhere to recommended dietary changes so long as patients and their families are adequately educated and professional surveillance is conducted. Overall, the data exemplified the feasibility of implementing new dietary habits in the midst of difficult working environments and stressful lives. The authors suggested a comprehensive strategy post cardiovascular episodes should include implementation of a cardioprotective diet in association with pharmacological treatment in order to decrease overall cardiovascular morbidity (Lorgeril et al. 1998).

Additionally, a study by Chow et al. 2010, researched the association of behavioral changes with short-term risk reduction of cardiovascular events within six months after acute coronary syndrome. The study followed 18, 809 participants from 41 countries. Patients were followed-up with first at the thirty-day mark and secondly at the six-month mark and their compliance with diet, exercise, and smoking modification was assessed at both appointments. The results of the study found adherence to smoking cessation, diet modification, and increased physical activity resulted in a substantially

lower rate of short-term major cardiovascular outcomes and all-cause mortality within the first thirty days. At the six-month mark, patients who reported persistent smoking and nonadherence to diet and exercise experienced a 3.8 fold increased risk of myocardial infarction, stroke, and death compared to nonsmokers and patients who adopted diet and exercise modification (Chow et al. 2010). Overall, the benefits that greatly accrued within six months include improved plaque stabilization as a result of less oxidative stress damage and fewer arrhythmias resulting from membrane stabilization. Lastly, adherence to pharmaceutical therapy was higher than adherence to behavioral modifications at both the thirty-day and six-month follow-ups. Thus, in an effort to emphasize the priority of lifestyle changes over sole drug therapy, the authors recommended immediate implementation of post-event behavioral modifications by physicians and other medical professionals in order to prevent further cardiac events (Chow et al. 2010).

Another study conducted in Greece also evaluated whether behavioral changes were associated with better short-term prognosis on acute coronary syndromes in 2,172 patients. Unlike the researched conducted by Chow et al. 2010, this study specifically researched the dietary benefits of the Mediterranean Diet though similar results were found. Adherence to the Mediterranean Diet, moderate alcohol consumption, smoking abstinence, and increased physical activity levels were associated with decreased levels of myocardial damage markers along with overall better patient prognosis. The results of the study showed adherence to two or more of the aforementioned protective factors was significantly correlated with a seventy percent decreased risk of hospital mortality and eighty percent decreased risk of experiencing recurrent cardiac events. The authors also observed about forty percent of the recurrent events were attributed to adverse lifestyle

habits and could have possibly been prevented if healthier behavioral modifications were adopted (Panagiotakos et al. 2006).

The Mediterranean Diet is characterized by a high intake of monounsaturated fatty acids mainly sourced from olive oil, plant proteins, high fiber foods such as vegetables and fruits, whole grains, legumes, and fish. It is also characterized by moderate intake of alcohol, moderate to low intake of dairy products, and low intake of red meat, refined grains, and added sugar foods such as desserts and baked goods (Martinez-Gonzales et al. 2009, Nordmann et al. 2011, & Trichopoulou et al. 2006). Numerous other studies have shown a higher degree of adherence to the Mediterranean Diet is associated with reduced total mortality, and improvements in most of the cardiovascular risk factors compared with adherence to a low-fat diet (Martinez-Gonzalez et al. 2009, Nordmann et al. 2011, Lluis Serra-Majem et al. 2006, & Trichopoulou et al. 2003). Some of these said improvements include reduction on blood lipid components such as lowered total cholesterol, low-density lipo-protein cholesterol, total triglycerides, apoprotein B, very-low density lipo-protein cholesterol levels, body weight, body mass index, and wait circumference and increased levels of high-density lipo-protein cholesterol and total plasma antioxidant capacity (Lluis Serra-Majem et al. 2006 & Nordmann et al. 2011). Results also suggest benefits of the Mediterranean diet are due to the biologic interactions between different food components instead of an effect caused by only one food group (Martinez-Gonzalez et al. 2009). Cumulative evidence suggests the protective role of the Mediterranean Diet may be due to the monounsaturated fatty acids abundantly found in the diet, more specifically in the use of virgin olive oil. Since, virgin olive oil has repeatedly shown beneficial results as a supplement of the

Mediterranean Diet, its use is often greatly emphasized. Some of the benefits include lowering blood pressure in normotensive and hypertensive individuals more specifically due to the modifications in the fatty acid composition of the cell, improving blood lipid profiles, decreasing insulin resistance, and reducing inflammatory molecule concentrations such as C-reactive protein (Martinez-Gonzalez et al. 2009, J.S. Perona et al. 2006, & Nordmann et al. 2011). In one specific study, endothelium function improved and endothelial-dependent vasodilation was increased with higher consumption of nuts as part of the Mediterranean Diet (Lluis Serra-Majem et al. 2006). However, these same results were seen in two different studies but with the consumption of olive oil (J.S. Perona et al. 2006 & Nordmann et al. 2011). These similar results demonstrate again, the consumption of one specific food item or food group is not the sole means to produce protective benefits. A diet rich in variety is wholly beneficial. Thus the Mediterranean Diet has been adopted into many cardiopulmonary rehabilitation programs.

Rehabilitation Programs

Cardiopulmonary rehabilitation programs are a multi-factorial intervention process delivered via a number of methods addressing lifestyle choices, behavioral changes, and biochemical marker changes (McKellar et al. 2008). Based on one recent study's results, the authors determined behavioral goals are easier to attain than biochemical targets due the convenience and ease of self-monitoring (Luisi et al. 2015). Therefore, in a cardiopulmonary rehabilitation program, patients' dietary intake is one of the major factors that should be measured in order to evaluate the behavioral changes needed (McKellar et al. 2008 & B. Johnson et al. 1999).

Measurement Tools

Multiple studies have discovered the relationship between nutritional habits and their direct involvement in the etiology of diseases (Schroder et al. 2001). Accurately estimating food intake is thus highly important when assessing the nutritional status of any population and its association to their health status because invalid information on dietary intake may produce invalid diet-disease associations (Fernandez-Ballart et al. 2010 & Streppel et al. 2013). Dietary assessment tools not only measure a patient's eating behaviors, but they also identify and provide immediate feedback on an individual's specific educational needs (McKellar et al. 2008). However, all dietary data collection methods have some limitations, so there is no gold standard instrument used in epidemiological studies. Thus studies mostly use full-length food frequency questionnaires to evaluate diets and their association with specific nutritional profiles such as the Mediterranean Diet and chronic diseases (Hamdan et al. 2012 & Fernandez-Ballart et al. 2010). Food frequency questionnaires are not only used because of their cost-effectiveness, but also because they can measure habitual dietary intake over a longer period of time (Hamdan et al. 2012, Fernandez-Ballart et al. 2010, & G.C. George et al. 2004).

As with any data collection tool, there are limitations and various degrees of error capacity. Self-reporting of food intake usually leads to recall bias and misjudgment (Hamdan et al. 2012 & Fernandez-Ballart et al. 2010). This is often accredited to subject variability in food intake, difficulties with memory recall of amount and types of food consumed, and ability to report or not report food consumption. Also, these full-length questionnaires are unfortunately very time consuming usually requiring thirty to sixty

minutes to complete, and they contain a restricted pre-determined food list that may not be applicable to specific/all populations (Deschamps et al. 2009, National Institute for Health 2017 & Zhuang et al. 2012). Food journals are an additional data collection tool used in clinical settings. Food journals are able to reflect the diverse nature of realistic dietary patterns (G.C. George et al. 2004). However, there are numerous inadequacies produced by the food journals including a lack of detailed dietary patterns, which in turn do not provide a sufficient portrayal of a patient's overall diet (Eysteinsdottir et al. 2012). Diet records also place an immense burden on subjects such as the amount of detail and memory recall required to accurately report daily diets and fear of judgment by the professional interpreters. This subsequently persuades subjects to falsely report dietary components and/or decrease response rate altogether (Zhuang et al. 2012 & Deschamps et al. 2009). Short simplified screeners have therefore been developed to reduce data collection time as well as to appropriately assess adherence to the Mediterranean Diet (Schroder et al. 2011 & Martinez-Gonzalez et al. 2009). Reliable instruments are vitally necessary to identify the exact components of the Mediterranean Diet that can accurately explain the paradox of high cardiovascular risk factor but low coronary heart disease (Schroder et al. 2001).

CHAPTER THREE

Methods

Design

Assessing the validity of the screener was essential before it is used in diet

assessments and education interventions in the cardiopulmonary rehabilitation program

as well in future research studies. There are many ways to analyze and critique validity

because there are also multiple aspects of it including content validity, relative validity,

construct validity, and face validity (B. Johnson et al. 1999). A tool is considered valid if

it correctly measures the underlying phenomenon, diet, or disease (Nse et al. 2015). More

specifically, validity examines the extent to which the interested concepts are

comprehensively represented by the questions in the screener (Nse et al. 2015). For the

purposes of the current study, relative validity of the screener must be determined to

conclude if the questions accurately reflect compliance to the modified Mediterranean

Diet.

The research team at the cardiopulmonary rehabilitation program in the Baylor

Scott and White Hillcrest, Ted and Sue Getterman Wellness Center comprised of a

rehabilitation exercise physiologist and the manager of the clinic (the research team)

constructed the overall design of the study. The study received approval by the

Institutional Review Board for Human Subjects of Baylor University and Baylor Scott

and White Hillcrest in July of 2016. The cardiologist in the rehabilitation program

developed a nutritional guide based on the published scientific study by Estruch et al.

2013. The premise of the study was to determine if two different modified Mediterranean Diets, one supplemented with one liter of olive oil consumption a week and the other supplemented with thirty grams of a mixed-nut variety of walnut, hazelnut, and almond consumption, would reduce the incidence of major cardiovascular events in persons that did not have cardiovascular disease. The other components of the baseline Mediterranean Diet included four or more tablespoons of olive oil a day, three or more servings of tree nuts and peanuts per week, two or more servings of vegetables per day, three more servings of fruits per day, three or more servings of fish, especially fatty fish, per week, three or more servings of legumes per week, two or more servings of Sofrito sauce per week, and consumption of white meat instead of red meat when possible. The diet also recommended consuming less than one soda drink a day without specifying amount in ounces, three or less servings of baked goods, pastries, or sweets per week, less than one serving of spread fats a day, and less than one serving of red meat a day (Estruch et al. 2013) The results of the study indicated a Mediterranean Diet supplemented with either olive oil or nuts was effective at reducing cardiovascular risk factors. The cardiologist at the clinic used this information to formulate the basis for the modified Mediterranean diet and complete nutrition curriculum. The added diet modifications included consuming one hundred percent whole grains, cooking with herbs and spices instead of salt, and recommended not purchasing canned, bagged, boxed, or drive-thru foods. The research team used this information to construct the question content and develop the entire screener in English. The screener was originally a thirty-question survey with a five answer choice scale ranging from never to always. However, nine questions were cut for the purpose of the study and instead directly used in the educational part of the rehab

program. Thus twenty-one questions were maintained with the intent of assessing patients' adherence to the modified Mediterranean diet (see Appendix C.1 for example of the screener).

The design of the study included all participants answering the newly developed screener and filling out a seven-day detailed food journal. A food frequency questionnaire was not chosen as a reference method because they are often extremely long and time consuming. In regards to validation studies, multiple-day diet recall or food journals were considered an appropriate reference method to questionnaires or in this case a screener. Compared to food journals, twenty-four hour diet recalls are less time consuming, but much like food frequency questionnaires, they are less likely to accurately represent the average diet (Cena et al. 2008). The cost-effectiveness as well as the ease of patient self-administration and memory independency, allow for a larger number of dietary data to be collected without depleting excessive resources (Hamdan et al. 2012). Among the various dietary measurement tools, the seven-day food journal completed via weight or estimation of portion sizes provides an accurate method of estimating actual food intake (Luevano-Contreras et al. 2013). Diet records have also been reported in studies to have the least correlated errors with questionnaires thus the decision was made to use the seven-day food journal as the appropriate method for validity comparison (Zhuang et al. 2012). Furthermore, for the purpose of this study, a seven-day food journal was chosen as opposed to a shorter length food journal because the screener assessed food intake for an entire week and to make appropriate comparisons a food journal of equal length was required.

Subjects, who consented to participate in the study, were given verbal instructions on how to complete the food journal at their first appointment. The research team explained the patients would take the food journal home and record exact meals, snacks, and beverages for seven days. They were told to not simply list a food item such as a sandwich, but instead list every item in the sandwich including serving sizes, type of bread, meat, vegetables, and sauces used. Patients were also told to write down what type of butter, oil, or alternative they used to cook with and to always list the fresh, frozen or canned source of fruits and vegetables. Participants were scheduled to return to the clinic within one week of food journal completion. At their second appointment, the research team members escorted patients into a private patient room where they turned in the food journal and were given instructions on how to complete the screener. In regards to the screener, participants were told to notice the answer choices on the top of the page ranging from never to always and to use their best judgment when answering how often they consumed foods from each group. They were given as much time as needed to complete the screener and the research team members were in the same room available for questions.

Due to the study's design, there was no randomization. Instead, the research team at the center collected all the data from the food journals and screeners, number coded everything, and excluded any personal information. The need for a nutritional expert to interpret the data was discussed. The research team and faculty advisors agreed the qualifications as a Dietetic Technician, Registered, and Bachelor of Science in Nutritional Sciences degree were sufficient achievements to qualify as the nutrition expert for this research study. As a result, the specific research role for this portion of the

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study was to receive the number coded data, interpret and analyze it to determine the screener's validity without human subject interaction in order to eliminate bias. All of the data received were anonymous so confidentiality was maintained and only aggregated data were sent via email.

Sample

A convenience sample of patients enrolled in the cardiopulmonary rehabilitation program at the Baylor Scott and White Hillcrest, Ted and Sue Getterman Wellness Center was used for this study. Most of whom were also enrolled in the diet modification component of the rehab program. Participants were recruited via direct word of mouth by the research team at the Wellness Center. The team also directly distributed and collected the dietary measurement tools. All patients who agreed to participate in the study were advised on the overall research protocol, assured their personal information would be kept private, and signed a consent form prior to completing either of the measurement tools.

Most patients seen in the clinic had multiple risk factors for cardiac diseases or have multiple disease states. Major risk factors for cardiovascular disease include smoking, hypertension, obesity, diabetes, and an atherogenic lipid profile (Sanchez-Tainta et al. 2008).

Patients in the clinic were also between the ages of 50 to 90 years old. Inclusion criteria included: patients between 50-90 years of age and multiple risk factors or disease sates. Patients were excluded if they were not literate in English and if they were not patients in the cardiopulmonary rehab program. In total, 49 patients were recruited between June and September of 2016 and 31 participants completed the entire study. For

an illustration of the patient demographics see Table 3.1. Of the 31 patients, 21 had

Coronary Artery Disease and were obese, four had hypertension, five had Chronic

Obstructive Pulmonary Disease, and one had atrial fibrillation.

Table 3.1. Patient Demographics.

Demographics	Total (Percentage)	Mean	Range (Oldest, Youngest)	Race (Total Percentage)
Total	31	71.23	83, 61	30 Caucasian (96.77%), African American 1 (3.23%)
Female	21 (67.74%)	71	83, 61	20 Caucasian, 1 African American
Male	10 (32.26%)	71.7	82, 65	10 Caucasian

Face Validity

Often times when new measurement tools are designed, face validity is

ascertained before the instrument is distributed and tested on a study's subjects. Face

validity precisely specifies the extent to which the instrument questions equate to current

expert opinions, and thus its evaluation is a necessary step in measuring the validity of

any new dietary instrument (B. Johnson et al. 1999). Because of its importance to overall

validation, a survey was created to evaluate the screener using Qualtrics Survey Software,

and eight Registered Dietitians were recruited to participate in the screener's assessment.

Registered Dietitians were the experts recruited because of their educational

backgrounds, extensive training, and expertise in analyzing nutritional instruments, diets,

and scientific studies. Out of the eight recruited dietitians, five completed the survey, two

of which were professors in the Nutrition Sciences department at Baylor University and

the other three were clinical dietitians at a local hospital. The design of the survey was

based on a study conducted by Mackison et al. 2010. The overall process included asking the five expert participants to complete the developed screener, which was emailed to each one, followed by nine questions, one of which was open-ended and allowed the participants to leave comments, ideas, or critiques. The other eight questions addressed understandability of questions, verbiage understanding, layout organization, font legibility, ease of completion, overall length, and completion time.

Statistical Analysis

The statistical analysis of the data was challenging for several reasons. Foremost, the screener was not designed or developed to accommodate an in depth method of quantitative statistical analysis.

The research team first provided five categories to answer the screener questions. These classifications were categorical based ranging from never to always. A category interpretation key was developed, which translated the categories into number of days per week ranging from zero to seven. See Table 3.2 for an example of the answer interpretation key (key). The 7-day food journal was a standard food journal that allowed participants to list exact foods, number of servings, serving sizes, and location of meals, snacks, or beverages. See Appendix B for an example of the daily food journal. Interpretation of the data initially converted the food journals into servings per day and week to get a more accurate depiction of actual dietary consumption. However, since the key was set up in number of days consumed not servings, data from the food journals were classified using the same scale as the screener.

Further guidance for statistical analysis was recruited from the Department of Statistical Science at Baylor University. Upon completion of the initial meeting with the

statistics professionals, it was concluded that since a statistician was not consultaed in the development stages of the screener, the overall format including question verbiage and answer categories was not set up properly for inferential statistics. Therefore, descriptive statistics were used to analyze and describe the reporting differences between each measurement tool.

The data collected were organized into frequencies of reported answers in both the seven-day food journals and screeners. In other words, the data from the screener were organized into number of times the thirty-one participants answered each of the twenty-one questions according to the five answer choices (reference Table 3.2). The data from the journals were also translated into number of times per week each item from the twenty-one groups had been reported. Subsequently, the thirty-one answer frequencies from both tools were tallied and recorded in each of the five answer categories and differences between the tools were calculated to show equal, under, and over reporting in the screener in regards to actual recorded consumption in the food journals. A table was constructed to clearly organize and summarize the data.

Table 3.2 Short Screener Measurement Keys

Actual Screener Categories	Interpretation Key
Never	No designated servings during the week
Some	Appropriate servings 1-2 days of the week
Moderately	Appropriate servings 3-4 days of the week
A lot	Appropriate servings 5-6 days of the week
Always	Appropriate servings 7 days a week

CHAPTER FOUR

Results

Face Validity

Five nutritional experts with various educational backgrounds and trainings completed the screener and Qualtrics survey. The results of the face validity assessment were varied with zero out of the eight questions scoring complete agreement. The majority of participants (eighty percent) found the questions easy to understand, font legible, and the questionnaire did not take more than ten minutes to complete. Eighty percent of participants either strongly agreed or agreed the length of the questionnaire was appropriate and sixty percent agreed the layout was clearly organized, while twenty percent neither agreed nor disagreed on this. Two questions received mixed results in regards to the font size and verbiage. Sixty percent of participants disagreed and did not find the verbiage confusing, while twenty percent neither agreed nor disagreed, and twenty percent strongly agreed it was confusing. Forty percent disagreed that the font was large enough to easily read, twenty percent strongly agreed, agreed, and neither agreed nor disagreed (see Appendix E for the complete report of results). Participants had the opportunity to leave comments, ideas, or critiques on question nine of the survey. The subjective feedback is provided unchanged or edited in Table 4.1.

Overall, the face validity results indicated the screener was not valid. Four out of the eight answers received majority consensus, however the remaining four received mixed answers indicating in those four areas, the screener in not valid. Additionally, the

direct feedback from the dietitians revealed major limitations including the screener such as the answer scale not being equal and the potential for misunderstanding and misinterpretations of terms. Until the changes are addressed, the screener cannot be considered to have face validity.

Table 4.1 Face Validity Direct Participant Feedback

Question 9: Please leave any additional comments, ideas, or critiques. We greatly appreciate any feedback.	
#1	People may not know what Sofrito sauce is. Is there a reason it is in the survey?
#2	Somewhat wordy but overall simple as long as the target audience is educated.
#3	Indent the questions under each heading.
#4	People will not understand categories if scale is not given. And if it is given, place it on the top of the survey so it is clearly seen.
#5	Scale itself is not equal.
#6	Why qualify butter as okay? Just ask what they use.

Statistical Analysis

The mean age of the thirty-one sample participants was 71.23 years and 67.74 percent were women. Data collected from the screeners were compared to the seven-day food journals using descriptive statistical analysis. Reference Appendix F for the complete table of the results of the twenty-one food group statistics. Frequencies were tallied for each measurement tool and the difference was calculated to show equal, under, and over reporting in the screener in regards to actual recorded consumption in the food journals. For the *never* answer category, only two out of the twenty-one food group categories, fresh or frozen fruits and vegetables and the no sugar added foods were

consistent with information in the food journals. The screener over reported in three groups, the sugar added beverages, white meat, and other dairy, while there was under reporting in the remaining sixteen groups. The frequencies in the *some* category presented equal reporting in only the white meat category where three participants recording consuming white meat one to two times a week on the screener and actually consumed white meat one to two times a week according the their food journals. Over reporting happened in fourteen food groups, and under reporting in six: vegetables, fruit, seafood, 100% whole grains, olive oil, and water. *Moderately* was the only category with the least difference between under and over reported. There was equal reporting in both tools in the fruit group, over reporting in twelve food groups and under reporting in eight. The *a lot* category had equal reported tallies in the processed or packaged foods and Sofrito sauce groups. Seventeen food groups experienced over reporting and the remaining no sugar added foods and other dairy groups were under reported. Finally, the *always* category had equal reporting in the Sofrito sauce group, over reporting in sixteen groups, and under reporting in four: fresh or frozen fruits and vegetables, other dairy, processed or packaged foods, and no sugar added foods.

The *never* category experienced the largest amount of screener under reporting whereas the majority of reported answers in the other four categories was over reporting. There was not a single food group documented in any of the five answer categories with the same frequency. In other words, there was not one food group that received unanimous reporting in the screener and food journal in any of the answer categories.

CHAPTER FIVE

Discussion

The research team at the cardiopulmonary rehabilitation program developed the short screener based on the nutrition curriculum created by the cardiologist. This was the first dietary questionnaire not only developed for patients in central Texas based on a modified Mediterranean diet but also reported for its validation.

The results of the study determined the screener was not valid at assessing a patient's adherence to a modified Mediterranean diet as indicated by the inconsistencies in the face validity survey and descriptive statistics. The frequencies of the thirty-one completed screener answers and the frequencies actually met as determined by the data from food journals indicate the screener did not accurately reflect intake as recorded in the food journals.

Limitations

Sample

The sample size was small with only thirty-one total participants completing the entire study. It also lacked diversity in gender and ethnicity. The majority of participants, exactly 67.74 percent were female and 96.77 percent were Non-Hispanic White.

Development

The objectives driving the creation of the screener were well intended to add a measurement tool to the literature that would be beneficial for educating patients in the

Wellness Center as well as in other clinics. However, there are major limitations to the current screener design and development process. The development process did not include the consultations of a Registered Dietitian or a statistician. Both types of professionals should have been consulted and recruited to help in the creation process of the survey. The screener's development was also based on the nutrition curriculum used in the clinic that is constructed from a single research study conducted to determine the efficacy of a Mediterranean type diet on primary cardiovascular prevention in Spain. The study does produce positive results indicating the components of a Mediterranean diet are in fact beneficial. But in order to effectively educate and treat the variety of patient's needs and disease states, the curriculum should be based on extensive literature review in order to fundamentally develop nutritional content that will best encompass and address the variety of conditions. A literature review should have also been conducted to gather ideas regarding layout, question wording, answer scales, and most importantly survey content.

The team did purposely recruit the help of a nutrition professional to analyze and validate the screener, but early consultation and recruitment of a dietitian would have provided the needed content expertise for the creation of the survey.

McKellar et al. 2008 designed and validated a Diet Habits Questionnaire (DHQ) to use in cardiac rehabilitation programs. The purpose of the study was to specifically design a survey tool that could quickly assess dietary habits and identify individual educational needs without the help of a dietitian or other trained nutrition professional. Though results from other studies have directly shown improved diet related outcomes when receiving education from a dietitian compared to any cardiac rehab staff, not all

rehab programs obtain the resources to provide dietitian services or individualized nutrition counseling. The authors of the DHQ intentionally developed the questionnaire questions from the literature and from the input of an experienced clinical dietitian. The overall design, collection process, and results validated the reliability of the questionnaire to be used in cardiac rehab programs (McKellar et al. 2008). This research study is a great example of utilizing dietitians in the development of a survey in order to create a reliable, well rounded and researched survey to be used in rehabilitation programs that do not have a dietitian on staff.

Face Validity

In an effort to compensate for the lack of dietitian involvement in the development process, a survey was created to assess face validity and gather feedback to improve the screener. The results of the face validity survey relayed important feedback that could have definitely improved the results of the survey. However, due to timing of participant recruitment, the changes needed to improve the survey were not made because several subjects had already completed the study before the face validity survey was completed. This proved to be highly problematic with analyzing all of the results because a few of the comments addressed the answer choice scale. One participant said the scale itself was not equal, and another said if the scale was not given then the answer categories could not be understood. Those comments were also two of the biggest concerns so effort was made to get the team at the Wellness Center to give the answer key, but it did not happen because data collection had already started and could not be stopped to adjust the screener. Thus, when analyzing the screener, it was assumed

patients understood the translation of the answer choices in regards to number of days per week.

Variances of this issue were seen throughout the entire process of analyzing the data. Some participants who thoroughly reported their dietary intake on the food journals chose the accurate answer category on the screener. However, participants more commonly had discrepancies between their self-reported data and the answers on the screener. This was likely due to the omission of the answer key, but also to the lack of information provided to educate subjects on food and beverage serving sizes.

Screener Sections

The original version of the screener included two additional sections addressing eating habits and food labels. The habits section asked how many times the participant eats out and how willing the participant was to gradually make dietary changes to improve his or her health. The food labels section asked when reading a food label do participants look at the sodium, trans-fat, saturated fat, sugar, and total calories. Participants were also asked if he or she did the grocery shopping, cooking, and if he or she understands how much food equals a serving size. Though the general answer categories were not applicable to some of the questions such as the willingness to make changes and understanding of serving sizes, the two sections in general could have been beneficial to overall interpretation of the data specifically in regards to understanding serving sizes and eating out habits. It was apparent through the analyzing process of the food journals, patients were unaware of an actual serving size. Most patients also reported eating out at restaurants but there was nowhere to translate this on the survey

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except for the one or fewer servings of food from bag, box, can, package or drive-thru per week question.

Omission of the last two sections was not known until the data were emailed. The research team believed the sections were not necessary and chose to address those sections directly with the patients during their appointments. Additionally, it was suggested to the team at the clinic to provide serving size handouts and pictures to the subjects when handing out the seven-day food journals, but data collection had already began. Thus for future studies, it is highly recommend the team of researchers give patients either educational handouts of serving size explanations and pictures or actual food models, which are commonly used by dietitians for counseling purposes though this option is more expensive and would require additional monetary resources.

Altogether, the answer measurement scale and the statistical analysis of the data proved to be the major limitations of the entire study. The scale produced several problems in the statistical analysis of the screener because it was not developed to properly measure serving sizes or exact number of days, which was needed to specifically analyze correlation between the screener and seven-day food journals. The screener responses did not align numerically with the food journals and since the scale was not developed properly, inferential statistics to assess numerical correlation between the measurement tools could not be calculated and instead descriptive statistics were needed to interpret the data. Since this research is a pilot study, the method used to analyze the data is a preliminary way to assess the screener's validity and future studies should adjust the screener's scale and recruit a professional statistician in the development process.

Bias

Self-reported bias is always a possibility with food journals and diet surveys, which can skew reporting of actual eating habits. There will always be too many variable to control for self-reporting bias, so patients should always be encouraged to report as truthfully as possible by non-judgmental affirmation.

<center>*Strengths*</center>

The research study is a pilot study meaning it was the first dietary questionnaire not only developed for patients in central Texas based on a modified Mediterranean diet but also reported for its validation. Once adjustments to the questionnaire are made, it could be beneficial for educational purposes in cardiopulmonary rehabilitation clinics. The screener also included culturally common foods such as tortillas.

A strength of self-reported questionnaires as reported by other epidemiological studies is the validity of questionnaire reporting increases with age (Deschamps et al. 2009). The mean participant age of the study was 71.23 years, thus even with all of the limitations, the sample age may have helped the results' accuracy.

<center>*Suggestions*</center>

Based on the feedback observed while interpreting the data, there are several suggestions in order to better improve the questionnaire. In order to produce valid results, the screener either needs to be re-developed using the data recommendations found in this study, or revisions need to be made to the current screener.

Wording of several of the questions needs to be altered due to a lack of clarity. Numerous subjects either wrote they did not know what the question meant or simply put question marks by the butter substitute and margarine question, Sofrito sauce question, and the sugar added beverage question. The butter substitute and Sofrito sauce questions were also addressed by two of the nutrition professionals in the face validity survey. Thus, it would be beneficial to reword the questions and to directly explain why only butter substitutes are used in the question. In regards to the Sofrito sauce, it is a culturally common food in Spain and not widely recognized a common dish in the United States or in McLennan County. Therefore, it is advised a substitution for a similar culturally appropriate food item be made. Additionally, some patients reported sweetening their beverages with Stevia. In particular, one patient sweetened all of her beverages multiple times a day with Stevia, but did not report on the survey ever consuming sugar added drinks. Though Stevia is a natural sweetener, it needs to be considered as a sugar substitute in this question. In regards to added sugars, the question about meals, snacks, or sauces that are non-sweet tasting is a bit confusing. There are copious amounts of foods that contain artificial and natural added sugars and a large amount of people are unaware of this fact. The exact meaning of the foods in this question need to be clarified otherwise the question should be omitted. One other question that requires explanation is the one or fewer servings from a bag, box, can, package, or drive-thru question. There are countless food items in packages, bags, boxes, and cans such as cereal, pre-packaged salads, frozen vegetables and fruits, oatmeal, whole-grain snacks, freshly squeezed juices, canned legumes and vegetables, and many other foods that are acceptable healthy

options. This question implies foods and beverages from such sources should not be consumed more than once a week. Therefore, this question also needs clarification to be included in the survey.

There were inconsistencies with participants recording their nut intake because of the types of nuts included in the survey question. Almonds, hazelnuts, and walnuts were the only three types included in the question, however many participants reported regularly eating peanuts, pecans and cashews on their food journals and proceeded to also answer the question on the survey despite not consuming any of the three types of listed nuts. Future questionnaires should consider adding those nut options as well. One other variation noticed while interpreting the data was several participants reported consuming low-fat dairy products on the survey, but in reality were not drinking low-fat milk or consuming low-fat yogurt according to their recorded intake on the food journals. Since there is such a variety of dairy products available, it is vitally important patients are educated according to product specifications.

Communication

Based on the experiences learned from this research study, data collection in future studies should begin only after all face validity results, critiques, suggestions, and changes are made to the survey. Communication between all members of the research team should be constant, open, and timely to ensure appropriate information is utilized to produce the best possible results. Consequently, it is critically important for future studies to be fully prepared before any type of data collection has commenced.

Sample Size

Future studies should first calculate the exact sample size needed to effectively validate the questionnaire and modify the methods of recruitment. The recruitment period for this study only lasted four months and was done solely by word of mouth by the team members at the clinic. Incentives may want to be offered for higher participant numbers and greater retention rates.

Translation

Finally, populations throughout the geographical regions in the world adhere to immensely different diets for reasons including culture, food supply and availability, and customs. Since there is such a diverse range of dietary habits in population groups, there will never be a universally accepted and applicable screener, food-frequency questionnaire, or any dietary measurement tool (Liu et al 2013). Therefore it is incredibly important to create, research, and validate tools that will accommodate the population being served because relative validity may be altered in different languages (Streppel et al 2013). In this case, with 19.1 percent of the population in McLennan County speaking a language other than English and 15.4 percent being Spanish, it is highly recommended that a revised screener be translated to Spanish not only for future research on the screener but also to accommodate the large Spanish speaking population in the area (United States Census Bureau 2016).

CHAPTER SIX

Conclusion

Overall, the face validity results signified the screener was not valid in accordance to current expert opinion and the descriptive statistical results determined the screener is not valid for assessing adherence to a modified Mediterranean Diet in cardiopulmonary rehabilitation patients. The entire process of this pilot research study including the questionnaire development, statistical analysis, and interpretation of results demonstrated the crucially important need for involvement of trained professionals. In order to successfully develop a dietary measurement tool, a nutrition professional must be involved in the entire development process. Their knowledge, expertise, and experiences are unparalleled and need to be utilized by any type of rehabilitation clinic that does not have a dietitian on staff. Though efforts to involve nutritional professionals in this study were made, they proved to be too late to add any advantageous advancements of the screener before data collection commenced and analysis was conducted. Additionally, the statistical challenges verified the need for the recruitment of a statistician to also help with the questionnaire development in order to ensure the tool is designed for reliable analysis and subsequently validation of the questionnaire.

Since this was a pilot study and is used as a learning tool, it can be concluded that the statistical analysis was a preliminary method of determining the relative validity of the screener. Future research should consider the results of the current study and

implement the necessary changes and suggestions to improve the content and overall

validation.

APPENDICES

APPENDIX A

Timeline of Events

Development	• The measurement tool was created by the two Registered Certified Exercise Physiologists research team members at the cardiopulmonary rehabilitation clinic in the Baylor Scott and White Hillcrest, Ted and Sue Getterman Wellness Center.
Recruitment	• The developers recruited my help to analyze the data and determine if it is valid for use in a cardiopulmonary rehabilitation clinic. • The research team at the clinic recruited patients to participate in the study.
Methods	• A face validity survey was constructed and sent to five nutrition professionals to gather feedback regarding the screener. • The study simultaneously began at the clinic.
Methods	• The data were collected, number coded, and made anonymous. • The research team at the clinic emailed over all the data.
Analyze	• The data were analyzed and interpreted.

APPENDIX B

Definition of Terms

- The traditional Mediterranean Diet is characterized by:
    - High intake of monounsaturated fatty acids usually from olive oil and nuts
    - Plant proteins
    - High fiber foods such as vegetables, fruits, legumes, cereals and whole grains
    - Moderate to high intake of fish
    - Moderate intake of alcohol
    - Low intake of red meat, refined grains, and sugar added foods such as desserts and baked goods
    - Low to moderate consumption of dairy products

- The Modified Mediterranean Diet used as the basis for the creation of the screener is characterized by:
    - Abundant use (up to 1 liter a week) of olive oil for cooking and dressing foods
    - 2 or more servings of vegetables daily
    - 2-3 servings of fruit daily
    - 3 or more servings of legumes per week
    - 3 or more servings of fish per week
    - 1 or more servings (30 g = one serving) of hazelnuts, almonds, and walnuts per week
    - 1 or less servings of red meat per week
    - Two or more servings of Sofrito sauce per week
    - Select white meats instead of red meats
    - Consume low-fat dairy daily
    - Consume 100% whole-grains daily
    - No butter substitutes or margarines
    - Do not purchase foods from cans, bags, boxes, or drive-thrus
    - 2 or less sugar added beverages per week
    - 1 or less baked good, dessert, or pastry per week
    - Cook with spices and herbs instead of salt
    - 64 oz. or more of water daily

- A screener is classified as a short dietary assessment measurement to obtain basic information gathered from a specific list of food and beverages about dietary habits. The information is usually used for characterizing a population's median intakes, examining interrelationships between diet and other variables, and

discriminating among individuals or populations with regard to higher versus lower intakes (National Institute of Health 2017).

APPENDIX C

Modified Mediterranean Diet Screener

Modified Mediterranean Diet Screener

I eat...	Never	Some	Moderately	A lot	Always	
vegetables and fruit that are fresh or frozen.						Veg
2 or more servings of fresh vegetables per day						Veg
2-3 servings of fresh fruit per day						Frt
1 or more handfuls of walnuts, almonds or hazelnuts per week (not candied or salted)						N/L
3 or more servings of beans or legumes per week						N/L
Low-fat options of milk, cheese, or yogurt						Dairy
2 or fewer servings of milk, cheese, ice cream and other dairy products (butter, sour cream, puddings, custard etc.) per day						Dairy
1 or fewer servings per week of red meat, cured ham, cured cheeses or processed meats (i.e., sausage, bacon, and others) per week						Meat
White meats (i.e., turkey, chicken and fish)						Meat
3 or more servings of seafood per week (1 serving from cold water fish (i.e., salmon, sardines, tuna, herring, lake trout, etc)						Seafood
1 or fewer sweet tasting baked goods weekly						Wheat/Prsd/Sgr
Bread, rice, pasta, tortillas, and cereals made of 100% whole grains.						Wheat
1 or fewer servings of food from bag, box, can, package or drive-thru per week.						Prsd
Meals, snacks, or sauces that are not sweet-tasting (no added sugar or artificial sweeteners)						Sgr
I prepare my foods with.......						
Butter substitutes or margarines (solid at room temperature) no more than once per week; butter is okay.						Oils
1 tablespoon or more of olive oil per day						Oils
herbs and spices						Sodium
homemade "sofrito" sauce 2 or more times a week						
salt while cooking or at the table						Sodium
I drink.......						
2 or fewer sweet tasting drinks daily (with sugar or artificial sweeteners; including any types of juices or milk)						Sgr
64 ounces or 8 cups of water per day						Hyd

APPENDIX D

Food Journal

		Servings(circle one)	Foods	Frequency	Location(circle one)
MONDAY	**Breakfast**	Tb/tsp/cup/oz	_____	servings	Home/Restaurant
		Tb/tsp/cup/oz	_____	servings	Home/Restaurant
		Tb/tsp/cup/oz	_____	servings	Home/Restaurant
		Tb/tsp/cup/oz	_____	servings	Home/Restaurant
	Lunch	Tb/tsp/cup/oz	_____	servings	Home/Restaurant
		Tb/tsp/cup/oz	_____	servings	Home/Restaurant
		Tb/tsp/cup/oz	_____	servings	Home/Restaurant
		Tb/tsp/cup/oz	_____	servings	Home/Restaurant
	Dinner	Tb/tsp/cup/oz	_____	servings	Home/Restaurant
		Tb/tsp/cup/oz	_____	servings	Home/Restaurant
		Tb/tsp/cup/oz	_____	servings	Home/Restaurant
		Tb/tsp/cup/oz	_____	servings	Home/Restaurant
	Snacks	Tb/tsp/cup/oz	_____	servings	
		Tb/tsp/cup/oz	_____	servings	
		Tb/tsp/cup/oz	_____	servings	
		Tb/tsp/cup/oz	_____	servings	
	Beverages	____ Oz/cups	_____	servings	
		____ Oz/cups	_____	servings	
	Condiments	Tb/tsp/cup/oz	_____	servings	
		Tb/tsp/cup/oz	_____	servings	

APPENDIX E

Face Validity Survey Results

Questions	Answers						
	Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree	Yes	No
1. Are the questions easy to understand		4 (80%)		1 (20%)			
2. Is the verbiage confusing?	1 (20%)		1 (20%)	3 (60%)			
3. Is the layout of the questionnaire clear and well-organized?		3 (60%)	2 (40%)				
4. Is the font legible?	1 (20%)	4 (80%)					
5. Is the font size large enough to easily read?	1 (20%)	1 (20%)	1 (20%)	2 (40%)			
6. Is the questionnaire easy to complete?		4 (80%)	1 (20%)				
7. Is the length of the questionnaire appropriate?	1 (20%)	3 (60%)	1 (20%)				
8. Does the questionnaire take more than ten minutes to complete?						4 (80%)	1 (20%)

APPENDIX F

Measurement Tool Frequency Results

	Frequencies as Reported by Both Measurement Tools														
Food Groups	Never (0)			Some (1-2)			Moderately (3-4)			A lot (5-6)			Always (7)		
	S	J	D	S	J	D	S	J	D	S	J	D	S	J	D
Fresh/Frozen Fruit and Vegetables	0	0	0	3	0	+3	6	1	+5	13	6	+7	9	23	-14
Vegetables	0	3	-3	7	12	-5	8	11	-3	12	2	+10	4	3	+1
Fruit	4	9	-5	8	10	-2	5	5	0	8	5	+3	6	2	+4
Nuts	4	17	-13	9	4	+5	5	6	-1	5	2	+3	7	2	+5
Legumes	3	16	-13	13	10	+3	10	5	+5	4	0	+4	1	0	+1
Low-Fat Dairy	2	7	-5	16	8	+8	5	9	-4	7	4	+3	11	3	+8
Other Dairy	2	1	+1	10	2	+8	10	7	-3	4	9	-5	5	12	-7
Red Meat	6	22	-16	6	3	+3	8	2	+6	8	2	+6	3	2	+1
White Meat	2	0	+2	3	3	0	7	15	-8	14	11	+3	5	2	+3
Seafood	8	13	-5	9	12	-3	8	6	+2	5	0	+5	1	0	+1
Baked Goods	3	22	-19	7	6	+1	11	2	+9	4	0	+4	6	1	+5
100% Whole Grains	1	3	-2	5	9	-4	6	8	-2	11	8	+3	8	3	+5
Processed/Packaged Foods	4	17	-13	14	0	+14	4	2	+2	6	6	0	3	6	-3
No Sugar Added Foods	0	0	0	14	2	+12	4	8	-4	11	14	-3	2	7	-5
Butter Substitutes	8	24	-16	8	5	+3	8	0	+8	2	1	+1	5	1	+4
Olive Oil	8	19	-11	6	8	-2	5	3	+2	9	0	+9	3	1	+2
Herbs and Spices	5	27	-22	5	2	+3	7	1	+6	6	1	+5	8	0	+8

	S	J	D	S	J	D	S	J	D	S	J	D	S	J	D
Sofrito Sauce	27	31	-4	3	0	+3	1	0	+1	0	0	0	0	0	0
Salt	6	29	-23	11	0	+11	7	0	+7	6	2	+4	1	0	+1
Sugar Added Beverages	8	4	+4	10	7	+3	2	3	-1	5	2	+3	6	1	+5
Water	8	22	-14	4	5	-1	8	2	+6	5	1	+4	6	1	+5

Legend of Frequencies

S = Screener
J = Journal
D = Difference

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