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A Cost Effectiveness Analysis Of The Nutritious Eating With Soul Study

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DEDICATION

This body of work is dedicated first to God almighty for directing my path, because with Him all things are possible. This body of work is dedicated to my parents, grandparents and godparents who instilled in me the value of faith, education, hard work, excellence, service, leadership and perseverance. This body of work is dedicated to my home team- my husband and our three children. They have been my biggest supporters and my personal cheering squad (literally) along the way. I will be forever grateful for their sacrifices during my time in the program. This body of work is dedicated to my siblings, my family members, friends, mentors, church family, sorority sisters and colleagues who have prayed for me, encouraged me, and supported me in various capacities. Lastly, this body of work is dedicated to: all stakeholders who endeavor to work towards the elimination of health disparities in the African American community; those in the African American community who are stiving to break cycles of generational health ailments; and participants of the Nutritious Eating With Soul Study. You all are appreciated.

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ABSTRACT

PURPOSE

Historically, African Americans (AA) have been underrepresented in nutrition-related behavioral research despite their disproportionate higher risk of cardiovascular disease (CVD). The Nutritious Eating with Soul (NEW Soul) Study is one of the first of its kind to recruit an AA only study group to examine CVD prevention via a clinical trial to examine changes in CVD risk factors across two cohorts who are randomly assigned to a plant-based, soul food vegan diet or low-fat omnivorous (omni) diet. The purpose of cost effectiveness analysis (CEA) is to inform clinical and policy decisions and the costs of interventions that society is willing to pay for. However, few studies have examined the cost effectiveness of behavioral interventions for AA adults. The purpose of this study was to evaluate the cost effectiveness of the nutrition and behavior change interventions of the NEW Soul Study, from a societal perspective, by examining direct costs to deliver the intervention, and indirect costs reported by participants associated with intervention adherence.

METHODS

Primary data were collected from AA adults (n=105) between the ages of 18-65 from the Midlands SC region, who enrolled in the NEW Soul Study, across two cohorts, and were identified as having overweight or obesity (BMI 25–49.9 kg/m^2). Upon completion of baseline assessment of weight, and other laboratory measures,

participants were randomized to follow a vegan or low-fat omni diet. A cost effectiveness analysis (CEA) of this randomized control trial is based on one-year outcomes collected in April 2019 for Cohort 1 and June-July 2020 for Cohort 2. An incremental cost effectiveness ratio (ICER) over the one-year study period was calculated based on the intervention (direct) and societal (indirect) costs and weight loss. Total Costs = Costs to deliver the intervention (ingredients for cooking demonstrations, meals) + participants' average cost of weekly groceries + average weekly costs of dining out. Quality adjusted life year (QALY) was calculated based on Short Form-12 survey responses that were collected at baseline and one year. Variations in weight loss between cohorts 1 and 2 before COVID-19 and during COVID-19 were assessed using a difference-in-difference (DD) study design.

RESULTS

The incremental cost effectiveness ratio (ICER) was $2,888.57 per pound of weight loss. The results fall within quadrant II of the cost effectiveness plane which indicates that the vegan diet group, as compared to the omni diet group was more cost effective, as participants in that diet group experienced greater weight loss in addition to the intervention costing less. Results from the least squares means estimate from DD models (adjusted for covariates) reveal that both diet groups experienced some gains in QALY from baseline to 12 months (omni @baseline = 0.7889; omni @ 12 months= 0.804; vegan @baseline =0.8027; vegan @12 months = 0.808), however there was no statistically significant DD in QALY between diet groups ($Pr > |t| = 0.6485$). Pre-COVID, Cohort 1 participants lost an average of 10.2 pounds at 12 months from baseline. During COVID, Cohort 2 participants lost an average of 3.7 pounds at 12 months from baseline. The difference-in-differences in

weight loss pre-COVID and during COVID by diet group revealed a statistically significant change in weight loss at 12 months compared to baseline between cohorts 1 and 2 for the vegan diet group ($p=0.0408$). Pre-COVID (C1), the vegan diet group lost an average of 11 pounds. During COVID (C2), the vegan diet group lost an average of 3.47 pounds.

CONCLUSIONS

The vegan diet intervention produced clinically relevant weight loss at a lower cost and was therefore cost-effective. Both diet groups experienced similarly minimal gains in QALYs and the DD in QALYs between the vegan and omni groups was not statistically significant. DD analysis suggests that the COVID-19 pandemic had an impact on participants' ability to achieve greater weight loss in Cohort 2 (compared to Cohort 1), and significantly inhibited weight loss of participants in the vegan diet group.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER 1

INTRODUCTION

Cardiovascular disease (CVD) accounts for an estimated $448.5 billion in 2008, from direct (patient care) and indirect (loss/reduced productivity) healthcare expenditures, an estimated $555 billion in 2016, and a projected estimate of $1.1 trillion by 2035.[1,2] To address the rising costs of health care related to CVD, identifying the root cause is key[3]. The primary risk factor for CVD is poor nutrition.[4] Poor nutrition is one of the reasons for racial-ethnic disparities in the prevalence of CVD, primarily due to disproportionate differences in health status facing African Americans (AA).[4,5]

Worldwide, CVD is the reason for most deaths for men and women of all races.[6] According to 2018 data, 30.3 million American adults were diagnosed with cardiovascular disease.[6] CVD has been the leading cause of death in the United States for 95 years; for 95 years more AA adults disproportionately die from CVD more than cancer or any other chronic disease condition.[2,7–10] AAs in the United State (U.S.) have higher rates of obesity due to poor nutrition, a risk factor of CVD, compared to Whites and Hispanics.[2] AA foodways, known as the intersection of food and culture, is a unique contributor to CVD. At the heart of AA foodways is soul food, as it symbolized the enduring identity of AAs who persevered through slavery by using high amounts of fat and sodium to prepare soulful dishes from garden produce, food scraps and the poorest parts of meats.[11] This type of cooking has been passed down from generation-to-

generation and has contributed to the disparity of AAs being diagnosed with CVD at higher rates.[11]

Healthful plant-based diets have been shown to help prevent and treat CVD and promote a healthy body weight. [12,13] Nutrition intervention trials have examined the impact of weight loss and CVD risk of those following vegan or vegetarian (veg) diets compared to omnivorous (omni) diets and a recent meta-analysis presented that participants following a veg diet lost more weight than those assigned to an omni diet.[14,15] However, most of these interventions had minimal participation from AAs and have shown a combination of higher attrition and lower weight loss, that may be due to a failure to incorporate and address aspects of AA foodways.[16] This disparity in participation results in significant clinical and healthcare spending burdens.[17]

Hence, there is a critical need to identify and implement culturally relevant research-based nutrition interventions that are also financially sustainable to combat CVD within the AA population. Existing literature supports the novel theoretical concept of applying a cost effectiveness analysis (CEA) to dietary interventions.[18–25] Currently, a cost-effective nutrition intervention for AAs has not been identified, which makes it difficult to decrease healthcare spending for CVD and make nutrition recommendations that are culturally acceptable and affordable for those who present with CVD risk factors.

The NEW Soul study, which began in 2017, is one of the first randomized control trials (RCT) with solely AA participants that incorporates AA foodways through partnering with local soul food restaurants/chefs to deliver two behavioral nutrition interventions (vegan and omni low-fat) to AA adults and examines changes in risk factors for CVD over a two-year period.[26] There has been a call to focus on diets versus single

nutrients in research.[27] Both diets of the NEW Soul Study are guided by the Oldways African Heritage Pyramid, which emphasizes intake of fruits, vegetables, particularly leafy greens and tubers, and whole grains.[28] The NEW Soul Study tests whether a vegan diet, compared to an omni diet, is effective for CVD prevention and obesity treatment among an AA population. Prior to this study, no randomized study has examined differences between these diets among AAs. The design of this intervention is guided by the Social Cognitive Theory with the goal of increasing participant's self-efficacy around sustainable dietary change.[29] However, advising future community-based approaches and population health decision making requires regard of cultural acceptability, costs, and benefits. A CEA of the NEW Soul Study is innovative because there has not been an economic analysis, from a societal perspective, of a randomized study that examined the differences between a vegan and low-fat omni diet among AAs.

STATEMENT OF PURPOSE

The purpose of this cost effectiveness analysis is to: evaluate the NEW Soul Study for large-scale implementation by assessing the incremental cost per unit of weight loss in pounds, taking into consideration direct costs to deliver the vegan and omni nutrition interventions. In our analysis, we will adopt a societal perspective by also considering the cultural acceptability of dietary recommendations and the costs borne by participants receiving these interventions. Finally, we will also conduct a cost utility analysis to determine the cost per quality-adjusted life year (QALY) gained by program participants.

A cost effectiveness analysis of the NEW Soul Study can help carry out the mission of the NIH to enhance health and reduce disease by adding new knowledge of a

culturally relevant nutrition intervention for AAs that will be socially acceptable and may improve health policy and future health disparities efforts in community and physician practice settings to reduce the disproportionate burden of CVD.

Costs examined in this study include the costs to deliver and implement the interventions, such as cooking demonstrations and catering, monetary costs of participants to follow the assigned diet based on average cost of weekly groceries and societal costs such as average time spent by participants shopping for food and average time spent by participants to prepare meals. The major outcome of interest for this study is weight loss that will be used to calculate an incremental cost effectiveness ratio (ICER). Furthermore, a change in QALY calculation that will be generated for the two diet groups based on results of participants' Short Form-12 (SF- 12) health status survey at baseline and one year. Additionally, a difference-in-differences (DD) analysis will be performed to estimate the impact of the COVID-19 pandemic on weight loss of participants in both diet groups. Based on the results of this study, our long-term goals are to inform stakeholders and policy makers AA-specific results of this theory-based intervention and facilitate the process of policy changes related to: physician recommendations for AA patients who present with risk factors of CVD; and funding and implementation of interventions in community settings that are affordable and sustainable.

RESEARCH AIMS & METHODLOGY OVERVIEW

Cost effectiveness analysis factors in how interventions improve health, the resources required, how interventions can reduce health inequities, and affordability and feasible expectations of the population to adhere to interventions analyzed.[30–32] Knowledge of the cost effectiveness of The NEW Soul Study will inform the literature to

the unknown question of whether a vegan diet or low-fat omni diet is more cost effective, affordable and feasible within the AA population for weight loss and quality of life. Additionally, the estimated effect of the COVID-19 pandemic on weight loss of the diet groups will inform the literature of how global crisis may affect AA participants enrolled in dietary interventions.

Primary Aim

1a: To test the difference in average weight loss between diet groups.

- If weight loss is normally distributed, we will use a t-test. If this assumption is violated, we will use the Wilcoxon test.

  Y (dependent variable) = average weight loss

  X (independent control variable) = diet group

1b: To conduct a difference-in-difference (DD) regression analysis to explain the difference in weight loss between diet groups while controlling for age, sex, education, employment, class attendance, physical activity, and cohort.

$Y = b_0 + b_1{*}t + b_2{*}$*diet group* $+ b_3{*}$*diet group*$*t + b_4{*}$*age*$+ b_5{*}$*sex* $+ b_6{*}$*education* $+ b7$ **employment + b8 *class attendance + b9*physical activity + b10* cohort*

H_0 for 1b & 1c: Avg Weight $loss_{Vegan}$=Avg Weight $loss_{Omni}$

H_A for 1b & 1c: Avg Weight $loss_{Vegan} \neq$Avg Weight $loss_{Omni}$

Y (dependent variable) = weight loss at time t t=0 if baseline; t=1 if 12 months

X (independent variable)= diet group

X (independent control variable) = age, sex, education groups, employment, class attendance, physical activity, cohort

1c: To conduct a cost effectiveness analysis with weight loss as an outcome of two different culturally tailored nutrition interventions at 12 months.

Findings will be presented as an incremental cost effectiveness ratio. A sensitivity analysis will be conducted to account for degrees of uncertainty.

$$ICER = \frac{Total\ Cost_{vegan} - Total\ Cost_{omni}}{Weight\ loss_{vegan} - Weight\ loss_{omni}}$$

To calculate weight loss, participants' weight was taken at baseline and 12 months using a calibrated digital scale (Healthometer®model 500 KL, McCook, IL). Two measurements at each time period were taken and averaged. Total weight loss from baseline to 12 months was averaged for each dietary group. Total costs are calculated from a societal perspective. This perspective includes aspects of non-health effects that provide insight into participant's net benefits or costs associated with the intervention.[44] Total Costs = Costs to deliver the intervention (ingredients for cooking demonstrations, meals) + participants' average cost of weekly groceries + average weekly costs of dining out. Cooking demonstration and meal costs to deliver the intervention were collected and totaled from accounting reports from year one for each diet group and averaged for each diet group. Literature has determined a connection between costs of food, diet quality, and obesity and particularly and advocates for the need to identify dietary patterns that are rich in nutrients and affordable in order to reduce health and nutrition disparities. [27,33] Therefore, participants' average cost of weekly groceries and dining out was collected at baseline and 1-year assessments periods. Total costs will be divided by the number of total participants from each diet group.

Secondary Aim:

2a: To test the difference in average QALY between diet groups.

- If average QALY is normally distributed we will use a t-test. If this assumption is violated, we will use the Wilcoxiam test.
- Y (dependent variable) = average QALY
- X (independent variable) = diet group

2b: To conduct a difference-in-difference (DD) regression analysis to explain the difference in average QALY between diet groups while controlling for age, sex, education, employment, class attendance, and physical activity.

$Y = b_0 + b_1{*}t + b_2{*}$*diet group* $+ b_3{*}$*diet group*$*t + b_4{*}$*age*$+ b_5{*}$*sex* $+ b_6{*}$*education* $+ b7$ **employment + b8 *class attendance + b9*physical activity + b10* cohort*

H_0 for 2b & 2c: Avg $QALY_{Vegan}$=Avg $QALY_{Omni}$

H_A for 2b & 2c: Avg $QALY_{Vegan} \neq$Avg $QALY_{Omni}$

Y (dependent variable) = Avg QALY at time t t=0 if baseline; t=1 if 12 months

X (independent variable)= diet group

X (independent control variable) = age, sex, education groups, employment, class attendance, physical activity, cohort

A systematic review of the literature concluded that the Short Form-36 (SF-36) health status survey was the most widely used measurement tool when assessing the impact of dietary habits on health related quality of life in a wide variety patients in clinical settings and persons surveyed is social and research settings.[34,35] The SF-36 measures eight domains: physical functions; physical role limitations; bodily pain; general health perceptions; energy/vitality; social functioning; emotional role limitations;

and mental health.[36(p36)] The Short Form-12 (SF-12) health status survey was developed in 1994 as a sub-set of the SF-36 in order to both reduce respondent burden and to provide a significant measure of health status; as it measures the same eight domains as the SF-36.[35] The literature suggests that the SF-12 correlates highly with the SF-36 in patients of all BMI groups and may be more appropriately used in place of the SF-36 when more obesity-related quality of life measures are being used and when respondent burden is a concern.[37] Respondent burden was a concern for our study population since participants in this study volunteered and completed several other surveys including dietary food recall surveys at measurement time periods. Therefore, the SF-12 was selected as the instrument of choice to assess health status for participants enrolled in the NEW Soul Study at baseline and 12 months.

The Short Form- 6D (SF-6D) is a preference-based instrument for economic evaluation and was used for this study due to its to classify responses from the SF-12 and assign health state preference values that were used to calculate QALY via the SF-6D scoring table.[38,39] The decision to utilize this instrument for classification of responses was based on exploration and conclusions from prior studies that compared the three most widely used classification systems in the literature: EuroQol five-dimensional (EQ-5D); Health Utilities Index (HUI) and the SF-6D.[31] Although the EQ-5D is widely used all over the world in research, clinical settings and for cost utility analysis, it does not completely capture mental health components for international heart patients who present with similar heart disease risk factors as participants in this study; nor has it been included in any large-scale general population surveys in the US.[40,41] According to the literature, the HUI classification instrument is valid and reliable, it is specific to HUI

questionnaires, so it cannot be applied to classify our participant responses from the SF-12.[31,42] The SF-6D has been applied widely in the literature as an instrument to estimate quality of life in lifestyle interventions in the US for diverse populations with overweight/obesity.[31,43,44]

In order to classify SF-12 responses, the number of dimensions is reduced from eight to six by excluding the general health item and combining the role limitation dimensions (physical and emotional).[38] In 2004, four models (algorithms) to calculate utility were reported in the literature. [38] Models 1 and 2 represent the algorithms to calculate utility based on classifying responses from the SF-36. Models 3 and 4 represent the algorithms to calculate utility based on (SF-12). Model 4 was utilized for this study because it was determined in the literature to be the more consistent and preferred model because it does not include variables that are not significant at $p < 0.05$.[38] Additionally, levels of each dimension in Model 4 were aggregated if there were any inconsistencies.[38] However, this method is limited because it is not current.

More recent literature uses Short Form-6 Dimensions version 2 (SF-6Dv2), an updated version of the SF-6D that addresses limitations, to classify responses from SF-12.[45] This classification presents six models of algorithms to calculate utility that were tested.[45] Results indicated Model 3 as the recommended algorithm to estimate QALYs because of its efficient design using established experimental design procedures and also due to the model being ordered within dimensions, where increasing severity results in a decrease in utility.[45] However, due to its recent results, this model has not been widely tested in US populations with AA adults presenting with overweight/obesity. Both methods were used to calculate utility and the distribution of utility score estimates.

An average QALY for participants in each diet group will be determined from SF-12 responses, using both SF-6D and SF-6Dv2 algorithms, by taking 12 month QALY – baseline QALY of each participant and then calculating an average QALY for participants in each diet group.[31] The objective of this aim is to determine the efficacy of vegan versus omni diet interventions on QALY. The benefits of assessing QALY as a measure of health output is that it can simultaneously depict gains from reduced morbidity and mortality and incorporates it into one measure.[31]

Tertiary Aim:

3a. To test the difference in average weight loss between cohorts and diet groups.

- If weight loss is normally distributed we will use a t-test. If this assumption is violated, we will use the Wilcoxon test.
  - Y (dependent variable) = weight loss from baseline to 12 months
  - X (independent variable) = cohort, diet group

3b. To conduct a difference-in-differences (DD) estimation to assess the likely impact of COVID-19 on the weight loss in pounds by comparing the changes in Cohort 2 (affected by COVID-19 at 1 year) to Cohort 1 (not affected by COVID-19 at 1 year).

$Y = b_0 + b_1 * t + b_2 * cohort + b_3 * cohort * t + b_4 * age + b_5 * sex + b_6 * education + b7 * employment + b8 * class\ attendance + b9 * physical\ activity + b10 * diet\ group$

H_0: Avg Weight $lossC1_{precovid}$ = Avg Weight $lossC2_{duringcovid}$

H_1: Avg Weight $lossC1_{precovid} \neq$ Avg Weight $lossC2_{duringcovid}$

Y (dependent variable) = average weight loss

X (covariates) = age, sex, education groups, employment, class attendance, physical activity, diet group

Time (Dummy Variable) => 1= DURING COVID-19 0= Pre COVID-19

Intervention (Dummy Variable)=> 1= DURING COVID- 19 0 = PRE COVID-19

For this study, difference-in-differences estimation is a group of methods that is utilized to assess the likely impact of the COVID-19 pandemic on weight loss between cohorts and diet groups.

ORGANIZATION OF THE DISSERTATION

The subsequent chapters provide in-depth details of the literature regarding the theoretical application of cost effectiveness analysis to nutrition interventions, the purpose for conducting a CEA of the NEW Soul Study, and the methods utilized to conduct this research. Additionally, subsequent chapters also provides details of the literature regarding potential COVID-19 effects on health and weight loss within various settings (clinical, research and community) and methods used to assess the impact of COVID-19 on weight loss for participants enrolled in the NEW Soul Study. Chapter 2 provides a critical review of the literature and serves as the foundation and justification for this research. Chapter 3 provides a comprehensive description of the methodology used to conduct this research. Chapter 4 details the research conducted to assess the more cost-effective intervention for African American participants in the NEW Soul Study, and the findings, limitations, and implications of this study. Chapter 5 details the clinical assessment protocol established to conduct assessments during the COVID-19 pandemic and an estimation of the likely impact of COVID-19 on weight loss, and the findings, limitations and implications of this study.

CHAPTER 2

LITERATURE REVIEW

This chapter provides a comprehensive review of the literature related to the dissertation research topic. This chapter details: 1) cardiovascular disease (CVD) incidence and prevalence in the United States (US); 2) the disproportionate burden experienced by African Americans (AA); 2) CVD incidence and its effect on healthcare spending; 3) the relationship between nutrition and CVD health; 4) the ability of primary care physicians to provide nutrition counseling to reduce AA CVD; 5) underrepresentation of AAs in nutrition interventions that address CVD; 6) the NEW Soul Study dietary intervention; 7) theoretical perspectives of applying economic evaluation to dietary interventions; 8) effects of COVID-19 on health; 9) the purpose of this research; and 10) the gaps in the literature that will be addressed through this study.

Cardiovascular Disease in the US

Cardiovascular disease has been the leading cause of death in the United States and causes 1 out of 4 deaths.[6,46] In 1979, The U.S. Department of Health and Human Services launched Healthy People, after the release of Surgeon General Julius Richmond's report entitled, *Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention.*[47] 10-year goals and objectives related to improving the overall health and well-being of the American population and preventing death and

injury have been released since its inception in addition to a framework for public health prevention priorities and action items.[48] The first Healthy People 10 year goals were released in 1990 and included objectives to reduce heart disease, a major cause of death.[48,49]

For the past two decades, Healthy People objectives have focused on the reduction and potential elimination of health disparities by keeping track of mortality rates, morbidity, health-related risk behaviors, and access to preventative health care by socioeconomic status and geographic location.[49] Healthy People (HP) 2010, 2020 and 2030 specifically stated the intent to improve population cardiovascular health and quality of life through prevention, detection, and treatment of risk factors for heart attack and stroke; early identification and treatment of heart attacks and strokes; prevention of repeat cardiovascular events; and reduction in deaths from cardiovascular disease. [47,48,50]

The most common type of heart disease is coronary heart disease. In fact, when people talk about "heart disease" they often mean coronary heart disease.[51] About 630,000 Americans. die from heart diseases each year.[51] More than 1 of every 10 (11.7%) of American adults have been diagnosed with heart disease.[7,51] Coronary heart disease and cardiovascular disease are two medical conditions related to the cardiovascular system. The term Cardiovascular Disease (CVD) refers to a group of diseases related to the heart and blood vessels. Coronary heart disease is one of these diseases.[51]

Progress was made towards some objectives related to CVD, and recessions were noted in other objectives. However, the commitment to improving cardiovascular to health and to decrease disparities associated with this disease remains. The goal to "improve cardiovascular health and quality through prevention, detection, and treatment

of risk factors for heart attack and stroke; early identification and treatment of heart attacks and strokes; prevention of repeat cardiovascular events; and reduction in deaths from cardiovascular disease," remains a public health priority. [47]

Cardiovascular disease represents a wide range of illnesses, including diseases of the cardiac muscle and the vascular system that supplies the heart, brain and additional vital organs of the body, such as atrial fibrillation, congestive heart failure, coronary heart disease, high blood pressure and stroke.[52,53] Disease does not occur alone, and cardiovascular disease is not an exclusion. Cardiovascular health is considerably affected by the physical, social, and political environment.[5,49] The Framingham Heart Study was a longitudinal cohort study beginning in 1948 that paved the way for much of the information known today surrounding CVD and cardiovascular (CV) function and the role that unhealthy diets play in its development.[54] The study identified many risk factors associated with CVD. Risk factors of cardiovascular disease include genetic predisposition, diabetes, high blood pressure, smoking, a sedentary lifestyle, obesity, access to affordable and quality health care, and the availability of community support and resources.[24,49,54]

CVD incidence increases healthcare spending. According to a 2009 report published in the New York Times, health care absorbed approximately one dollar in every six dollars that the nation spent, and this figure surpassed shares spent by any other nation.[20] The Congressional Budget Office projected that this figure will double by 2035.[20] Healthcare spending in the United States is the most significant contributor to the country's debt and deficits, but our health outcomes are worse that nations who spend much less on healthcare.[21] In the U.S. approximately 1 out of every 3 adults present with

some form or CVD risk factors.[21] The costs of CVD care contribute greatly to U.S. health care spending because it is one of the most expensive conditions to treat in US hospitals.[6,55,56] In 2006, the American Heart Association estimated that the cost of CVD (including CHD, stroke, hypertensive heart disease, and CHF) was $457 billion.[57] In order to put this into perspective, costs for CVD were equal to: "more than half of what the federal, state, and local governments combined spent on education ($812 billion); more than two-thirds of what was spent on defense ($622 billion); and more than what was spent on welfare ($320 billion) and transportation ($229 billion)."[58]

According to the CDC, nearly 5 million emergency room visits in 2017 were connected to problems associated with heart and blood vessel problems and more than 72 million Americans made appointments to see their physician related to heart disease.[58] The CDC estimated that between 2016-2017 health care costs of heart disease for direct care ranged from $214 billion to $351 billion with $137 billion going towards care for lost productivity and $11.5 billion accounting for hospital care from heart attacks.[58] Recent projections estimate that by 2035, more than 45 percent of the population will have cardiovascular disease at a total cost of $1.1 trillion with $748.7 billion going towards direct medical care costs and $368 billion going towards indirect costs (such as productivity loss). [52,58] As the nation engages in efforts to reduce healthcare spending, policy research perspectives published by the American Medical Association show that lifestyle modifications including nutrition components can contribute to the reduction of annual health care costs.[59]

Obesity/Disproportionate burden of CVD for African Americans/CVD Determinants

Nutrition components to address CVD aim to reduce obesity prevalence. Obesity is defined as excess body weight along with an unusually high proportion of body fat, and is measured by a body mass index (BMI)- $\frac{weight\ in\ kilograms}{height\ in\ square\ meters}$ - of ≥30.[39,40] Obesity has been characterized by the American Heart Association as one of the major risk factors for CVD diseases, such as heart failure (HF), coronary heart disease (CHD), sudden cardiac death, and atrial fibrillation, and is associated with reduced overall survival.[59,60]

Obesity has adverse effects on cardiovascular structure and function and studies show that an increase in obesity prevalence will result in an increased risk of CVD.[59] Obesity rates in the United States are alarming and have reached global epidemic proportions. US obesity prevalence in 2017-2018 was 42.4%.[61] For African Americans, prevalence rates are greater. Between 2017-2018, AA obesity prevalence was 49.6%, as compared to Hispanics (44.8%) and Whites (44.7%). [2,42] Furthermore, the literature reveals from population studies, totaling approximately 3.5 million people, that obesity as measured by BMI has consistently predicted CVD mortality.[62–72] Cardiovascular disease is the leading cause of death in the US, claiming the life of one person every 36 seconds; although there was a 60% reduction in CVD mortality between 1950-1999; however, since that time, there has been a consistently widening racial gap in CVD mortality that has contributed to the black-white life expectancy.[7–10,73,74] AA have higher mortality rates from CVD than any other race (Figure 2.1). [4-7]

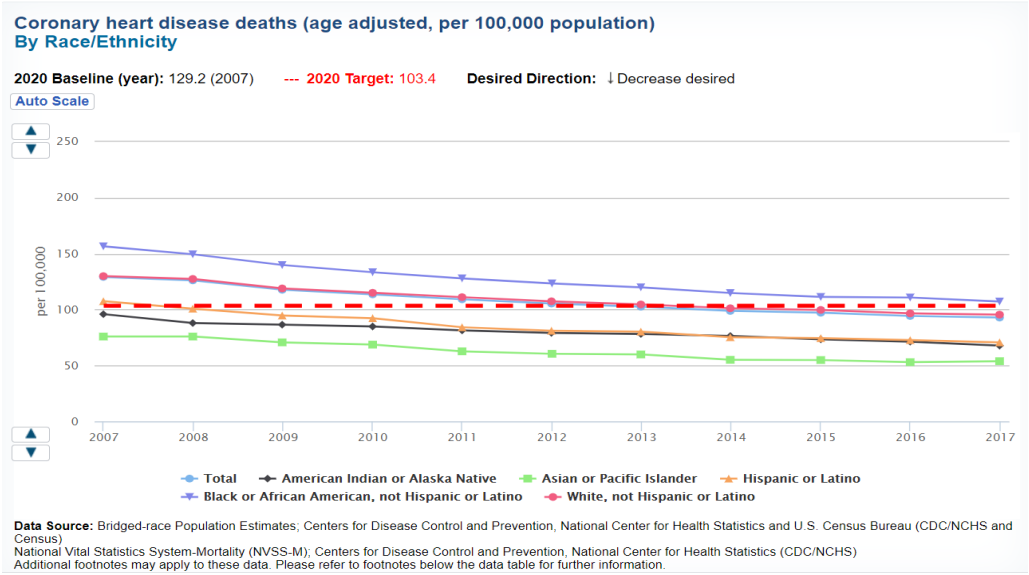


Figure 2.1 Coronary Heart Disease Deaths (age adjusted per 100,000 pop) By Race/Ethnicity[75]

Southern food culture is the center of southern hospitality, tradition and heritage and is directly related to CVD prevalence. Southern foodways, (the intersection of food and culture), contributes to a higher prevalence of obesity.[76]African Americans define southern food as soul food to symbolize the enduring identity of African Americans who persevered through slavery. Stories of enslaved African Americans describe preparing soulful dishes from rations, garden produce, and the poorest parts of meats that were hunted on the plantation and this type of cooking has been passed down from generation-to-generation.[10] Soul food consumed by African Americans contribute to the disparity of blacks suffering from obesity and being diagnosed with cardiovascular disease at higher rates than any other racial and ethnic group.[9] In 2010, CVD mortality rates per 100,000 were 192.2 for white women, 260.5 for black women, 278.4 for white men, and 369.2 for black men, whereas the overall death rate from CVD of all races in 2009 was 236.1 per 100,000.[19] These alarming statistics are influenced by the social determinants of health:

genetics, behavior, environmental and physical influences, medical care and social factors.

Nutrition is key to CVD health. CVD relates to a variety of disorders affecting the heart and blood vessels, and the likelihood of developing CVD is related to an unhealthy diet such as: high consumption of sodium, added sugars, processed foods, animal products and unhealthy fats.[77] In 1908, Alexander Ingatowski provided the first piece of evidence that demonstrated that nutrition contributes to the onset and progression of CVD proving that high cholesterol intake caused the development of atherosclerosis in rabbits.[78] From that time until the 1990s, nutrition science focused on single-nutrient based strategies, but it did not appear to be enough to mitigate the onset of CVD.[78] Consequently, nutrition science has moved away from examining isolated nutrients and has advanced towards the importance of food and how overall dietary patterns contributes to chronic disease or the absence thereof.[77]

A review of the literature indicates that healthy dietary patterns reveal commonalities that include high consumption of fiber, whole grains, antioxidants, vitamins, minerals, polyphenols, monosaturated and polyunsaturated fatty acids and limited consumption of sodium, refined sugar, saturated and trans fats, and low glycemic foods.[77,78,79] This translates to a high intake of fruits, vegetables, legumes, fish and seafood, nuts, seeds, whole grains, vegetable oils (mainly, extra virgin olive oil [EVOO]), and dairy foods together with a low intake of pastries, soft drinks, and red and processed meat.[79,80]

A number of epidemiological studies have explored differences in health-related outcomes based on dietary pattern.[81] These patterns have included vegan (contains no

animal products, favoring grains, legumes, vegetables, and fruit), vegetarian (veg; contains dairy and eggs), pesco-vegetarian (pesco-veg; contains seafood), semi-vegetarian (semi-veg; contains all food groups but red meat is limited), and omnivorous (omni; contains all foods) diets.[8]

Plant-based diets and low-fat diets are consistently mentioned in the literature in relation to reduced risk of obesity. Findings from the European Prospective Investigation into Cancer and Nutrition (EPIC-Oxford) study concluded that people following a vegan diet gain significantly less weight as they age compared with people following an omnivorous diet.[82] Converting to a diet with higher amounts of plant-based foods also seems to be protective against weight gain, as does following a pesco-veg diet in women.[82]

The first major study to evaluate these dietary patterns within the U.S. was conducted among the Seventh-day Adventists religious group. Data from the Adventist Health Study-2 (AHS-2) revealed a strong relationship between meat consumption and risk of CVD.[83] The Adventist Health Study-2 (AHS-2), a large prospective observational study that has a considerable population of both vegans and AAs, examined diet and health outcomes among both whites and AAs. Research from the AHS-2 examining different plant-based eating styles among AAs found that compared with AA omnivores, AA vegetarians/vegans had significantly lower risk of hypertension, diabetes, and high total and LDL cholesterol and also concluded that vegans have the lowest body mass indices (BMIs) and the lowest prevalence of type 2 diabetes.[83]

Vegan and vegetarian diets have been described extensively in the literature as beneficial to decrease the risk of cancer, especially in African Americans. Another AHS-

2 paper found that vegan diets were provided protection against total cancer incidence (hazard ratio (HR) 0.84, 95% confidence interval (CI) 0.72–0.99) and cancers that are specific to the female population (HR 0.66, 95% CI 0.47–0.92) as compared with four other plant-based dietary patterns.[84] Plant-based diets may provide even more protection against chronic disease for AAs than for whites. For example, in an AHS-2 cohort study examining diabetes risk, diet pattern, and race, researchers found that AA vegans (odds ratio (OR) 0.381, 95% CI 0.236–0.617), vegetarians (OR 0.618, 95% CI 0.503–0.760), and semi-vegetarians (OR 0.486, 95% CI 0.312–0.755) had a lower risk of diabetes than people following an omnivorous diet. [84] This study concluded that in AAs "the dimension of the protection associated with vegetarian diets was as great as the excess risk associated with black ethnicity."[24]

Vegan and vegetarian diets have also been found to improve overall cardiovascular health. A review of eight observational studies that evaluated the effect of plant-based diets on cardiovascular health, revealed that most of the studies revealed significantly better blood pressure[85–89] and fasting glucose levels[85–87,89–91] among vegetarians and vegans. Three studies found significantly lower waist circumferences in vegetarians and vegans as compared with individuals following other diets,[85–87] and two studies found better triglyceride levels among vegetarians and vegans.[86,89] A limitation of these studies examining dietary pattern and health outcomes is that they were all observational**,** which affects their ability to establish causality.

Consuming healthy fats and healthy carbohydrates also play a vital role in maintaining good cardiovascular health. A systematic review of low-fat diets and the effect of dietary saturated and trans-fat on heart disease revealed that 8-13% of mortality

was associated with a higher intake of saturated and transfat.[92] Studies also concluded that CVD was shown to decrease upon replacing saturated fats with polyunsaturated fats.[92,93] Studies have also shown that polyunsaturated fatty acid and monounsaturated fatty acid in place of saturated fats are effective at decreasing CVD-related events. Furthermore, eating a diet high in unrefined, high quality carbohydrates in place of saturated fats has been proven to also lower CHD events such as heart attacks and strokes.[93] Dietary-associated risk has therefore been established as the most important behavioral factor to target in the prevention of CVD and CVD mortality, and could also potentially reverse heart disease.[77,94] However, translating dietary recommendations into primary care practice has been difficult.[16,95]

Primary care physicians are not trained to provide adequate nutrition counseling to reduce AA CVD incidence and need cost-effective evidence-based interventions to ensure its sustainability. Public health is a multi-disciplinary field that aims to 1) prevent disease and death, 2) prolong life, and 3) create environmental conditions in which people can be healthy through organized interventions at the institutional, community and societal levels.[96,97] Public health signifies the aspiration of society to improve the overall health and well-being of the population through dependence on the roles of: government; private sector; the public; and the social determinants of population health.[98] The government's role in public health is determined by laws that are authorized and implemented at the federal, state and local levels to protect the health of the population through agencies that issue regulations and execute public health programs.[97]

Literature has identified that the relationship between the physician and the patient is very important to help address the public health's aim to prevent disease and death.[25] National objectives and guidelines present a call to action for physicians to aide in the reduction of chronic diseases by advising patients on nutrition.[15] An objective of health services research is to help identify how the prevention and treatment of obesity can be provided to the population at a reasonable cost.[18] Primary care settings are visited most often by obese patients weight- and health-related risk factors of CVD, and in these settings are also where treatment and nutrition policy recommendations, such as the United States Department of Agriculture's (USDA) dietary guidelines, food pyramid and myplate diagrams are provided.[18,99–101] Therefore, primary care physicians have a distinctive opportunity to intervene and that intervention is vital to improve the health of the population.

However, a physician's ability to uphold the public health aim to prevent disease is dependent upon his or her ability to identify and implement theory and evidence-based interventions.[97,102,103] A survey of adult primary care patients interested in preventing or reducing risk of CVD disease revealed that when visiting primary care physicians to address their health needs, they are very concerned about their overall health and well-being and desire more suitable nutrition counseling.[104] Furthermore, patients feel that wellness and disease prevention should be priority.[102] Even though most physicians express interest in the association between health and nutrition and desire to uphold public health aims to prevent disease, they report several barriers to communicating and making nutrition recommendations to their patients due to a lack of training and knowledge.[5,15,16,24,26,27] Public health researchers have a role by connecting physicians,

policy makers and community stakeholders to sustainable evidence-based interventions that address health disparities of CVD.

AAs are historically underrepresented in evidence-based nutrition interventions that address CVD, and The NEW Soul Study addresses this gap in literature and provides an opportunity to explore a culturally-appropriate health economic evaluation of this intervention. Immense progress has been made to address CVD. Robust National Institutes of Health (NIH)-funded CVD research is our country's greatest chance to uncover innovative ways to prevent, treat and ultimately create cures for cardiovascular disease.[52] Greater than 90% of research and training focused on nutrition is funded by the NIH and the United States Department of Agriculture (USDA).[105] In 2012, the NIH invested $1.7 billion for 4600 nutrition-related research projects and more than half of all nutrition-related research is funded by the National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), the National Heart, Lung and Blood Institute (NHLBI) and the National Cancer Institute (NCI).[105] NIH-funded biomedical research has resulted in approximately a 70 percent decline reduction in the CVD mortality over the last one-hundred years. [52] However, CVD is still the number one killer, prevalence projections are on the rise, and AAs continue to be disproportionately affected by CVD.[106,107]

Literature shows strong evidence relating food to CVD.[106] Eating frequency has increased across: the number of meals consumed each day; the consumption and amount of snack foods; eating out in restaurants and fast-food; and getting take- out meals.[108–114] Additionally, both home and meals purchased elsewhere included higher proportions of fried and processed foods.[112,113,115,116] Due to the persistent prevalence of CVD and the

connection with food, the American Society for Nutrition (ASN) has been very involved in advocacy efforts for expanded nutrition research support and established nutrition-related behavior as a nutrition research priority.[105]

Research, mostly observational, has indicated that plant-based and low-fat diets are associated with prevention of chronic disease, healthier body weights, and lowering CVD risk factors; however, AAs are underrepresented in existing nutrition interventions.[86–91,117–122] A systematic review of weight loss and dietary interventions involving AAs reveal poor weight loss outcomes and difficulties maintaining weight loss long-term. [123–126] Research also shows smaller sample sizes and higher attrition rates of African Americans in nutrition interventions.[127–129] Neglecting to address cultural matters that are applicable to the AA population is one possible reason why it has historically been difficult to recruit and retain AA research participants for dietary interventions.[83,84]

The NEW Soul study is significant because it goes beyond studies and is the first randomized control trial that thoroughly examines the impact of a vegan diet and a low-fat omni diet and CVD outcomes solely in AAs. Both interventions include aspects of the African American culture, that is often lacking in existing research, such as the connection between food and religion and modifying traditional soul food recipes to fit within the study's dietary guidelines that incorporate the Oldways African Heritage Diet Food Pyramid.[28,130] The NEW Soul diet for the participants randomized to the vegan group consists of no dairy or animal products, no added oils, 6 servings of grains (mostly whole grains) daily, 1 – 1 ½ cups of legumes daily, 1 tablespoon of nuts/seeds daily, 2-4 servings of fruit daily, 3-5 servings of vegetables daily and green leafy vegetables daily.[26] The NEW Soul diet for participants randomized to the omni group consists of 3-5 ounces

of lean meats daily, an additional 2 servings of fish each week, ½ - 1 cup of legumes daily, eggs no more than 2 times/ week, 2-3 servings of low-fat dairy each day, 1 tablespoon of nuts/seeds daily, and healthy oils such as olive/canola, 6 servings of grains (mostly whole grains) daily, 2-4 servings of fruit daily, 3-5 servings of vegetables daily and green leafy vegetables daily.[26] The goal of the NEW Soul study is to establish the differences between the two diets on body weight, lipids and blood pressure.

Previous behavioral interventions have shown challenges recruiting AA research participants due to: a lack of effective recruitment strategies that also do not include a variety of recruitment methods and historical mistrust of research.[131,132] The NEW Soul Study utilized multiple recruitment methods including, radio advertisements, word of mouth, TV interviews that results from press releases, online and social media postings, promotion at local historically black colleges and universities, events that celebrated black history and culture, and tabling at community outreach at community events.[130]

Literature reveals that a lack of trust is a significant barrier to positive outcomes of community-based public health interventions.[133] A culturally competent workforce seeks to build understanding and show respect with others who have different cultural values, beliefs, and religious practices.[105] Establishing a trusting relationship between researchers and participants through cultural competence is vital since culture influences individual behavior.[134]

Recruitment methods utilized in the NEW Soul study included important aspects to help overcome a long history of mistrust associated with harm done to AA research participants and a lack of transparency.[131] The NEW Soul Study addressed these elements

by facilitating in-person orientation sessions, conducted by a majority AA staff, that: engaged participants on a personal level through fun introductions of all persons in attendance; acknowledged harm that was done to AA research participants through unethical practices; educated participants about the role of the Institutional Review Board; detailed operating procedures implemented to protect participants and the privacy of sensitive information; expressed a commitment to open communication and feedback on results; engaged interested persons in respectful conversations about AA food and culture; and provided multiple opportunities for interested persons to ask questions about the intervention.

Health economic evaluation is critical because resources such as money, time, and services are limited and costs can be reallocated to prevention strategies that generate positive health outcomes for vulnerable populations at higher risk for CVD. Therefore, decision making related to resource management that is guided by systematic analysis is preferred.[31] Systematic analysis helps to identify alternatives that are significant and reduces the chances of an important alternatives being excluded from consideration.[31] For example, when deciding to introduce a new program that aims to reduce morbidity, prevention programs may be more efficient than treatment-related programs.[31] Additionally, without quantification, assessments may be misleading.[31] An observational study, based on 12,278 patients who were a part of the Kaiser Permanente CVD registry, determined that the total mean annual direct medical care costs were $18, 953 for the sample.[4] To best manage resources and address health care spending associated with CVD disparities, the costs of prevention programs is essential to consider.

With this approach, scientific assessments to explain evidence are specific, and in turn offers accountability for decisions made on behalf of the population.[31]

Cost effectiveness analysis is one form of health economic evaluations that evaluates costs and consequences of alternative interventions. The goal of CEA is to "maximize societal health benefits" while operating within a constricted budget.[32] With CEA, the ratio of a benefit to cost shows how much of that benefit is achieved per dollar spent- this can be often described as the "bang for the buck".[135] In comparison, the intervention providing the largest "bang for the buck" is generally preferred and deemed as more efficient.[135]

Cost effectiveness analysis (CEA) is important to: (1) evaluate sustainability and feasibility of the NEW Soul study for large-scale implementation; (2) provide AAs with evidence-based dietary recommendations to promote healthy weight loss and address CVD prevention; and (3) address healthcare spending associated with CVD by identifying an intervention that will generate a positive return on investment.[31] Based on the burden of CVD on health care spending and the disproportionate morbidity and mortality of CVD experienced by AAs, a CEA of the NEW Soul Study addresses a gap in the literature that has not yet been analyzed. Furthermore, existing literature supports the novel theoretical concept of applying a cost effectiveness analysis (CEA) to: obesity-related and dietary interventions; chronic disease-related and dietary interventions.[18–25]

Cost effectiveness analysis is important to evaluate feasibility of interventions by considering costs (inputs) and outcomes (consequences) of two different courses of action implemented via a randomized control trial. [31,136]

CEA of the NEW Soul Study will help to identify the cost per pound of weight loss the vegan diet group achieves as compared to the omni diet group. A systematic review of the literature including studies assessing the cost effectiveness of behavioral interventions concluded that future research should focus on the sustainability of interventions to evaluate their long-term adherence and benefits due to decreased adherence related to out-of-pocket participant costs.[137,138] Population-based primary interventions for prevention that include lifestyle modifications can lower CVD risk factors without increasing healthcare costs, but literature calls for actions to consider cultural factors, such as acceptability, since they play an important role in allocating resources towards interventions for scalability purposes.[139,140] A CEA analysis of the NEW Soul Study from a societal perspective includes components that will assess the financial sustainability of interventions via affordability of foods/meals, time spent to shop and prepare foods/meals, and cultural acceptability.

Cost effectiveness analysis shows a long history in the literature to provide estimates of cost-effective medical care options. In 1981, Ludbrook conducted a CEA of options for chronic renal failure treatments that were cost effective and produced an outcome of life years gained.[31] Since that time, CEA has expanded to studies that can be linked to improved patient outcomes and studies related to prevention interventions. CEA is beneficial to healthcare providers when advising patients on proper care during medical appointments.[31]

A key goal of health services research in obesity is to figure out how obesity prevention and treatment can reach the largest proportion of the population at the least

possible cost.[18] Primary care settings are where people most often seek treatment for weight-related conditions, so there is an opportunity for early intervention.[18,141] Weight loss interventions conducted in primary care settings to treat obesity support the application of a cost effectiveness analysis. However, results may vary and the literature advocates assessing long-term cost effectiveness of interventions lasting for two years or more.[18,142] Options include conducting randomized control trials for this length of time or via modeling. A microsimulation model to determine the Cost effectiveness of the Study of Technology to Accelerate Research (STAR), a weight loss intervention for children in a primary care setting, was conducted to estimate long-term cost effectiveness. The CEA of STAR revealed an expected population reach of approximately 2 million in ten years, with intervention costs of $119 per child and $237 per BMI unit reduced.[143] The simulation concluded that the STAR intervention may be more cost-effective than previous interventions because over the course of ten years, it is expected to prevent 43,000 cases and 226,000 life-years with obesity at a net cost of $4085 per case and $774 per life-year with obesity averted.[143] Assessing long-term cost effectiveness of weight loss interventions can help determine how obesity prevention and treatment can reach the largest proportion of the population at the least possible cost.

Cost effectiveness analysis of nutrition treatment for remission of chronic disease is also supported in the literature. A systematic review of cost effectiveness of nutrition for the maintenance of remission in Crohn's disease patients was conducted and concluded potential nutrition benefits versus no intervention in maintaining remission and preventing relapse.[19] Furthermore, CEA of interventions, that include

nutrition components, related to treatment options for gastrointestinal disease and breast cancer.[144,145]

In some cases, cost effectiveness can be difficult to determine based on where they fall in the cost effective plane (quadrants I and III). The cost effectiveness of a 12-month, school-based, healthy-eating and active living clustered randomized contrail trial was evaluated.[17] One group received the intervention and completed three measurement follow ups and the other group completed three measurement follow-ups but did not receive the intervention.[17] The intervention included three components: teachers provided an extra 30 minutes of daily physical activity; teachers taught interactive lessons about healthy lifestyles; and school-based cooking demonstrations were conducted with parents and students. The latter two intervention components proved to be acceptable and feasible and lower in cost, however the overall intervention was not cost-effective.[17] A systematic review of the cost effectiveness of non-surgical obesity interventions in men evaluated seven studies and concluded promising indication of cost effectiveness when interventions targeted high-risk groups.[22] Variation of the delivery of the interventions and imbalances at baseline methods contributed to high uncertainties, therefore cost effectiveness was not determined.[20,22]

In order to assess the highest level of cost effectiveness of dietary interventions, from a societal perspective, it is preferred that interventions targeting at-risk groups are culturally-tailored or adapted.[135] Minority women and men from diverse cultural and ethnic groups were randomized into groups that received nutrition and physical activity coaching from members of their community. The studies

highlighted community health workers from the targeted communities were trained to provide the culturally-adapted interventions and concluded that the interventions proved to be cost-effective and quality adjusted life years were also gained.[24,146]

An estimate of health states in the form of quality-of-life or cost-utility analysis (CUA) is a variant of CEA and is frequently supported in the literature as a secondary aim in CEA of dietary interventions.[31] The cost effectiveness of a two-year RCT that assessed weight loss during a dietary intervention with women postpartum was evaluated.[21] Quality of life was assessed using the 36-item Short Form Health Survey.[21] The study concluded that the dietary intervention was cost-effective and resulted in a two-year weight loss of 8% and cost per gained QALY was 1704-7889 USD. [21] Results of a CEA of a cluster-controlled trail that implemented a system-level workplace dietary intervention that included nutrition education from an employer perspective also proved to be cost-effective and improving health-related quality of life for employees. A CEA of LighterLife Total, a weight reduction program that worked to address behavioral change and offered group support, was conducted and compared to no treatment and three other weight reduction programs offered to participants with obesity. This program was determined to be associated with greater QALYs and more cost-effective, however it did not include costs from a societal perspective.[25]

A cost effectiveness analysis of the NEW Soul Study will provide cost effective and socially acceptable evidence-based dietary recommendations to promote healthy weight loss and address CVD prevention amongst AAs. Due to the excessive expenses associated with the rising costs of healthcare and limited resources,

economic evaluation via CEA within healthcare has been more popular and was a step towards controlling costs through rationing healthcare.[31,147] Randomized control trials are most widely used in health evaluation based on its strength in internal validity and reliability.[31] A CEA of this randomized control trial will address healthcare spending associated with CVD by identifying an intervention for AAs that will generate a positive return on investment.[31]

Scientific Premise for Primary & Secondary Aims.

A meta-analysis examining 12 mostly short-term randomized controlled trials (RCTs) (n=1,151 subjects) was conducted and compared vegan or veg diets to omni.[148] Researchers concluded that participants assigned to veg diets lost substantially more weight than those assigned to omni diets.[148] In sub-analyses, participants randomized to follow vegan diets lost more weight than participants assigned to veg diets.[148] The results of this study suggest that diet plays an important role in weight loss, which can improve CVD health. Healthy dietary choices has been shown to potentially reduce heart attacks by 80% and vegetarian diets may potentially reduce CVD mortality by 40%.[149] Furthermore, plant-based diets are the only known dietary patterns that have been proven to reverse coronary heart disease.[149] However, identifying interventions to prevent heart disease is not enough. Given the state of CVD disparities in the AA population and high healthcare spending that is not equating to better health outcomes, CEA is one tool decision-makers can use to assess which interventions provide the highest "value for money" and helps them choose the interventions that maximize the health of the population based on the available resources. It can also be useful for understanding how much an intervention may cost

per unit of health gained compared to an alternative intervention.[31] The results of a CEA of The NEW Soul Study, which focuses on heart disease prevention within the AA population, will enable decision makers to identify which nutrition intervention (vegan vs. omni), when presented as an incremental ratio, is cost saving when examining weight loss as an outcome. The results of a CEA examining quality as an outcome (also known as a cost utility analysis) will enable decision makers to identify which intervention produces the greatest health benefit. This study provides important evidence that will contribute to the reduction of CVD disparities by offering new insights that will inform future nutrition interventions and nutrition recommendations in clinical practice for AAs.

Scientific Premise for Tertiary Aim.

The world is currently working hard to recover from a global COVID-19 pandemic. Literature revealed that quarantine and isolation has disproportionately affected individuals in the US with obesity and their ability to manage their weight and health behaviors despite COVID-19 illness status.[148] When asked, patients in health care settings and public survey respondents consistently reported: spending more time at home; hardships achieving/maintaining weight loss goals; decreased physical activity; increased stress eating; decreased dietary restraint; and an increase in anxiety and depression.[148,149,150] A systematic review of the literature that included 36 studies identified similar trends at the global level.[153] However, a critical gap in knowledge about the impact of COVID-19 on African Americans were largely underrepresented in these studies. Understanding whether the pandemic had an impact on weight loss of AAs will

have important implications for future practices to mitigate the risk and spread of illness while collecting participant measurements such as weight and blood pressure.

CHAPTER 3

METHODOLOGY

This chapter begins with the study's purpose, then presents the aims, research design, how the data were collected, study participant information and limitations of the study.

Purpose

The purpose of this study is to evaluate the cost effectiveness of the NEW Soul Study. This was accomplished by assessing the incremental cost per unit of weight loss, taking into consideration direct costs to deliver the vegan and omni nutrition interventions. In our analysis, we adopted a societal perspective by also considering the costs borne by participants receiving these interventions. We will also report on the change in QALYs gained between the two diet interventions. According to guidelines for cost effectiveness analysis, a probabilistic sensitivity analysis was conducted in order to address uncertainties in the model.[31] Additionally, variations in weight loss between cohort 1 (before COVID-19) and cohort 2 (during COVID-19) were assessed using a DD study design.

Study Aims

This study has three aims.

Primary aim

1a: To test the difference in average weight loss between diet groups.

- If weight loss is normally distributed, we will use a t-test. If this assumption is violated, we will use the Wilcoxon test.

  Y (dependent variable) = average weight loss

  X (independent control variable) = diet group

1b: To conduct a difference-in-difference (DD) regression analysis to explain the difference in weight loss between diet groups while controlling for age, sex, education, employment, class attendance, physical activity, and cohort.

$Y = b_0 + b_1*t + b_2*$*diet group* $+ b_3*$*diet group*$*t + b_4*$*age*$+ b_5*$*sex* $+ b_6*$*education* $+ b7$ **employment + b8 *class attendance + b9*physical activity + b10* cohort*

H_0 for 1b & 1c: Avg Weight $loss_{Vegan}$=Avg Weight $loss_{Omni}$

H_A for 1b & 1c: Avg Weight $loss_{Vegan} \neq$Avg Weight $loss_{Omni}$

Y (dependent variable) = weight loss at time t t=0 if baseline; t=1 if 12 months

X (independent variable)= diet group

X (independent control variable) = age, sex, education groups, employment, class attendance, physical activity, cohort

1c: To conduct a cost effectiveness analysis with weight loss as an outcome of two different culturally tailored nutrition interventions at 12 months (Figure 3.1).

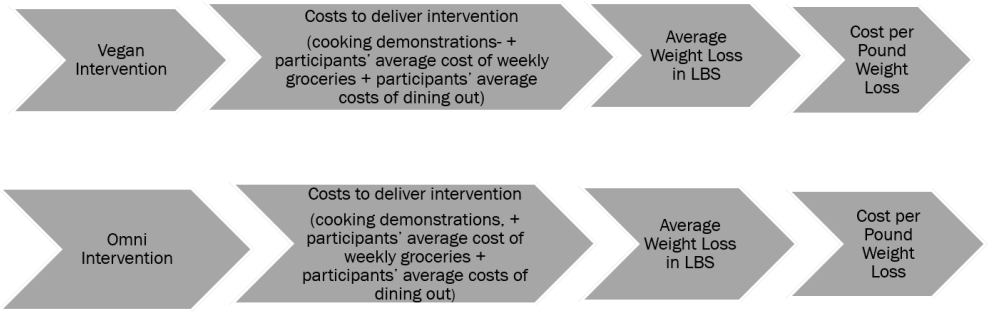
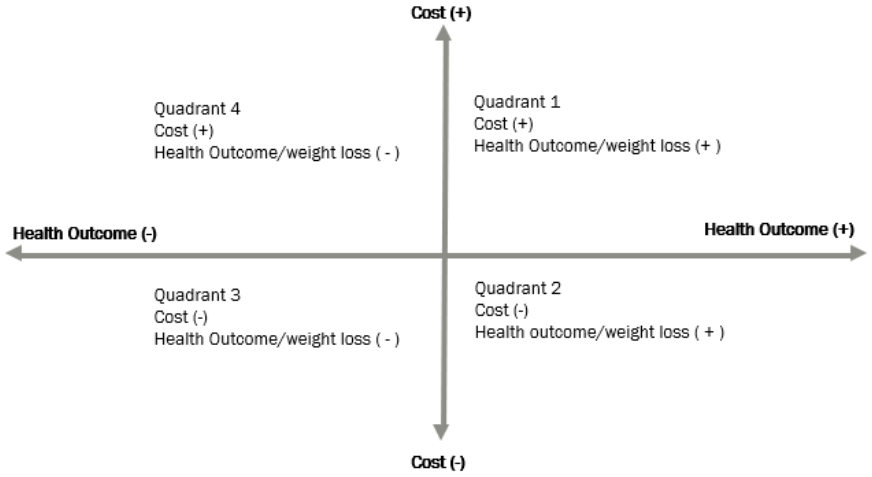


Figure 3.1 Cost Effectiveness Analysis

- Findings will be presented as an incremental ratio. A sensitivity analysis will be conducted to account for degrees of uncertainty.
  - $ICER = \frac{Total\ Cost_{vegan} - Total\ Cost_{omni}}{Weight\ loss_{vegan} - Weight\ loss_{omni}}$
- A four-quadrant figure of cost difference plotted against effect difference will be used to interpret the ICER (Figure 3.2).



- *Figure 3.2 Cost Effectiveness Plane*

Secondary Aim:

2a: To test the difference in average QALY between diet groups.

- If average QALY is normally distributed we will use a t-test. If this assumption is violated, we will use the Wilcoxon test.

Y (dependent variable) = average QALY

X (independent variable) = diet group

2b: To conduct a difference-in-difference (DD) regression analysis to explain the difference in average QALY between diet groups while controlling for age, sex, education, employment, class attendance, and physical activity.

$Y = b_0 + b_1*t + b_2*$*diet group* $+ b_3*$*diet group*$*t + b_4*$*age*$+ b_5*$*sex* $+ b_6*$*education* $+ b7$ **employment + b8 *class attendance + b9*physical activity + b10* cohort*

H_0 for 2b & 2c: Avg $QALY_{Vegan}$=Avg $QALY_{Omni}$

H_A for 2b & 2c: Avg $QALY_{Vegan} \neq$Avg $QALY_{Omni}$

Y (dependent variable) = Avg QALY at time t t=0 if baseline; t=1 if 12 months

X (independent variable)= diet group

X (independent control variable) = age, sex, education groups, employment, class attendance, physical activity, cohort

Tertiary Aim:

3a. To test the difference in average weight loss between cohorts.

- If weight loss is normally distributed we will use a t-test. If this assumption is violated, we will use the Wilcoxon test.
    - Y (dependent variable) = weight loss from baseline to 12 months
    - X (independent variable) = cohort, diet group

3b. To conduct a difference-in-differences (DD) estimation to assess the likely impact of COVID-19 on the weight loss in pounds by comparing the changes in Cohort 2 (affected by COVID-19 at 1 year) to Cohort 1 (not affected by COVID-19 at 1 year).

$Y = b_0 + b_1*t + b_2*cohort + b_3*cohort*t + b_4*age + b_5*sex + b_6*education + b7 *employment + b8 *class attendance + b9*physical activity + b10* diet group$

H_0: Avg Weight $lossC1_{precovid}$ = Avg Weight $lossC2_{duringcovid}$

H_1: Avg Weight $lossC1_{precovid} \neq$ Avg Weight $lossC2_{duringcovid}$

Y (dependent variable) = average weight loss

X (covariates) = age, sex, education groups, employment, class attendance, physical activity, diet group

Time (Dummy Variable) => 1= DURING COVID-19 0= Pre COVID-19

Intervention (Dummy Variable)=> 1= DURING COVID- 19 0 = PRE COVID-19

Target Population

African American adults (18-65 years of age) in the Midlands region of South Carolina with overweight or obesity (BMI 25-49.9 kg/m^2) who enrolled in Cohorts 1 and 2 of the Nutritious Eating With (NEW) Soul Study, a behavioral nutrition intervention, were chosen for this study. See Table 3.1 for eligibility criteria. All participants completed an online screening questionnaire and follow-up phone screening to confirm eligibility criteria listed below.[26]

Upon completion of the baseline assessment, participants were randomized to one of two groups: the vegan group or the low-fat omnivorous diet group using a computer program allocation sequence and stratified by gender and baseline BMI. The cohorts were separated by one year. Cohort 1 began the study in May 2018 and Cohort 2 began the study in June 2019. See Table 3.2 for summaries of participant enrollment for both cohorts. See Table 3.3 for summaries of enrollment and randomization.

Table 3.1: NEW Soul Eligibility Criteria

Inclusion Criteria	**Exclusion Criteria**
Self-identify as African American	Following a vegan diet
Be between the ages of 18-65 years	Currently on medication for diabetes
Body Mass Index between 25-49.9kg.m2	Currently pregnant or breastfeeding or plan to become pregnant in the next 24 months
Live in Columbia, SC/Midlands area	
Be able to attend all monitoring and class visits	

Definition of Study Groups

The NEW Soul Study addresses CVD prevention by comparing two diets. Both diets: are guided by the Oldways African Heritage Food Pyramind; focus on healthier versions of soul food and traditional African dishes; and highlight meals that are low-fat and rich in plants.

For the purposes of this study's primary and secondary aims, the definition of the vegan group as defined by the NEW Soul study is used to identify participants who followed a diet that emphasized minimally-processed whole foods from plants, no added oils, no dairy, and meeting daily protein requirements through nuts, seeds, and beans.[26] The definition of the omni group as defined by the NEW Soul study was used to identify participants who followed an omnivorous diet that emphasized minimally-processed foods from plants, lean meats, vegetable oils and low-fat dairy products.[26]

Table 3.2 Demographics of NEW Soul Study Cohort 1 & 2 Participants (N=159)

	Before exclusion (N=159)					After excluding missing values (N=105)*			
	Cohort 1 (n=67)		**Cohort 2 (n=92)**			**Cohort 1 (n=40)**		**Cohort 2 (n=65)**	
Characteristics	**N**	**%**	**N**	**%**		**N**	**%**	**N**	**%**
Gender									
Female	59	88.05	67	72.82		36	90	52	80
Male	8	11.94	25	27.17		4	10	13	20
Ethnicity									
Hispanic or Latino	1	1.5	1	1.09		1	2.5	0	0
Not Hispanic or Latino	66	98.5	91	98.91		39	97.5	65	100
Race									
Black or African American	65	97.01	92	100		40	100	65	0
African American and other race	2	2.99	0	0		0	0	0	0
Age									
Mean (SE)	47.8 (1.4)		48.7 (1.1)	49.9 (1.7)			51.1 (1.2)		
Median (min, max)	50 (25, 65)		50 (25, 65)	52 (30, 65)			52 (25,65)		

*Note that all participants must self-identify as Black/African American to enroll in the study, but participants may indicate more than one race.

*Note: After excluding the missing values, there are 105 (66%) participants completed both measures at baseline and month 12. In Cohort 1, 40 (60%) participants completed both measures; and in Cohort 2, 65 (71%) participants completed both measures.

Table 3.3. NEW Soul Study Participant Enrollment and Randomization

	Cohort 1 Total Enrolled @ Baseline	**Cohort 2 Total Enrolled @ Baseline**	**Cohorts 1 & 2 Combined**	**Complete Data Cohorts 1 & 2 Combined (Baseline & 12 months)**
Omni Control	34	48	**82**	**53**
Vegan Intervention	33	44	**77**	**52**
Total Participants	67 (Female=59 Male=8)	92 (Female= 67 Male=25)	**159 (Female=126 Male=33)**	**105 (Female = 88 Male =17)**

Table 3.4 NEW Soul Study- Definition of Study (Dietary) Groups[26]

	VEGAN	**OMNI**
Dietary Recommendations	Emphasized minimally-processed whole foods from plants, no added oils, no dairy and meeting daily protein requirements through nuts, seeds and beans.	Emphasized minimally-processed foods from plants, lean meats, vegetable oils and low-fat dairy products
Whole Grains	6 servings (mostly whole grains)	6 servings (mostly whole grains)
Legumes/Beans	1- 1 ½ cups daily	½ cup – 1 cup daily
Nuts/Seeds	1 tbsp daily	1 tbsp daily
Fruit	2-4 servings daily	2-4 servings daily
Vegetables	3-5 servings (including green leafy vegetables)	3-5 servings (including green leafy vegetables)
Animal Protein	None	• 3-5 oz. daily of lean meats (non-processed) • Additional 2 servings of fish each week • No more than 2 eggs each week/unlimited egg whites
Dairy	None	2-3 servings of low-fat dairy each day

Study Design and Methods of Analysis

CEA

A cost effectiveness analysis study design was utilized to compare costs in relation to weight loss of The NEW Soul Study's vegan group and omni group. Primary data collection methods were utilized for this study. Weight loss has been previously used to determine power in NIH-funded dietary intervention trials. [28] Weight was collected at baseline and at 12 months. A calibrated digital scale (Healthometer®model 500 KL, McCook, IL) was used to collect participants' weight at baseline and 12 months. Two measurements at each time were taken and averaged. Total costs of the intervention were calculated from a societal perspective. This perspective includes aspects of non-health effects that provide insight into participant's net benefits or costs associated with the intervention.[44] Total Costs = Costs to deliver the intervention (ingredients for cooking demonstrations, meals) + participants' average cost of weekly groceries + average weekly costs of dining out. Cooking demonstration and meal costs to deliver the intervention were collected and totaled from accounting reports from year one for each diet group and averaged for each diet group. Literature has determined a connection between costs of food, diet quality, and obesity and particularly and advocates for the need to identify dietary patterns that are rich in nutrients and affordable in order to reduce health and nutrition disparities. [27,33] Therefore, participants' average cost of weekly groceries and dining out was collected at baseline and 1-year assessments periods. Total costs will be divided by the number of total participants from each diet group. The difference in costs between the vegan and omni diet interventions will then be divided by

difference in weight loss between the vegan and the omni diet interventions resulting in the incremental cost effectiveness ratio (ICER).

ICER Interpretation

A cost effectiveness plane is used to interpret the ICER.[31] The horizontal axis characterizes the difference in effect between the vegan diet intervention and the alternative (omni diet intervention).[31] The vertical axis characterizes the difference in costs; if the ICER falls in quadrants II or IV of the cost effectiveness plane, then the choice between whether the vegan diet intervention or the omni diet intervention is more cost effective is without question.[31] The ICER falls in Quadrant II and is interpretated as the vegan diet group being more effective and less costly than the omni diet intervention.[31] That would mean that the diet group intervention of interest dominates the alternative. If the ICER falls in quadrant IV, then the opposite applies- the alternative dominates the diet group intervention of interest. If the ICER falls within quadrants I or III, then the choice of the intervention is based on the maximum cost effectiveness ratio that the decision maker is willing to accept.[31]

Sensitivity Analysis

Probabilistic sensitivity analysis is required in guidelines for cost effectiveness analysis to address uncertainties in the model. [28] Therefore, a Monte Carlo probabilistic sensitivity analysis will be conducted to assess the robustness of the findings by examining what can potentially happen and the likelihood of each outcome in order to ensure that the results are acceptable for decisions related to scaling up this intervention in clinical and community settings.[38] Additionally, in relation to a clinical study, it is common that some participants have much higher costs that have more of an effect on the

mean costs, and skew the distribution.[31] Since the reported ICER is a ratio, it is not appropriate to use standard statistical techniques to assemble confidence intervals.[31]

A detailed literature review was conducted by Mihaylova and colleagues to describe alternative methods that can be used and three in particular were recommended: ordinary least squares (OLS) regression; OLS with transformation to the log scale and bootstrapping.[154] The OLS method is based on normal distribution but estimates of mean weight loss can be sensitive to extreme values for individual level participant costs. The OLS with transformation method can be used when the probabilities are larger than those of the exponential distribution.[31] Since our study consisted solely of individual patient-level data, the bootstrapping method is the more appropriate non-parametric alternative for this study to describe the distribution of possible mean values of weight loss.[31] This method uses resampling from the data with replacements to produce a practical estimate of the sampling distribution of mean costs.[31] 10,000 bootstrap samples were created to show the uncertainty and acceptability curve. By repeatedly drawing a random sample with replacement, a scatter plot of 10,000 bootstrapped incremental cost effectiveness ratios, this produced estimates of the likelihood that the vegan diet intervention was cost effective compared to the omni diet intervention based on the $50,000 - $150,000 US willingness to pay threshold.

Acceptability Curve

The acceptability probability was estimated as the proportion of accepted ICER out of the 10,000 ICER samples. The willingness to pay is based on 1.84 GDP per capita ($50,000) to 2.76 GDP per capita ($150,000), which is reflective of literature used to assess willingness to pay in the United States.[136] By increasing the willingness to pay,

acceptance probability values can be estimated. An acceptability curve can then be plotted with the x axis representing the willingness to pay per 1 pound of weight loss and the y axis representing the estimated acceptance probability.

Quality of Life Measurements

Quality of life (QOL) was measured using the SF-12, which includes 12 questions (Q). These 12 questions can be grouped in to 8 domains of general health (Q 1), physical functioning (Q 2-3), limitations in physical role functioning of physical health (Q 4-5), limitations in emotional problems (Q 6-7), pain (Q 8), mental health (Q 9-10), vitality (Q 11) and social functioning (Q 12).[38]

There are two steps to calculate QALY: 1) SF-12 must be converted into SF-6D health state classification system; and 2) utility scores must be estimated based on SF-6D classification. A search of the literature revealed two studies (2004, 2020) using two different methods to calculate utility.[38,45] Both methods will be applied to calculate QALY and the distribution of the results from the two methods will be compared.

In order to classify SF-12 responses, the number of dimensions is reduced from eight to six by excluding the general health item and combining the role limitation dimensions (physical and emotional).[38] By using SF-6D (2004), Q2 was selected for physical functioning domain; Q5 and Q6 were combined into 4 levels for role functioning (You have no problems with your work or other regular daily activities as a result of your physical health or any emotional problems; You are limited in the kind of work or other activities as a as a result of your physical health; You are limited in the kind of work or other activities as a as a result of emotional problems; You are limited in the kind of work or other activities as a as a result of your physical health and accomplish less than you

would like as a result of emotional problems); Q8 was selected for pain, Q10 was selected for mental health, Q11 was selected for virality and Q12 was selected for social functioning.

In the 2020 paper, Short Form-6 Dimensions version 2 (SF-6Dv2), an updated version of the SF-6D that addresses limitations, was developed to classify responses from SF-12.[45] Questions selected using the SF-6Dv2 (2020) paper were the same as SF-6D (2004), except that Q4 and Q6 was combined into 5 levels for role functioning (Accomplish less than you would like none of the time; Accomplish less than you would like a little of the time; Accomplish less than you would like some of the time; Accomplish less than you would like most of the time; and Accomplish less than you would like all of the time). Details are presented in Table 3.5.

Table 3.5- SF-12 Domain and Question Classification for SF-6D and SF-6Dv2

SF-12 Domains/items	Summary of contents	Response levels	Selected for SF-6Dv2 (2020 paper)	Selected for SF-6D (2004 paper)
General Health				
Q1	In general, would you say that your health is	1 - Excellent; 2 - Very good; 3 - Good; 4 - Fair; 5 - Poor	×	×
Physical functioning				
Q2	Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1 - Yes, limited a lot; 2 - Yes, limited a little; 3 - No, not limited at all	√ (3 out of 5 levels match)	√
Q3	Climbing several flights of stairs	1 - Yes, limited a lot; 2 - Yes, limited a little; 3 - No, not limited at all	×	×
Role functioning (physical health)				
Q4	During the past 4 weeks, how much of the time have you accomplished less than you would like as a result of your physical health	1 - All of the time; 2 - Most of the time; 3 - Some of the time; 4 - A little of the time; 5 - None of the time	√	×
Q5	During the past 4 weeks, how much of the time were you limited in the kind of work or other regular daily activities	1 - All of the time; 2 - Most of the time; 3 - Some of the time; 4 - A little of the time; 5 - None of the time	×	√

	you do as a result of your physical health			
Role functioning (emotional problems)				
Q6	During the past 4 weeks, how much of the time have you accomplished less than you would like as a results of any emotional problems, such as feeling depressed or anxious	1 - All of the time; 2 - Most of the time; 3 - Some of the time; 4 - A little of the time; 5 - None of the time	√	√
Q7	During the past 4 weeks, how much of the time did you do work or other regular daily activities less carefully than usual as a result of any emotional problems, such as feeling depressed or anxious	1 - All of the time; 2 - Most of the time; 3 - Some of the time; 4 - A little of the time; 5 - None of the time	×	×
Pain				
Q8	During the past 4 weeks, how much did pain interfere with your normal work, including both work outside the home and housework	1 - Not at all; 2 - A little bit; 3 – Moderately; 4 - Quite a bit; 5 - Extremely	√ (5 out of 6 levels match)	√
Mental health				
Q9	How much of the time during the past 4 weeks have you felt calm and peaceful	1 - All of the time; 2 - Most of the time; 3 - Some of the time; 4 - A little of the time; 5 - None of the time	×	×

Q10	How much of the time during the past 4 weeks have you felt downhearted and depressed	1 - All of the time; 2 - Most of the time; 3 - Some of the time; 4 - A little of the time; 5 - None of the time	√	√
Vitality				
Q11	How much of the time during the past 4 weeks did you have a lot of energy	1 - All of the time; 2 - Most of the time; 3 - Some of the time; 4 - A little of the time; 5 - None of the time	√	√
Social functioning				
Q12	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities like visiting with friends or relatives	1 - All of the time; 2 - Most of the time; 3 - Some of the time; 4 - A little of the time; 5 - None of the time	√	√

For step two, the utility score was calculated based on SF-6D and SF-6Dv2. In the 2004 paper using SF-6D, four models (algorithms) to calculate utility were reported in the literature. [38] Models 1 and 2 represent the algorithms to calculate utility based on classifying responses from the SF-36. Models 3 and 4 represent the algorithms to calculate utility based on (SF-12). Model 4 was utilized for this study because it was determined in the literature to be the more consistent and preferred model because it does not include variables that are not significant at $p < 0.05$.[38] Additionally, levels of each dimension in Model 4 were aggregated if there were any inconsistencies.[38] The SF-6Dv2 classification presents six models of algorithms to calculate utility that were tested.[45] Results indicated Model 3 as the recommended algorithm to estimate QALYs because of its efficient design using established experimental design procedures and also due to the model being ordered within dimensions, where increasing severity results in a decrease in utility.[45] However, due to its recent results, this model has not been widely tested in US populations with AA adults presenting with overweight/obesity. Both methods were used to calculate utility and the distribution of utility score estimates.

The algorithms for each are listed in Table 3.6. Our study participants completed the first version of the SF-12 and the levels for physical functioning and pain do not align. Therefore, our modified coefficients to estimate the utility score for physical function are: 0 (Limited in vigorous activities not at all); -0.034 (Limited in moderate activities a little); and -0.092 (Limited in moderate activities a lot). For pain: 0 (No pain); -0.076 (Very mild pain); -0.139 (Moderate pain); -0.46 (Severe pain); and -0.62 (Very severe pain). The range of utility scores by the SF-6Dv2 algorithm may exceed the 0-1 range. To account for this, we will cap the QALY at zero for any values below zero.

Table 3.6- SF-6D & SF-6Dv2 Utility Algorithms

SF-6Dv2 Classification System (2020)			**SF-6D Classification System (2004)**		
Physical functioning (5 levels)	**Match with SF-12**	**Model Coefficients**	**Physical functioning (3 levels)**	**Match with SF-12**	**Model Coefficients**
Limited in vigorous activities not at all	**Yes**	**0**	Your health does not limit you in moderate activities	**Yes**	**0**
Limited in vigorous activities a little	No	-0.019			
Limited in moderate activities a little	**Yes**	**-0.034**	Your health limits you a little in moderate activities	**Yes**	**0**
Limited in moderate activities a lot	**Yes**	**-0.092**	Your health limits you a lot in moderate activities	**Yes**	**-0.045**
Limited in bathing and dressing a lot	No	-0.186			
Role functioning (5 levels)			**Role functioning (4 levels)**		
Accomplish less than you would like none of the time	**Yes**	**0**	You have no problems with your work or other regular daily activities as a result of your physical health or any emotional problems	**Yes**	**0**
Accomplish less than you would like a little of the time	**Yes**	**-0.039**	You are limited in the kind of work or other activities as a as a result of your physical health	**Yes**	**-0.063**
Accomplish less than you would like some of the time	**Yes**	**-0.055**	You are limited in the kind of work or other activities as a as a result of	**Yes**	**-0.063**

			emotional problems		
Accomplish less than you would like most of the time	**Yes**	**-0.099**	You are limited in the kind of work or other activities as a as a result of your physical health and accomplish less than you would like as a result of emotional problems	**Yes**	**-0.063**
Accomplish less than you would like all of the time	**Yes**	**-0.102**			
Social functioning (5 levels)			**Social functioning (5 levels)**		
Social activities are limited none of the time	**Yes**	**0**	Your health limits your social activities none of the time	**Yes**	**0**
Social activities are limited a little of the time	**Yes**	**-0.008**	Your health limits your social activities a little of the time	**Yes**	**-0.063**
Social activities are limited some of the time	**Yes**	**-0.029**	Your health limits your social activities some of the time	**Yes**	**-0.066**
Social activities are limited most of the time	**Yes**	**-0.103**	Your health limits your social activities most of the time	**Yes**	**-0.081**
Social activities are limited all of the time	**Yes**	**-0.137**	Your health limits your social activities all of the time	**Yes**	**-0.093**
Pain (6 levels)			**Pain (5 levels)**		
No pain	**Yes**	**0**	You have pain that does not interfere with your normal work (both outside	**Yes**	**0**

			the home and housework) at all		
Very mild pain	**Yes**	**-0.076**	You have pain that interferes outside with your normal work (both outside the home and housework) a little bit	**Yes**	**0**
Mild pain	No	-0.097			
Moderate pain	**Yes**	**-0.139**	You have pain that interferes outside with your normal work (both outside the home and housework) moderately	**Yes**	**-0.042**
Severe pain	**Yes**	**-0.46**	You have pain that interferes outside with your normal work (both outside the home and housework) quite a bit	**Yes**	**-0.077**
Very severe pain	**Yes**	**-0.62**	You have pain that interferes outside with your normal work (both outside the home and housework) extremely	**Yes**	**-0.137**
Mental health (5 levels)			**Mental health (5 levels)**		
Depressed or very nervous none of the time	**Yes**	**0**	You feel downhearted and low none of the time	**Yes**	**0**
Depressed or very nervous a little of the time	**Yes**	**-0.026**	You feel downhearted and low a little of the time	**Yes**	**-0.059**
Depressed or very nervous some of the time	**Yes**	**-0.086**	You feel downhearted and	**Yes**	**-0.059**

			low some of the time		
Depressed or very nervous most of the time	**Yes**	**-0.236**	You feel downhearted and low most of the time	**Yes**	**-0.113**
Depressed or very nervous all of the time	**Yes**	**-0.324**	You feel downhearted and low all of the time	**Yes**	**-0.134**
Vitality (5 levels)			**Vitality (5 levels)**		
Worn out none of the time	**Yes**	**0**	You have a lot of energy all of the time	**Yes**	**0**
Worn out a little of the time	**Yes**	**-0.015**	You have a lot of energy most of the time	**Yes**	**-0.078**
Worn out some of the time	**Yes**	**-0.015**	You have a lot of energy some of the time	**Yes**	**-0.078**
Worn out most of the time	**Yes**	**-0.08**	You have a lot of energy a little of the time	**Yes**	**-0.078**
Worn out all of the time	**Yes**	**-0.121**	You have a lot of energy none of the time	**Yes**	**-0.106**
Worst		**-0.084**	**Worst**		**-0.077**

Change in QALY

QALY change from baseline to 12 months was calculated based on the change in utility scores multiplied by the duration of the study (1 year). Participants in the NEW Soul Study were asked to recall their health conditions during the past 4 weeks at baseline and 12 months. We believe the estimated utility score during the past 4 weeks for each measurement period appropriately reflects the health condition of our study participants.

Ethical Procedures Approval

The data used in this study was collected by NEW Soul Study Staff. Data is de-identified. Institutional Review Board approval was granted to collect this data.

Limitations

This CEA involves a comparison of two dietary "courses of action" of the NEW Soul study that aim to reduce obesity, a major CVD risk factor. The difference in costs of the vegan and omni diets s are compared with the difference in outcomes. However, there are some questions that a CEA of the NEW Soul Study cannot answer. This study is subject to limitations because it is limited in scope to the NEW Soul Study specifically and does not take into account all potential diet patterns to address CVD prevention. This study does not include all outcomes associated with the intervention, such as lipid panel results to assess cholesterol levels and blood pressure. Selection bias can also occur since all participants volunteered for this study. Participants may share social characteristics that are different from others who did not volunteer to participate. Life changing events, such as, but not limited to changes in: income, household size and marital status. However, we do not expect that these changes will be different between groups.

Threats to the validity of the study include: attrition; data underreporting or overreporting; and measurement error. Attrition is a threat to the validity of this study, because not all participants participated in the 12-month assessment where weight was collected. Data underreporting or overreporting may also have been present, as participants may have underreported or overreported the average amount of money they spent on groceries and dining out, and/or their time spent shopping and preparing food. If this data was underreported or overreported, it would not reflect the true costs associated with the diet group that is used to calculate the ICER. Measurement error may have also resulted due to participants answering questions retrospectively and inaccurately recalling information. Additionally, measurement error could have resulted during the collection of weight and/or during the entry of that data.

Significant measures were taken by the NEW Soul Staff to assure the reliability and validity of the data. These measures included: frequent communication with participants to maximize participation in assessments to collect weight; helpful text within the surveys to ensure that participants understood survey questions that were designed with an upper elementary reading level; and collecting two weight measurements that were recorded and triple checked upon entering the data.

Despite these challenges, cost effectiveness analysis clarifies and quantifies the potential impact of the NEW Soul Study and results provide useful information to determine feasible and culturally acceptable diet recommendations for CVD prevention. Because this analysis was conducted from a societal perspective, it provides the best indication of overall cost effectiveness of the interventions and is very useful for decisions related to the allocation of resources.[30,155]

CHAPTER 4

MANUSCRIPT ONE

A COST EFFECTIVENESS ANALYSIS OF THE NUTRITIOUS EATING WITH SOUL STUDY

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Abstract

Background

The present study is an economic evaluation of the NEW Soul Study (previously described in the literature)-comparing a vegan diet group to an omni diet group- for the prevention of cardiovascular disease (CVD) in an African American (AA) study population.[26]

Methods

Cost Effectiveness Analysis

Total costs were calculated from a societal perspective. Total Costs = Costs to deliver the intervention (ingredients for cooking demonstrations, meals) + participants' average cost of weekly groceries + average weekly costs of dining out. Weight loss and quality adjusted life year outcomes were evaluated at baseline and 12 months for each dietary group. Cost effectiveness analysis findings was reported as an incremental ratio (ICER) based on the total costs of the vegan diet minus the total cost of the omni diet, divided by the average weight loss of the vegan diet group minus the average weight loss of the omni group. A four-quadrant plane of cost difference plotted against weight loss difference was used to interpret the ICER. Probabilistic sensitivity analysis was used to test model robustness.

QALY

Quality of life was measured using the Short-Form 12 (SF-12) Health Status Survey. The SF-12 consists of 12 questions grouped into eight dimensions: general health, physical functioning, role functioning (physical health), role functioning (emotional health), pain, mental health, and social functioning. Each dimension was scored to calculate utility for

using the Short Form- 6 Dimensions (SF-6D) and Short Form-6 Dimensions version 2 (SF-6Dv2). The SF- 6D (6 domains) preference-based instrument was used to classify responses from the SF-12 (8 domains). Health state preference values (utilities) were calculated via Model 4 of the scoring table based on Brazier & Roberts distribution matching and methods with 0 indicating worst health/death and 1 indicating perfect health.[38] Classifying the 8 domains of SF-12 to SF-6 domains resulted in the removal of the general health question and combining role limitations questions to assess the physical and emotional aspects.[38] The SF-6Dv2 (6 domains), an updated classification instrument that addresses limitations of the SF-6D (resulting in a more narrow range of utilities), was also used to classify responses from the SF-12.[45] Utilities were calculated via Model 3 due to its efficient design using established experimental design procedures and the model being ordered within dimensions, where increasing severity results in a decrease in utility.[45] The distribution of utility score estimates from the SF-6D and the SF-6Dv2 algorithms were calculated and results were compared via a density plot. Quality adjusted life years (QALY) gained between baseline and 12 months were calculated for each classification method for each diet group using the formula: QALYs gained = (12 month utility – baseline utility) *1 (duration of the study). This formula focuses on the change in utility between baseline and 12 months and assumes that these values accurately reflect the health condition of participants over the course of the intervention.

Findings

The incremental cost effectiveness ratio (ICER) was $2,888.57 per pound of weight loss. The results fall within quadrant II of the cost effectiveness plane which indicates that the vegan diet group, as compared to the omni diet group, is dominate and by costing less and achieving greater weight loss for participants enrolled in the NEW Soul Study. Results on QALY based on SF-6D classification indicate that the difference in 12 month and baseline QALY for the omni diet group is 0.01508 and that the difference in 12 month and baseline QALY for the vegan diet group is 0.005327. The difference-in-differences (DD) in QALY between the vegan and omni diet groups is -.00975 and there is no statistically significant difference in QALY between the diet groups.

Conclusions

For AAs presenting with CVD risk factors, results of CEA indicate that the choice between the diet interventions is clear: the vegan diet intervention is more cost effective and the ideal choice for AAs desiring to lose weight. QALY calculations reveals no significant difference between the diet groups in terms of QALY gained from baseline to 12 months.

Keywords: economic analysis, cost effectiveness, cardiovascular disease, dietary intervention

Introduction

Worldwide, cardiovascular disease is the reason for most deaths for men and women of all races.[6] In 2018, 30.3 million American adults were diagnosed with cardiovascular disease.[6] Cardiovascular disease (CVD) accounts for an estimated $448.5 billion in 2008, from direct (patient care) and indirect (loss/reduced productivity) healthcare expenditures, an estimated $555 billion in 2016, and a projected estimate of $1.1 trillion by 2035.[1,2] In the United States, CVD has been the leading cause of death for almost 100 years; and for almost 100 years more African American (AA) adults disproportionately die from CVD more than cancer or any other chronic disease condition.[2,7–10] AAs in the United State (U.S.) have higher rates of obesity due to poor nutrition, a risk factor of CVD, compared to Whites and Hispanics.[2] African American foodways, known as the intersection of food and culture, is a unique contributor to CVD. At the heart of AA foodways is soul food, as it symbolized the enduring identity of AAs who persevered through slavery by using high amounts of fat and sodium to prepare soulful dishes from garden produce, food scraps and the poorest parts of meats.[11] This type of cooking has been passed down from generation-to-generation and has contributed to the disparity of AAs being diagnosed with CVD at higher rates.[11]

To address the rising costs of health care related to CVD, there is a critical need to identify and implement culturally relevant research-based nutrition interventions to combat CVD within the AA population that are sustainable and a good investment of

resources. Existing literature supports the novel theoretical concept of applying a cost effectiveness analysis (CEA) to dietary interventions.[18–25]

The NEW Soul study, as previously described in the literature, is one of the first randomized control trials (RCT) with solely AA participants that incorporates AA foodways through partnering with local soul food restaurants/chefs to deliver two behavioral nutrition interventions (veffgan and omnivorous low-fat) to AA adults and examines changes in risk factors for CVD over a two-year period.[26] However, advising future community-based approaches and population health decision making requires further investigations in regard of cultural acceptability, costs, and benefits. To our knowledge, a cost-effective nutrition intervention for AAs has not been identified, which makes it difficult to decrease healthcare spending for CVD and make nutrition recommendations that are culturally acceptable and affordable for those who present with CVD risk factors.

Therefore, this study is aimed to evaluate the NEW Soul Study for large-scale implementation by assessing the incremental cost per unit of weight loss in pounds, taking into consideration direct costs to deliver the vegan and omni nutrition interventions. In our analysis, we adopted a societal perspective by also considering the cultural acceptability of dietary recommendations and the costs borne by participants receiving these interventions. Additionally, we also calculated health state utilities to determine the cost per quality-adjusted life year (QALY) gained by program participants from baseline to 12 months and to determine the difference-in-differences of QALY for the diet groups.

Methodology

Population studied

African American adults (18-65 years of age) in the Midlands region of South Carolina with overweight or obesity (BMI 25-49.9 kg/m^2) who enrolled in Cohorts 1 and 2 of the Nutritious Eating With (NEW) Soul Study, a behavioral nutrition intervention, were chosen for this study. All participants completed an online screening questionnaire and follow-up phone screening to confirm eligibility criteria listed below (Table 4.1).[26]

Table 4.1: NEW Soul Eligibility Criteria

Inclusion Criteria	**Exclusion Criteria**
Self-identify as African American	Following a vegan diet
Be between the ages of 18-65 years	Currently on medication for diabetes
Body Mass Index between 25-49.9kg.m2	Currently pregnant or breastfeeding or plan to become pregnant in the next 24 months
Live in Columbia, SC/Midlands area	
Be able to attend all monitoring and class visits	

Upon completion of the baseline assessment, participants were randomized to one of two groups: the vegan group or the low-fat omnivorous diet group using a computer program allocation sequence and stratified by gender and baseline BMI. The cohorts were separated by one year. Cohort 1 began the study in May 2018 and Cohort 2 began the study in June 2019. See Table 4.2 for summaries of participant enrollment for both cohorts. See Table 4.3 for summaries of enrollment and randomization.

Table 4.2. Demographics of NEW Soul Study Cohort 1 & 2 Participants (N=159)

	Before exclusion (N=159)					After excluding missing values (N=105)*			
	Cohort 1 (n=67)		**Cohort 2 (n=92)**			**Cohort 1 (n=40)**		**Cohort 2 (n=65)**	
Characteristics	**N**	**%**	**N**	**%**		**N**	**%**	**N**	**%**
Gender									
Female	59	88.05	67	72.82		36	90	52	80
Male	8	11.94	25	27.17		4	10	13	20
Ethnicity									
Hispanic or Latino	1	1.5	1	1.09		1	2.5	0	0
Not Hispanic or Latino	66	98.5	91	98.91		39	97.5	65	100
Race									
Black or African American	65	97.01	92	100		40	100	65	0
African American and other race	2	2.99	0	0		0	0	0	0
Age									
Mean (SE)	47.8 (1.4)		48.7 (1.1)	49.9 (1.7)			51.1 (1.2)		
Median (min, max)	50 (25, 65)		50 (25, 65)	52 (30, 65)			52 (25,65)		

**All participants must self-identify as Black/African American to enroll in the study, but participants may indicate more than one race.

*** After excluding the missing values, there are 105 (66%) participants completed both measures at baseline and month 12. In Cohort 1, 40 (60%) participants completed both measures; and in Cohort 2, 65 (71%) participants completed both measures

Table 4.3 NEW Soul Study Participant Enrollment and Randomization

	Cohort 1 Total Enrolled @ Baseline	**Cohort 2 Total Enrolled @ Baseline**	**Cohorts 1 & 2 Combined**	**Complete Data Cohorts 1 & 2 Combined (Baseline & 12 months)**
Omni Control	34	48	**82**	**53**
Vegan Intervention	33	44	**77**	**52**
Total Participants	67 (Female=59 Male=8)	92 (Female= 67 Male=25)	**159 (Female=126 Male=33)**	**105 (Female = 88 Male =17)**

Definition of Study Groups

The NEW Soul Study addresses CVD prevention by comparing two diets. Both diets are guided by the Oldways African Heritage Food Pyramid, focusing on healthier versions of soul food and traditional African dishes; and highlighting meals that are low-fat and rich in plants.

For the purposes of this study, the definition of the vegan group as defined by the NEW Soul study is used to identify participants who followed a diet that emphasized minimally-processed whole foods from plants, no added oils, no dairy, and meeting daily protein requirements through nuts, seeds, and beans.[26] The definition of the omni group as defined by the NEW Soul study was used to identify participants who followed an omnivorous diet that emphasized minimally-processed foods from plants, lean meats, vegetable oils and low-fat dairy products (Table 4.4).[26]

Table 4.4 NEW Soul Study- Definition of Study (Dietary) Groups[26]

	VEGAN	OMNI
Dietary Recommendations	Emphasized minimally-processed whole foods from plants, no added oils, no dairy and meeting daily protein requirements through nuts, seeds and beans.	Emphasized minimally-processed foods from plants, lean meats, vegetable oils and low-fat dairy products
Whole Grains	6 servings (mostly whole grains)	6 servings (mostly whole grains)
Legumes/Beans	1- 1 ½ cups daily	½ cup – 1 cup daily
Nuts/Seeds	1 tbsp daily	1 tbsp daily
Fruit	2-4 servings daily	2-4 servings daily
Vegetables	3-5 servings (including green leafy vegetables)	3-5 servings (including green leafy vegetables)
Animal Protein	None	3-5 oz. daily of lean meats (non-processed) Additional 2 servings of fish each week No more than 2 eggs each week/unlimited egg whites
Dairy	None	2-3 servings of low-fat dairy each day

Study Design and Methods of Analysis

A cost effectiveness analysis approach was utilized to compare costs in relation to weight loss of the NEW Soul Study's vegan group and omni group. Primary data collection methods were utilized for this study.

Weight Loss

Weight loss has been previously used to determine power in NIH-funded dietary intervention trials.[28] Weight was collected at baseline and 12 months. A calibrated digital scale (Healthometer®model 500 KL, McCook, IL) was used to collect participant's weight. Two measurements each time were taken and averaged.

Costs

Total costs of the intervention were calculated from a societal perspective. This perspective includes aspects of non-health effects that provide insight into participant's net benefits or costs associated with the intervention.[44] Total Costs = Costs to deliver the intervention (ingredients for cooking demonstrations, meals) + participants' average cost of weekly groceries + average weekly costs of dining out. Cooking demonstration and meal costs to deliver the intervention were collected and totaled from accounting reports from year one for each diet group and averaged for each diet group. Literature has determined a connection between costs of food, diet quality, and obesity and particularly and advocates for the need to identify dietary patterns that are rich in nutrients and affordable in order to reduce health and nutrition disparities. [27,33] Therefore, participants' average cost of weekly groceries and dining out was collected at baseline and 1-year assessments periods. Total costs will be divided by the number of total participants from

each diet group. Table 4.5 contains a breakdown of the total cost of the vegan and omni diet interventions over 12 months and difference in costs between the two.

ICER Interpretation

ICER is calculated by the cost differences between the vegan and omni diet groups divided by the weight loss difference between the vegan and omni diet groups. A cost effectiveness plane is used to interpret the ICER.[31] The horizontal axis characterizes the difference in effect between the vegan diet intervention and the alternative (omni diet intervention).[31] The vertical axis characterizes the difference in costs; if the ICER falls in quadrants II or IV of the cost effectiveness plane, then the choice between whether the vegan diet intervention or the omni diet intervention is more cost effective is without question.[31] The ICER falls in Quadrant II and is interpretated as the vegan diet group being more effective and less costly than the omni diet intervention.[31] That would mean that the diet group intervention of interest dominates the alternative. If the ICER falls in quadrant IV, then the opposite applies- the alternative dominates the diet group intervention of interest. If the ICER falls within quadrants I or III, then the choice of the intervention is based on the maximum cost effectiveness ratio that the decision maker is willing to accept.[31]

Sensitivity Analysis

Probabilistic sensitivity analysis is required in guidelines for cost effectiveness analysis to address uncertainties in the model. [28] Therefore, a Monte Carlo probabilistic sensitivity analysis will be conducted to assess the robustness of the findings by examining what can potentially happen and the likelihood of each outcome in order to ensure that the results are acceptable for decisions related to scaling up this intervention

in clinical and community settings.[38] Additionally, in relation to a clinical study, it is common that some participants have much higher costs that have more of an effect on the mean costs, and skew the distribution.[31]

A detailed literature review was conducted by Mihaylova and colleagues to describe alternative methods that can be used and three in particular were recommended: ordinary least squares (OLS) regression; OLS with transformation to the log scale and bootstrapping.[154] The OLS method is based on normal distribution but estimates of mean weight loss can be sensitive to extreme values for individual level participant costs. The OLS with transformation method can be used when the probabilities are larger than those of the exponential distribution.[31] Since our study consisted solely of individual patient-level data, the bootstrapping method is the more appropriate non-parametric alternative for this study to describe the distribution of possible mean values of weight loss.[31] This method uses resampling from the data with replacements to produce a practical estimate of the sampling distribution of mean costs.[31] 10,000 bootstrap samples were created to show the uncertainty and acceptability curve. By repeatedly drawing a random sample with replacement, a scatter plot of 10,000 bootstrapped incremental cost effectiveness ratios, this produced estimates of the likelihood that the vegan diet intervention was cost effective compared to the omni diet intervention based on the $50,000 - $150,000 US willingness to pay threshold.

Among 105 participants, there are 53 in the omni diet group and 52 in the vegan diet group. For bootstrap sampling, 53 random samples were drawn from the omni diet group with replacements. The median cost change from baseline to 12 months (Cost change_Omni) and mean weight loss from baseline to 12 months (Cost change_Vegan)

were calculated and saved from this bootstrap sample. Cost difference and weight loss difference between the two diet groups were also calculated.

Cost difference = Cost change_Vegan -Cost change_Omni

Weight loss difference = Weight loss_Vegan - Weight loss_Omni

$$\text{ICER} = \frac{\text{Cost difference}}{\text{Weight loss difference}} = \frac{\text{Cost change\_Vegan} - \text{Cost change\_Omni}}{\text{Weight loss\_Vegan} - \text{Weight loss\_Omni}}$$

This will generate one ICER result based on one bootstrap sample. After repeating the above process for 10,000 times, we obtained 10,000 bootstrapped ICER. A scatter plot was created to display the distribution of ICER.

Acceptability Curve

The acceptability probability was estimated as the proportion of accepted ICER out of the 10,000 ICER samples. The willingness to pay is based on 1.84 GDP per capita ($50,000) to 2.76 GDP per capita ($150,000), which is reflective of literature used to assess willingness to pay in the United States.[136] By increasing the willingness to pay, acceptance probability values can be estimated. An acceptability curve can then be plotted with the x axis representing the willingness to pay per 1 pound of weight loss and the y axis representing the estimated acceptance probability.

Quality of Life Measurements

Quality of life (QOL) was measured using the SF-12, which includes 12 questions (Q). These 12 questions can be grouped in to 8 domains of general health (Q 1), physical functioning (Q 2-3), limitations in physical role functioning of physical health (Q 4-5), limitations in emotional problems (Q 6-7), pain (Q 8), mental health (Q 9-10), vitality (Q 11) and social functioning (Q 12).[38]

There are two steps to calculate QALY: 1) SF-12 must be converted into SF-6D health state classification system; and 2) utility scores must be estimated based on SF-6D classification. A search of the literature revealed two studies (2004, 2020) using two different methods to calculate utility.[38,45] Both methods will be applied to calculate QALY and the distribution of the results from the two methods will be compared.

In order to classify SF-12 responses, the number of dimensions is reduced from eight to six by excluding the general health item and combining the role limitation dimensions (physical and emotional).[38] By using SF-6D (2004), Q2 was selected for physical functioning domain; Q5 and Q6 were combined into 4 levels for role functioning (You have no problems with your work or other regular daily activities as a result of your physical health or any emotional problems; You are limited in the kind of work or other activities as a as a result of your physical health; You are limited in the kind of work or other activities as a as a result of emotional problems; You are limited in the kind of work or other activities as a as a result of your physical health and accomplish less than you would like as a result of emotional problems); Q8 was selected for pain, Q10 was selected for mental health, Q11 was selected for virality and Q12 was selected for social functioning.

In the 2020 paper, Short Form-6 Dimensions version 2 (SF-6Dv2), an updated version of the SF-6D that addresses limitations, was developed to classify responses from SF-12.[45] Questions selected using the SF-6Dv2 (2020) paper were the same as SF-6D (2004), except that Q4 and Q6 was combined into 5 levels for role functioning. Details are presented in Table 4.5.

Table 4.5- SF-12 Domain and Question Classification for SF-6D and SF-6Dv2

SF-12 Domains/items	Summary of contents	Response levels	Selected for SF-6Dv2 (2020 paper)	Selected for SF-6D (2004 paper)
General Health				
Q1	In general, would you say that your health is	1 - Excellent; 2 - Very good; 3 - Good; 4 - Fair; 5 - Poor	×	×
Physical functioning				
Q2	Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1 - Yes, limited a lot; 2 - Yes, limited a little; 3 - No, not limited at all	√ (3 out of 5 levels match)	√
Q3	Climbing several flights of stairs	1 - Yes, limited a lot; 2 - Yes, limited a little; 3 - No, not limited at all	×	×
Role functioning (physical health)				
Q4	During the past 4 weeks, how much of the time have you accomplished less than you would like as a result of your physical health	1 - All of the time; 2 - Most of the time; 3 - Some of the time; 4 - A little of the time; 5 - None of the time	√	×
Q5	During the past 4 weeks, how much of the time were you limited in the kind of work or other regular daily activities you do as a result of your physical health	1 - All of the time; 2 - Most of the time; 3 - Some of the time; 4	×	√

		- A little of the time; 5 - None of the time		
Role functioning (emotional problems)				
Q6	During the past 4 weeks, how much of the time have you accomplished less than you would like as a results of any emotional problems, such as feeling depressed or anxious	1 - All of the time; 2 - Most of the time; 3 - Some of the time; 4 - A little of the time; 5 - None of the time	√	√
Q7	During the past 4 weeks, how much of the time did you do work or other regular daily activities less carefully than usual as a result of any emotional problems, such as feeling depressed or anxious	1 - All of the time; 2 - Most of the time; 3 - Some of the time; 4 - A little of the time; 5 - None of the time	×	×
Pain				
Q8	During the past 4 weeks, how much did pain interfere with your normal work, including both work outside the home and housework	1 - Not at all; 2 - A little bit; 3 – Moderately; 4 - Quite a bit; 5 - Extremely	√ (5 out of 6 levels match)	√
Mental health				
Q9	How much of the time during the past 4 weeks have you felt calm and peaceful	1 - All of the time; 2 - Most of the time; 3 - Some of the time; 4 - A little of the time; 5 - None of the time	×	×
Q10	How much of the time during the past 4 weeks have you felt downhearted and depressed	1 - All of the time; 2 - Most of the time; 3 - Some of the time; 4 - A little of the time; 5 - None of the time	√	√

Vitality				
Q11	How much of the time during the past 4 weeks did you have a lot of energy	1 - All of the time; 2 - Most of the time; 3 - Some of the time; 4 - A little of the time; 5 - None of the time	√	√
Social functioning				
Q12	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities like visiting with friends or relatives	1 - All of the time; 2 - Most of the time; 3 - Some of the time; 4 - A little of the time; 5 - None of the time	√	√

For step two, the utility score was calculated based on SF-6D and SF-6Dv2. In the 2004 paper using SF-6D, four models (algorithms) to calculate utility were reported in the literature. [38] Models 1 and 2 represent the algorithms to calculate utility based on classifying responses from the SF-36. Models 3 and 4 represent the algorithms to calculate utility based on (SF-12). Model 4 was utilized for this study because it was determined in the literature to be the more consistent and preferred model because it does not include variables that are not significant at $p < 0.05$.[38] Levels of each dimension in Model 4 were aggregated if there were any inconsistencies.[38] The SF-6Dv2 classification presents six models of algorithms to calculate utility that were tested.[45] Results indicated Model 3 as the recommended algorithm to estimate QALYs because of its efficient design using established experimental design procedures and due to the model being ordered within dimensions, where increasing severity results in a decrease in utility.[45] However, due to its recent results, this model has not been widely tested in US populations with AA adults presenting with overweight/obesity. Both methods were used to calculate utility and the distribution of utility score estimates.

Algorithms for each are listed in Table 4.6. Our study participants completed SF-12 version 1 and there are 3 levels for physical functioning and 5 levels for pain. Our modified coefficients to estimate utility for physical function are: 0 (Limited in vigorous activities not at all); -0.034 (Limited in moderate activities a little); and -0.092 (Limited in moderate activities a lot). For pain: 0 (No pain); -0.076 (Very mild pain); -0.139 (Moderate pain); -0.46 (Severe pain); and -0.62 (Very severe pain). The range of utility scores by the SF-6Dv2 algorithm may exceed the 0-1 range. To account for this, we will cap the QALY at zero for any values below zero.

Table 4.6- SF-6D & SF-6Dv2 Utility Algorithms

SF-6Dv2 Classification System (2020)			**SF-6D Classification System (2004)**		
Physical functioning (5 levels)	**Match with SF-12**	**Model Coefficients**	**Physical functioning (3 levels)**	**Match with SF-12**	**Model Coefficients**
Limited in vigorous activities not at all	**Yes**	**0**	Your health does not limit you in moderate activities	**Yes**	**0**
Limited in vigorous activities a little	No	-0.019			
Limited in moderate activities a little	**Yes**	**-0.034**	Your health limits you a little in moderate activities	**Yes**	**0**
Limited in moderate activities a lot	**Yes**	**-0.092**	Your health limits you a lot in moderate activities	**Yes**	**-0.045**
Limited in bathing and dressing a lot	No	-0.186			
Role functioning (5 levels)			**Role functioning (4 levels)**		
Accomplish less than you would like none of the time	**Yes**	**0**	You have no problems with your work or other regular daily activities as a result of your physical health or any emotional problems	**Yes**	**0**
Accomplish less than you would like a little of the time	**Yes**	**-0.039**	You are limited in the kind of work or other activities as a as a result of your physical health	**Yes**	**-0.063**
Accomplish less than you would like some of the time	**Yes**	**-0.055**	You are limited in the kind of work or other activities as a as a result of	**Yes**	**-0.063**

			emotional problems		
Accomplish less than you would like most of the time	**Yes**	**-0.099**	You are limited in the kind of work or other activities as a as a result of your physical health and accomplish less than you would like as a result of emotional problems	**Yes**	**-0.063**
Accomplish less than you would like all of the time	**Yes**	**-0.102**			
Social functioning (5 levels)			**Social functioning (5 levels)**		
Social activities are limited none of the time	**Yes**	**0**	Your health limits your social activities none of the time	**Yes**	**0**
Social activities are limited a little of the time	**Yes**	**-0.008**	Your health limits your social activities a little of the time	**Yes**	**-0.063**
Social activities are limited some of the time	**Yes**	**-0.029**	Your health limits your social activities some of the time	**Yes**	**-0.066**
Social activities are limited most of the time	**Yes**	**-0.103**	Your health limits your social activities most of the time	**Yes**	**-0.081**
Social activities are limited all of the time	**Yes**	**-0.137**	Your health limits your social activities all of the time	**Yes**	**-0.093**
Pain (6 levels)			**Pain (5 levels)**		
No pain	**Yes**	**0**	You have pain that does not interfere with your normal work (both outside	**Yes**	**0**

			the home and housework) at all		
Very mild pain	**Yes**	**-0.076**	You have pain that interferes outside with your normal work (both outside the home and housework) a little bit	**Yes**	**0**
Mild pain	No	-0.097			
Moderate pain	**Yes**	**-0.139**	You have pain that interferes outside with your normal work (both outside the home and housework) moderately	**Yes**	**-0.042**
Severe pain	**Yes**	**-0.46**	You have pain that interferes outside with your normal work (both outside the home and housework) quite a bit	**Yes**	**-0.077**
Very severe pain	**Yes**	**-0.62**	You have pain that interferes outside with your normal work (both outside the home and housework) extremely	**Yes**	**-0.137**
Mental health (5 levels)			**Mental health (5 levels)**		
Depressed or very nervous none of the time	**Yes**	**0**	You feel downhearted and low none of the time	**Yes**	**0**
Depressed or very nervous a little of the time	**Yes**	**-0.026**	You feel downhearted and low a little of the time	**Yes**	**-0.059**
Depressed or very nervous some of the time	**Yes**	**-0.086**	You feel downhearted and	**Yes**	**-0.059**

			low some of the time		
Depressed or very nervous most of the time	**Yes**	**-0.236**	You feel downhearted and low most of the time	**Yes**	**-0.113**
Depressed or very nervous all of the time	**Yes**	**-0.324**	You feel downhearted and low all of the time	**Yes**	**-0.134**
Vitality (5 levels)			**Vitality (5 levels)**		
Worn out none of the time	**Yes**	**0**	You have a lot of energy all of the time	**Yes**	**0**
Worn out a little of the time	**Yes**	**-0.015**	You have a lot of energy most of the time	**Yes**	**-0.078**
Worn out some of the time	**Yes**	**-0.015**	You have a lot of energy some of the time	**Yes**	**-0.078**
Worn out most of the time	**Yes**	**-0.08**	You have a lot of energy a little of the time	**Yes**	**-0.078**
Worn out all of the time	**Yes**	**-0.121**	You have a lot of energy none of the time	**Yes**	**-0.106**
Worst		**-0.084**	**Worst**		**-0.077**

Change in QALY

QALY change from baseline to 12 months was calculated based on the change in utility scores multiplied by the duration of the study (1 year). Participants in the NEW Soul Study were asked to recall their health conditions during the past 4 weeks at baseline and 12 months. We believe the estimated utility score during the past 4 weeks for each measurement period appropriately reflects the health condition of our study participants.

Differences-in-Differences (DD) Regression of QALY

Difference-in-differences (DD) model is commonly used in health services research.[135] A difference-in differences (DD) regression analysis is able to directly estimate the effect difference (e.g. weight loss difference, QALY gain between 2 diet groups) while controlling for age, sex, education, employment, class attendance, and physical activity.

$Y = b_0 + b_1*t + b_2$*diet group + b_3*diet group*t + b_4*age+ b_5* sex + b_6*education + b7 *employment + b8 *class attendance + b9*physical activity + b10* cohort

Data is converted into "long" format. Each participant has two measures: one at baseline (which was denoted by t=0) and the other at 12 months (which was denoted by t=1). To address the within subject correlation, repeated measures regression was fitted using the unstructured covariance matrix. Least square means were estimated. The coefficient on the interaction term b3 provides the estimate of the effect difference between the vegan and omni diet groups.

All analysis was conducted using SAS. DD regression with repeated measures is fitted using the MIXED procedure.

Results

Cost Effectiveness Analysis

Since the distribution of cost is not normally distributed, the median of total cost was reported. A total costs savings of $747.51 was observed in the omni group intervention at 12 months from baseline. A total costs savings of $876.34 was observed in the vegan group intervention at 12 months from baseline. Each of the interventions resulted in total costs savings, the largest savings was observed in the vegan diet group intervention. The difference in cost savings between the vegan and omni diet interventions was $128.82 (Table 4.7).

An average weight loss of 6.18 pounds was observed in the omni group intervention between baseline and 12 months. An average weight loss of 6.22 pounds was observed in the vegan group intervention between baseline and 12 months (Table 4.7). Normality assumption checks were also performed and satisfied based on results from Q-Q plot distributions (Figure 4.1). Each of the interventions resulted in significant weight loss (Table 4.8). The largest savings was observed in the vegan group intervention, however the difference-in-differences (DD) in weight loss between the diet group interventions was not statistically significant (Table 4.9).

Table 4.7- CEA findings to calculate change in total costs

	OMNI (n=53)				**VEGAN (n=52)**				**Difference in median cost (Vegan - Omni)**
At baseline:	mean	Median	p25	p75	mean	median	p25	p75	
Cost of groceries	4530.87	4160	2600	5200	4802.25	3640	2600	7150	
Cost of dining out ($)	2830.57	1820	1040	3120	2802	2002	1040	4550	
Total	7361.43	6760	4160	8580	7604.25	5200	3900	10400	
At month 12:									
Cost of groceries	5668	5200	3120	7800	5005	3900	2600	5720	
Cost of dining out ($)	1354.94	1040	0	1560	1749	1300	520	2600	
Costs for cooking demonstrations	32.49	32.49	32.49	32.49	33.66	33.66	33.66	33.66	
Total	7055.43	6012.49	3932.49	8872.49	6787.66	5233.66	3933.66	8353.66	
Cost change in month 12, compared to baseline	-306	**-747.51**	-2567.51	1488.49	-816.59	**-876.34**	-2748.34	1593.66	**=(-876.34)-(-747.51)=-128.83**

Table 4.8- CEA findings to calculate average weight loss

Weight (Lbs)	**OMNI (n=53)**		**VEGAN (n=52)**		**Normality assumption check**	**Equality of Variances Tests check**	**t Tests**
	mean ± sd	(Min, Max)	mean ± sd	(Min, Max)			
Avg Weight at baseline	222.15 ± 49.52	(129.41 , 357.81)	224.35 ± 40.4	(150.8 , 304.24)	satisfied based on Q-Q plot	F value=1.5, numerator DF/denominator DF=52/51, p=0.1477, pooled t test	t value=-0.25, DF=103, p=0.8033
Avg Weight at month 12	215.97 ± 49.97	(124.12 , 376.77)	218.13 ± 41.75	(148.59 , 298.95)	satisfied based on Q-Q plot	F value=1.43, numerator DF/denominator DF=52/51, p=0.2012, pooled t test	t value=-0.24, DF=103, p=0.8107
Avg Weight loss (change in weight in month 12, compared to baseline	**-6.18 ± 13.05**	(-41.78 , 19.84)	**-6.22 ± 12.86**	(-44.75 , 28.66)	satisfied based on Q-Q plot	F value=1.03, numerator DF/denominator DF=52/51, p=0.9176, pooled t test	t value=0.02, DF=103, p=0.986

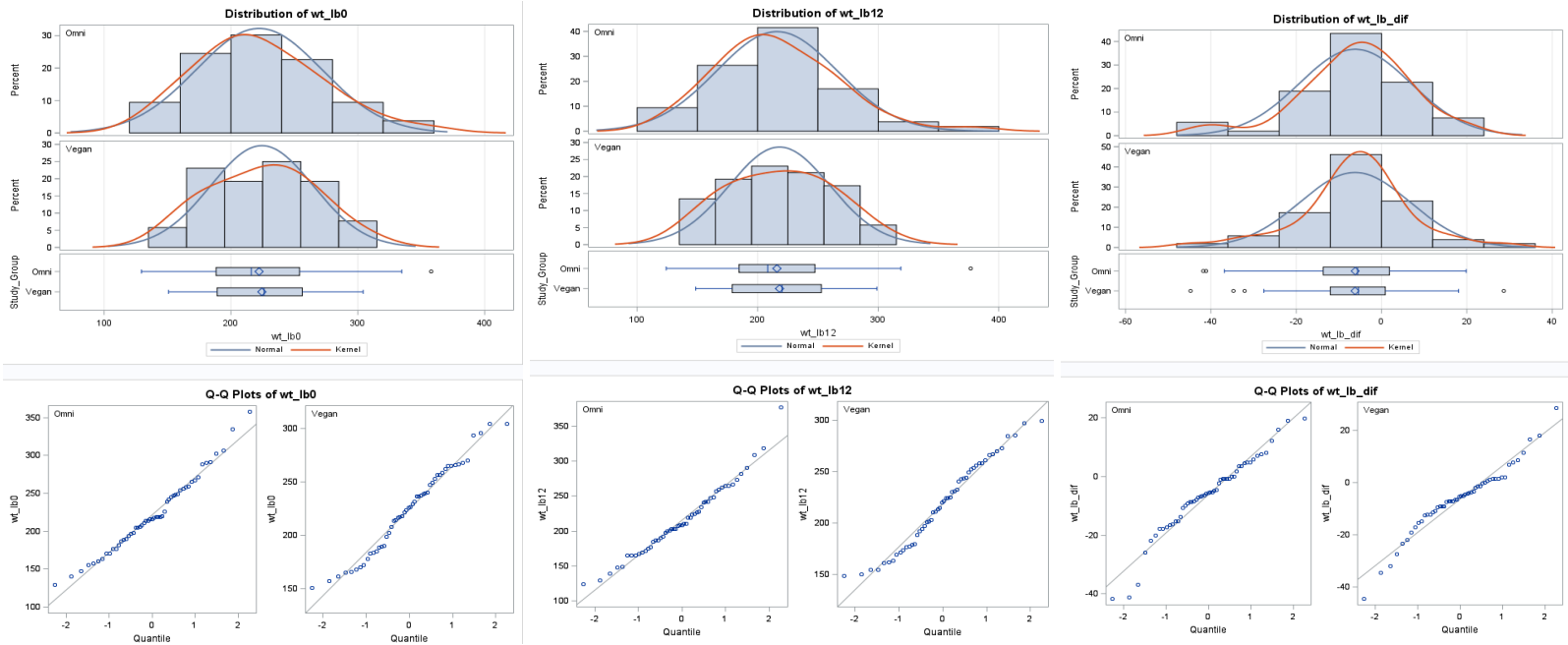

Figure 4.1- Q-Q Plots for average weight at baseline, 12 months and weight difference

Table 4.9- CEA findings to calculate DD of average weight loss

Weight Change (lbs)	**At baseline**		**At month 12**		**Weight Loss (weight at month 12 - weight at baseline)**		**Test**		
	Estimate	Standard error	Estimate	Standard error	Estimate	Standard error	DF	t Value	Pr > |t|
OMNI	233.57	9.1734	227.4	9.1734	-6.1771	1.7795	103	-3.47	0.0008
VEGAN	231.69	8.7947	225.46	8.7947	-6.2217	1.7965	103	-3.46	0.0008
DD in weight loss (vegan - omni)					-0.0446	2.5286	103	-0.02	0.986

With regards to intervention costs per pound of weight loss, the incremental cost effectiveness ratio is noted below (Table 4.10).

Table 4.10- CEA ICER results

	Weight Difference		**Cost difference**	
	Mean	Standard error	Median	**ICER**
OMNI (n=53)	-6.1771	1.7795	**-747.51**	
VEGAN (n=52)	-6.2217	1.7965	**-876.34**	
Vegan-Omni difference	-0.0446	2.5286	**-128.83**	**2888.57**

$$\text{ICER} = \frac{\text{Cost difference}}{\text{Weight loss difference}} = \frac{-128.83}{-0.0446} = \$2{,}888.57 \; per\ pound\ of\ weight\ loss$$

Compared to the omni group intervention, the vegan group intervention is dominate (cost effective) due to greater weight loss at a lower cost, positioning it in the quadrant (II) on the cost effectiveness plane.

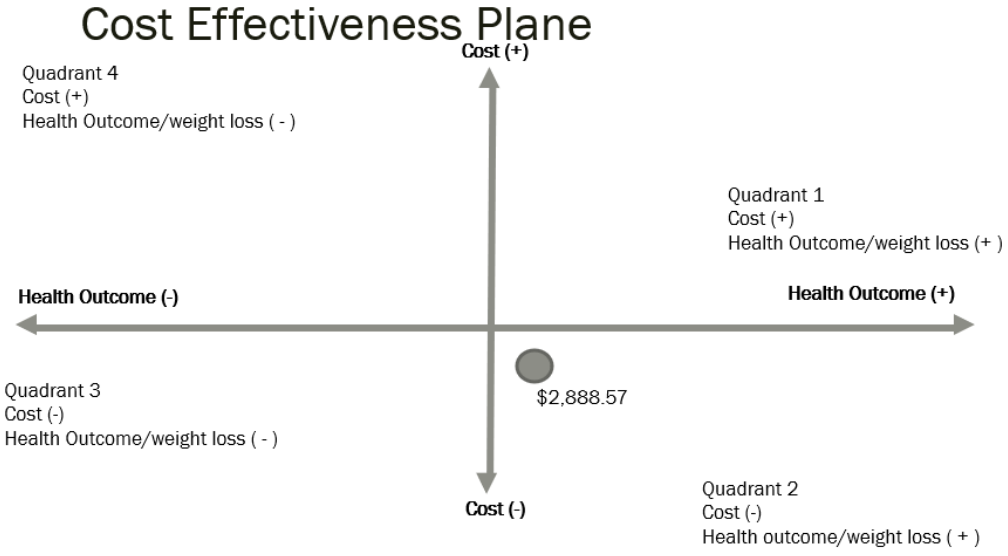

Figure 4.2 Cost Effectiveness Plane of ICER

Figure 4.3 represents the scatter plot of bootstrapped ICER based on 10,000 samples. The variance of the ICER is large, which might be attributed to the small difference in weight loss between the vegan and omni diet groups.

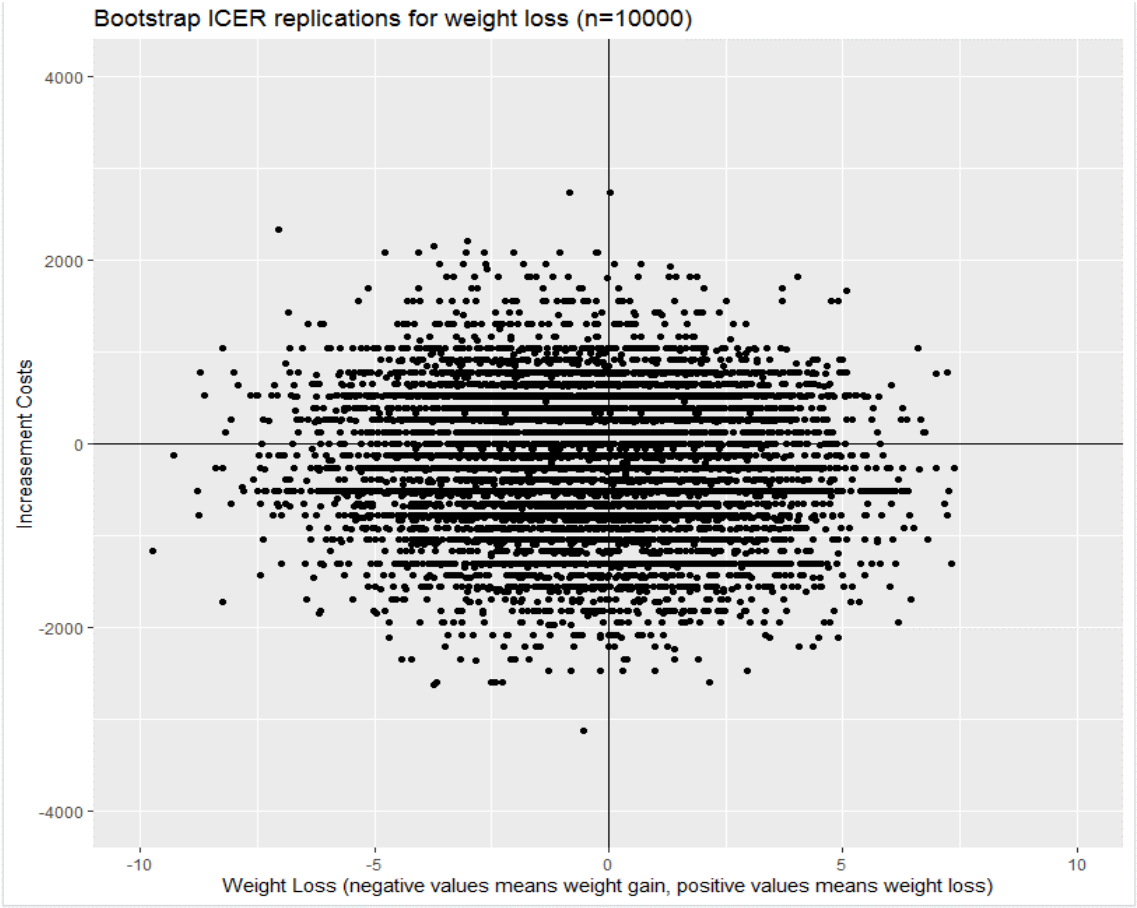

Figure 4.3- Monte Carlo (Bootstrap) Scatter Plot of BootStrapped ICER (n= 10000)

Acceptability Curve

The acceptability probability was estimated as the proportion of accepted ICER out of the 10,000 ICER samples. The x axis represents the willingness to pay in the United States- 1.84 GDP per capita ($50,000) to 2.76 GDP per capita ($150,000.[136] The y axis represents the estimated acceptance probability. By increasing the willingness to

pay, acceptance probability was around 43% indicating that as the willingness to pay increases, the probability that the ICER is below the maximum willingness to pay does not change much (Figure 4.2).

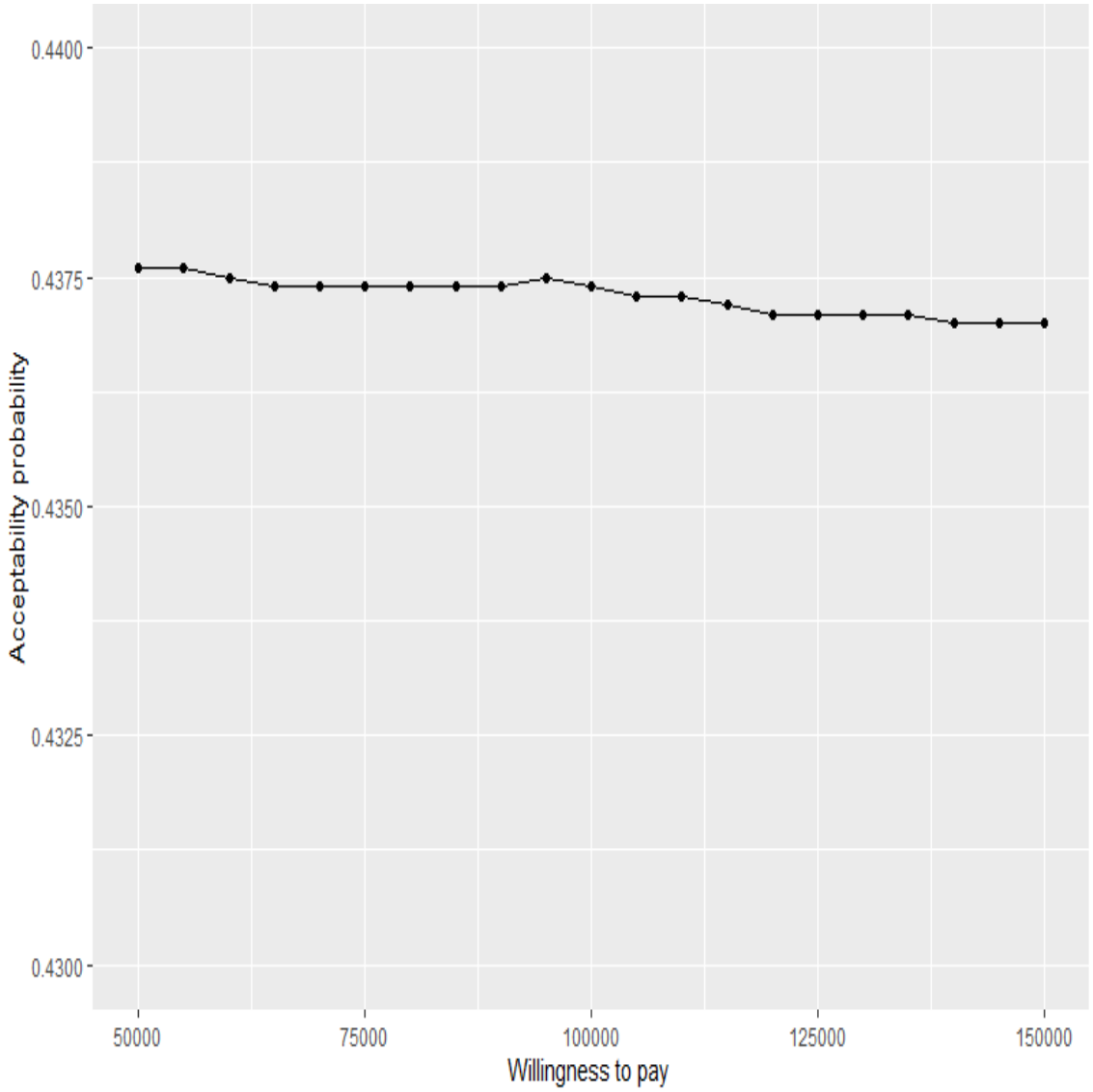

Figure 4.4- Monte Carlo (Bootstrap) sensitivity analysis acceptability curve

The estimated utility scores based on both algorithms had a similar distribution (Table 4.11) and the density plot of utility scores was plotted at baseline in Figure 4.5 and at 12 months in Figure 4.6.

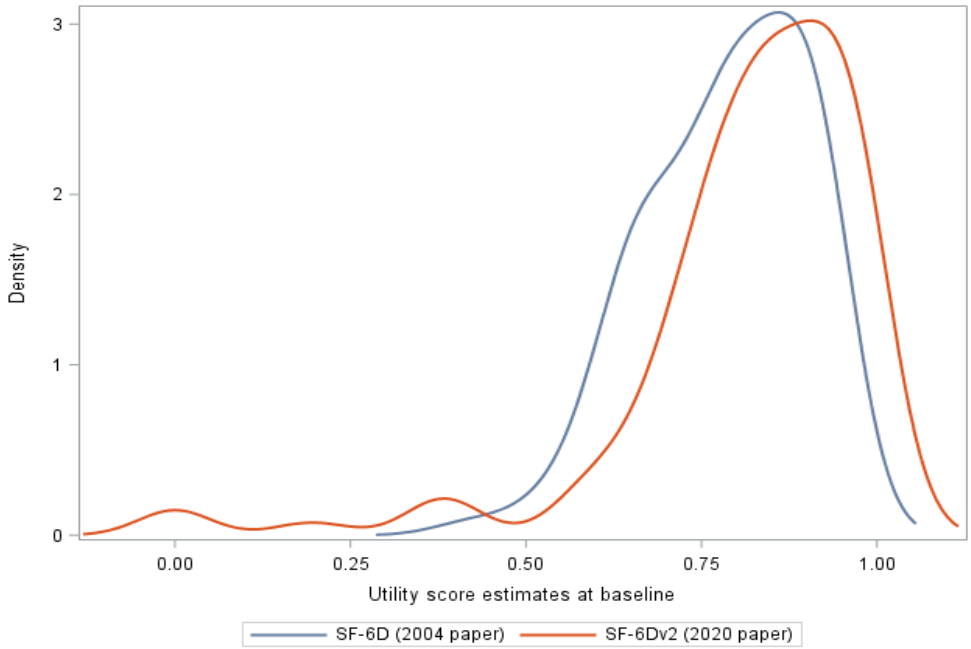

Figure 4.5-Distribution of Utility Score Estimates at Baseline By SF-6D and SF-6Dv2 Algorithms

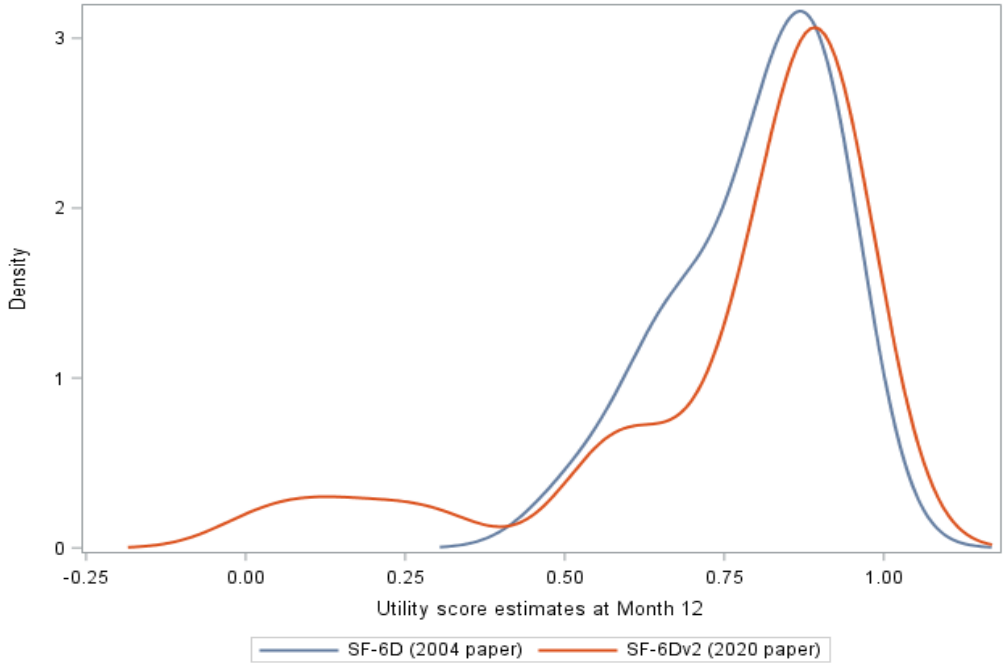

Figure 4.6-Distribution of Utility Score Estimates at 12 months by SF-6D and SF-6Dv2 Algorithms

Table 4.11-Distribution of Utility Score Estimates at Baseline and 12 by SF-6D and SF-6Dv2 Algorithms

Algorithm	Time	N	Mean	SD	Median	p25	p75	min	max
SF-6D (2004 paper)	At baseline	105	**0.79**	0.11	**0.8**	0.7	0.86	0.42	0.92
	At month 12	105	**0.8**	0.12	**0.82**	0.71	0.92	0.47	1
SF-6Dv2 (2020 paper)	At baseline	105	**0.81**	0.18	**0.85**	0.76	0.93	0	0.99
	At month 12	105	**0.76**	0.25	**0.87**	0.68	0.91	0	0.99

QALY change from baseline to 12 months was calculated based on the change in utility scores multiplied by the duration of the study (1 year) based on SF-6D results (Table 4.12) and SF-6Dv2 (Table 4.13). Participants in the NEW Soul Study were asked to recall their health conditions during the past 4 weeks at baseline and 12 months. We believe the estimated utility score during the past 4 weeks for each measurement period appropriately reflects the health condition of our study participants. Estimated utility scores from both algorithms are close to each other, however results calculated from SF-6Dvs are not normally distributed, so QALYs gained based on the SF-6D algorithm is used for the DD regression analysis, as these results are normally distributed.

Table 4.12- QALYs Gained Based on Calculations from SF-6D Utility Scores

QALY (2004)	**OMNI (n=53)**		**VEGAN (n=52)**		**Normality assumption check**	**Equality of Variances Tests check**	**Tests**
	mean ± sd	(Min, Max)	mean ± sd	(Min, Max)			
Utility Score at baseline	0.77 ± 0.11	(0.51 , 0.92)	0.8 ± 0.12	(0.42 , 0.92)	satisfied based on Q-Q plot	F value=1.28, numerator DF/denominator DF=51/52, p=0.3729, pooled t test	t value=-1.08, DF=103, p=0.2843
Utility Score at month 12	0.79 ± 0.13	(0.47 , 0.92)	0.8 ± 0.12	(0.48 , 1)	satisfied based on Q-Q plot	F value=1.09, numerator DF/denominator DF=52/51, p=0.7536, pooled t test	t value=-0.58, DF=103, p=0.5607
QALY gained in month 12, compared to baseline	0.02 ± 0.09	(-0.2 , 0.23)	0.01 ± 0.13	(-0.32 , 0.27)	satisfied based on Q-Q plot	F value=1.92, numerator DF/denominator DF=51/52, p=0.0206, Satterthwaite t test	t value=0.46, DF=92.68, p=0.6496

Table 4.13- QALY Gained Based on Calculations from SF-6Dv2 Utility Score

QALY (2020)	**OMNI (n=53)**				**VEGAN (n=52)**				**Normality assumption check**	**Wilcoxon rank-sum test**
	mean	median	p25	p75	mean	median	p25	p75		
Utility score at baseline	0.81	0.84	0.76	0.91	0.82	0.87	0.77	0.95	Not satisfied	p=0.3458
Utility score at month 12	0.76	0.87	0.65	0.91	0.75	0.86	0.72	0.91	Not satisfied	p=0.9898
QALY gained in month 12, compared to baseline	-0.05	-0.02	-0.12	0.05	-0.06	0	-0.08	0.04	Not satisfied	p=0.9591

A difference-in differences (DD) regression analysis was conducted to explain the difference in average QALY (based on utilities scores from SF-6D) between diet groups while controlling for age, sex, education, employment, class attendance, and physical activity.

$Y = b_0 + b_{1*}t + b_2$*diet group + b_3*diet group*t + b_4*age+ b_5* sex + b_6*education + b7 *employment + b8 *class attendance + b9*physical activity + b10* cohort

H_0 for 2b & 2c: Avg $QALY_{Vegan}$=Avg $QALY_{Omni}$

H_A for 2b & 2c: Avg $QALY_{Vegan} \neq$Avg $QALY_{Omni}$

There was no statistically significant difference in average QALY gain between diet groups while controlling for age, sex, education, employment, class attendance, and physical activity. Therefore, we fail to reject the null hypothesis. Table 4.14 shows the results from the least squares means estimate from the DD regression model. The DD in QALY between the vegan and omni diet groups was not statistically significant.

Table 4.14- Solution for Fixed Effects based on SF-6D DD Models

Effect	Levels	Estimate	Standard Error	DF	t Value	Pr > |t|
Intercept		0.5482	0.06899	94	7.95	<.0001
t	At month 12	0.01508	0.01501	103	1	0.3174
	At baseline	0	.	.	.	.
Diet Group	Vegan	0.01377	0.02295	103	0.6	0.55
	Omni	0	.	.	.	.
t*Diet_Group	At month 12*Vegan	-0.00975	0.02132	103	-0.46	0.6485
	At month 12*Omni	0	.	.	.	.
	At baseline*Vegan	0	.	.	.	.
	At baseline*Omni	0	.	.	.	.
Cohort	1	0.0157	0.02188	103	0.72	0.4747
	2	0	.	.	.	.
Age		0.002357	0.001195	103	1.97	0.0513
Sex	Male	0.03902	0.03041	103	1.28	0.2023
	Female	0	.	.	.	.
Physical activity	High	0.02652	0.02833	103	0.94	0.3514
	Low	0.01939	0.02368	103	0.82	0.4148
	Moderate	0	.	.	.	.
Class_Attendance		0.001041	0.000755	103	1.38	0.1709
Education	High school or equivalent, Some college	0.009625	0.02802	103	0.34	0.7319
	College	0.004247	0.02414	103	0.18	0.8607
	Advanced degree	0	.	.	.	.
Employment	Unemployed	-0.02078	0.03219	103	-0.65	0.5201
	Employed	0	.	.	.	.

Table 4.15- SF-6D Least Squares Means Estimate from DD Models Adjusted for Covariates (Repeated Measures Reg Results)

QALY	**At baseline**		**At month 12**		**QALY (at month 12 - at baseline)**		**Test**		
	Estimate	Standard error	Estimate	Standard error	Estimate	Standard error	DF	t Value	Pr > |t|
OMNI	0.7889	0.02269	0.804	0.02269	**0.01508**	0.01501	103	1	0.3174
VEGAN	0.8027	0.02187	0.808	0.02187	**0.005327**	0.01515	103	0.35	0.7258
DD in qaly (vegan - omni)					**-0.00975**	0.02132	103	-0.46	0.6485

Discussion

This study sought to determine the cost effectiveness of a culturally tailored dietary intervention, which included participants being assigned to either a vegan diet group or an omni diet group. The vegan diet group demonstrated more weight loss at less cost, compared to the omni diet group and was determined to be the clear choice (dominant) of the interventions.

The findings from this economic evaluation supplement the findings from economic analysis of the Food Choice at Work Study and Postpartum Diet that suggests the importance of opportunities for community stakeholders, policy makers, and health care providers to recommend programs that promote weight loss through dietary changes. Additionally, results complement the findings in the literature that reveal that healthful plant-based are associated with prevention of chronic disease, healthier body weights, and lowering CVD risk factors for AAs. [86–91,117–122]

When considering the second outcome measure of the DD in QALY between the vegan and omni intervention, there was no statistically significant difference. Generally speaking, both diet groups experienced a small increase in QALY from baseline to 12 months; however, the values were not statistically significant.

Advising future community-based approaches and population health decision making requires regard of cultural acceptability, costs, and benefits. Because this analysis was conducted from a societal perspective, it provides the best indication of overall cost effectiveness of the interventions and is very useful for decisions related to the allocation of resources.[30,155]

From a health services research perspective, there is a critical need to identify and implement culturally relevant research-based nutrition interventions that are also financially sustainable to combat CVD within the AA population. Existing literature supports the novel theoretical concept of applying a cost effectiveness analysis (CEA) to dietary interventions.[18–25] This study suggests that a vegan diet can potentially offer the best value, from a societal perspective, in terms of weight loss and dietary recommendations that are culturally acceptable and less costly for those who present with CVD risk factors.

The primary strength of this economic evaluation is that it is the only study to our knowledge that evaluates the cost effectiveness of a culturally-tailored dietary intervention, comparing a vegan and omni diet, for an all AA study population presenting with CVD risk factors. The reported QALYs gained is another strength of this study. The Medical Research Council advises that interventions shown to be effective in improving health are more likely to be scaled up for future implementation if results are relevant to decision makers.[156] Public health professionals, policy makers and medical providers observe the impact of CVD and other chronic disease disparities on quality of life, community health and healthcare spending and desire solutions. This study also minimized the need for assumptions because it included primary data collection measures and prospective cohort study with randomization.

This study is not without limitations. This cost effectiveness analysis involves a comparative of two dietary "courses of action" of the NEW Soul study that aim to reduce obesity, a major CVD risk factor. The difference in costs of the vegan and omni diets s are compared with the difference in outcomes. However, there are some questions that a

CEA of the NEW Soul Study cannot answer. This study is subject to limitations because it is limited in scope to the NEW Soul study specifically and does not take into account all potential dietary patterns to address CVD prevention. Additionally, another limitation of this analysis is that it does not include all outcomes associated with the intervention, such as lipid panel results to assess cholesterol levels and blood pressure. Time spent shopping and meal prepping were not assessed at baseline, therefore these costs were imputed based on data collected for these measures in the literature. Future studies should assess these measures at all time points. Selection bias can also occur since all participants volunteered for this study. Participants may share social characteristics that are different from others who did not volunteer to participate in this study. Furthermore, life changing events, such as, but not limited to changes in: income, household size and marital status. However, we do not expect that these changes will be different between groups.

Threats to the validity of the study include: attrition; data underreporting or overreporting; and measurement error. Attrition is a threat to the validity of this study, because not all participants participated in the 12 month assessment where weight was collected. Data underreporting or overreporting may also have been present, as participants may have underreported or overreported the average amount of money they spent on groceries and dining out, and/or their time spent shopping and preparing food. If this data was underreported or overreported, it would not reflect the true costs associated with the diet group that is used to calculate the ICER and ICUR. Measurement error may have also resulted due to participants answering questions retrospectively and

inaccurately recalling information. Additionally, measurement error could have resulted during the collection of weight and/or during the entry of that data.

Significant measures were taken by the NEW Soul Staff to assure the reliability and validity of the data. These measures included: frequent communication with participants to maximize participation in assessments to collect weight; helpful text within the surveys to ensure that participants understood survey questions that were designed with an upper elementary reading level; and collecting two weight measurements that were recorded and triple checked upon entering the data.

Conclusion

While this study presents a cost effective intervention for AAs presenting with heart disease risk factors, that considers direct and indirect costs, future research should include data collection beyond 12 months in order to further assess health effects such as lipid panel results to assess cholesterol levels and blood pressure that were not represented in this study.

CHAPTER 5

MANUSCRIPT TWO

CONDUCTING CLINICAL ASSESSMENTS FOR THE NUTRITIOUS EATING WITH SOUL STUDY DURING COVID-19 & ITS IMPACT ON WEIGHT LOSS

[1]Wilson, M.J., Crouch, E., Turner-McGrievy, B., Chen, B., Hung, P.…To be submitted.

Abstract

Background

Historically, African Americans have been underrepresented in research. The Nutritious Eating With Soul (NEW Soul) Study is the first of its kind to recruit an African American (AA) only study group to examine heart disease prevention via a clinical trial to examine changes in heart disease risk factors across two cohorts who are randomly assigned to a plant-based vegan diet or low-fat omnivorous diet. The purpose of this study is to describe the clinical assessment methods implemented by the NEW Soul Study, in order to conduct research in a safe environment with special emphasis on methods used to help mitigate the risk and spread of COVID-19 within an all-AA study population and to also examine the impact that COVID-19 had on our study population's weight loss.

Methods

University IRB approval was granted to resume in-person research based on established protocol. Staff were tested for COVID-19 and trained on safety measures and social distancing protocol to conduct assessments. Participants received a detailed account of safety measures in place via personal phone calls, email and text message. Participants completed a sign up for an individual time slot between 6am and 10am to complete the assessment. Options for a full (weight, bp and bloodwork) or partial assessment (weight and/or bp only) were provided based on the comfort level of participants. Partial assessments were offered indoors or outdoors under a covered patio based on participant preference. A COVID-19 symptom screening and temperature check was required, and

personal protective equipment was required and provided to staff and participants prior to entering the assessment location.

Findings

Across the two cohorts, full or partial assessment completion at 1-year prior to COVID-19 and during COVID-19 fell within the 80th percentile: Cohort 1 pre COVID-19 (88%) and Cohort 2 during COVID-19 (80%). The difference-in-differences in weight loss in Cohort 1 (pre-COVID) and Cohort 2 (during COVID) resulted in a statistically significant difference of 6.5 pounds.

Conclusions

Detailed COVID-19 protocol for conducting assessments and communication of this to participants, along with staff training to execute assessment protocol were key to conducting clinical assessments. In comparison to weight loss prior to the pandemic, COVID-19 significantly impacted our participant's weight loss.

Keywords: clinical assessment, COVID-19, dietary intervention, weight loss

Introduction

During the COVID-19 pandemic, there has been increasing attention put on patients with cardiovascular disease risk factors, such as hypertension, as these patients are at a higher risk for developing more serious cases of COVID-19.[157,158] Obesity has also been linked to increased susceptibility to COVID-19 and a higher risk for respiratory failure.[158,159] The pandemic revealed that health disparities in the African American community have become even more prominent; AAs, compared to non-Hispanic White people, were disproportionately affected by COVID-19 (2.6 times higher cases), were hospitalized 4.7 times more, and were 2.1 times more likely to die as a result of the illness.[146,147]

Literature also suggested that quarantine and isolation disproportionately impacted weight management, health behaviors and psychosocial health amongst individuals in the US with obesity, regardless of COVID-19 illness status.[148] Patients in medical settings and public survey respondents consistently reported: spending more time at home; hardships achieving/maintaining weight loss goals; decreased physical activity; increased stress eating; decreased dietary restraint; and an increase in anxiety and depression.[148,149,150] A systematic review of the literature that included 36 studies identified similar trends at the global level.[153] However, a critical gap in knowledge about the impact of COVID-19 on vulnerable populations remains, as African Americans were largely underrepresented in these studies. Therefore, this study aims to examine implemented research measures to help mitigate the risk and spread of COVID-19 during

the NEW Soul Study's clinical assessments, assessment completion rates, and the impact of COVID-19 on weight loss for African American participants at high risk for CVD and COVID-19 illness and mortality. We hypothesize that participants impacted by the COVID-19 pandemic during 12-month assessments will experience reduced weight loss, compared to participants not affected by the COVID-19 pandemic during 12-month assessments.

Methodology

Study Design and Participants

African American adults (18-65 years of age) in the Midlands region of South Carolina with overweight or obesity (BMI 25-49.9 kg/m^2) who enrolled in Cohorts 1 and 2 of the Nutritious Eating With (NEW) Soul Study, a behavioral nutrition intervention, were chosen for this study. All participants completed an online screening questionnaire and follow-up phone screening to confirm eligibility criteria listed below.[26]

Table 5.1: NEW Soul Eligibility Criteria

Inclusion Criteria	**Exclusion Criteria**
Self-identify as African American	Following a vegan diet
Be between the ages of 18-65 years	Currently on medication for diabetes
Body Mass Index between 25-49.9kg.m2	Currently pregnant or breastfeeding or plan to become pregnant in the next 24 months
Live in Columbia, SC/Midlands area	
Be able to attend all monitoring and class visits	

Upon completion of the baseline assessment, participants were randomized to one of two groups: the vegan group or the low-fat omnivorous diet group using a computer program allocation sequence and stratified by gender and baseline BMI. The cohorts were separated by one year. Cohort 1 began the study in May 2018 and Cohort 2 began the study in June 2019. See Table 5.2 for summaries of participant enrollment for both cohorts. See Table 5.3 for summaries of enrollment and randomization.

Table 5.2 Demographics of NEW Soul Study Cohort 1 & 2 Participants (N=159)

	Cohort 1 (n=67)		**Cohort 2 (n=92)**	
Characteristics	**N**	**N%**	**N**	**N%**
Gender				
Female	59	88.05	67	72.82
Male	8	11.94	25	27.17
Ethnicity				
Hispanic or Latino	1	1.50	1	1.09
Not Hispanic or Latino	66	98.50	91	98.91
Unknown	0	0	0	0
Age				
Mean (SE)	47.7 (1.4)		48.7 (1.1)	
Median (min, max)	50 (25, 65)		50 (25, 65)	
Race				
American Indian/Alaskan Native	0	0	0	0
Asian	0	0	0	0
Nat Hawaiian/Other Pac Islander	0	0	0	0
Black or African American	65	97.01	92	100
White	0	0	0	0
Other	0	0	0	0
African American and other race	2	2.99	0	0
Unknown	0	0	0	0

**Note that all participants must self-identify as Black/African American to enroll in the study, but participants may indicate more than one race.

Table 5.3 NEW Soul Study Participant Enrollment and Randomization

	Cohort 1 Total Enrolled @ Baseline	**Cohort 2 Total Enrolled @ Baseline**	**Cohorts 1 & 2 Combined**	**Complete Data Cohorts 1 & 2 Combined (Baseline & 12 months)**
Omni Control	34	48	**82**	**53**
Vegan Intervention	33	44	**77**	**52**
Total Participants	67 (Female=59 Male=8)	92 (Female= 67 Male=25)	**159 (Female=126 Male=33)**	**105 (Female = 88 Male =17)**

Definition of Study Groups

For the purposes of this study, study groups are defined as cohorts. Cohort 1 at 1-year assessments was not affected by COVID-19. Cohort 2 at 1-year was affected by COVID-19 (Table 5.4). See Table 5.5 for measurements collected during assessments.

Table 5.4 Definition of Study Groups

	Cohort 1: 1-year assessments (April 2019)	**Cohort 2: 1-year assessments (June-July 2020)**
Affected by COVID-19?	No Assessments occurred prior to the pandemic	Yes Assessments occurred during the pandemic

Clinical Assessment Protocol During COVID-19

In response to the threat of COVID-19 on the health of the public, an executive order from the South Carolina Governor's office was issued and all system institutions of the University of South Carolina were closed beginning March 16, 2021. University IRB approval was granted to resume in-person research based on established protocol set forth by NEW Soul supervisory staff for workers and participants. Workers hired to conduct assessments were tested for COVID-19 and were trained both virtually and in-person on safety measures and social distancing protocol. Staff training included proper handwashing and mask wearing. Additionally, staff was trained on work shift check-in procedures that included a temperature check and answering COVID-19 screening questions prior to each shift to assess potential illness and exposure. Staff were also trained on participant interaction and appointment check-in. Participants received a detailed account of safety measures in place via phone calls, email and text message.

Table 5.5 Summary of All Measures Being Collected at 1-year Assessments

Cohort	**Cohort 1 1 year**	**Cohort 2 1 year**
Calendar month and year	April 2019	June-July 2020
Measure	Collected	
Weight	X	x
Physical Activity (ActiGraph Accelerometer GT1M model)	X	---
Blood Pressure	X	x
Bloodwork (Fasting Lipids, Glucose, and Insulin)	X	x
Body Fat (DEXA Scan)	X	x
Waist-to-Hip Circumference	X	-----
Class Attendance and Use of Intervention Components	X	x

Table 5.6 COVID-19 Clinical Assessment Protocol

COVID Procedures	**Participant Details**	**Staff Details**
Assessment appointment signup	Follow the signup genius link to sign up for an individual time slot between 6am and 10am to complete your assessment. Options for a full (weight, bp and bloodwork) or partial assessment (weight and/or bp only) are available based on your comfort level. Please contact us with any additional requests/questions that you might have so that we can best accommodate you.	Review appointment sign-ups and any notes/requests from participants. Provide appointment confirmation and send reminders 2 days and 1 day prior to the appointment. Call participants if they do not arrive within 10 minutes of their scheduled appointment time.
Screening process to determine the <u>COVID-19 risk status</u> of volunteers and staff (e.g. questionnaire regarding health status, recent travels, body temperature, etc.).	Upon arrival, participants will sit in their car and call the number sent to them via the instruction sheet. A staff member will respond and ask them questions regarding health status, travel, and recent exposures. This staff member will also take their temperature before allowing them in the facility.	Pass PPE through the window and instruct participant to put on gear prior to talking. COVID-19 Screening questions. 1) Have you recently had a fever, cough, or shortness of breath within the last week? Circle: Yes/No 2)Have you been around anyone sick within the last week? Circle: Yes/No If participant answers "yes" to either one of these questions, please inform the participant that in order to prevent the spread of COVID-19, that they will not be able to complete the lab assessment and that the project manager will be

		in touch to reschedule your appointment. Inform participant that you must conduct a temperature screening prior to entry into the building. *If participant is running a fever over 100 °F, inform the participant that in order to prevent the spread of COVID-19, that they will not be able to complete the lab assessment and that Mary will be in touch to reschedule their appointment.
Social distancing requirements	All participants will wait in their car to avoid any overlap with other participants. All participants and staff will be wearing a mask and gloves. Each participant will be working with one specific staff member to minimize contact.	Assist your assigned participant in completing all measurements (blood pressure and weight). Maintain 6 feet distance outside of required contact for measurements.
Use of Personal Protective Equipment (PPE), including what is required and how it will be obtained	All participants will be wearing a face mask that are provided by the study and will be asked to wear them prior to entering the facility and remain wearing them at all times. Gloves will be available but are optional. Hand sanitizer will be provided throughout the facility. All staff members will also be wearing a face mask and gloves. New	Masks are required. Gloves are required and must be changed before contact with each participant. No eating or drinking in the lab. A morning break mid-shift will be provided for workers to properly distance to consume snacks outside of the lab.

	gloves will be used between participants.	
Proper cleaning of materials, equipment and commonly touched areas where the activities will take place	Each room will be sanitized between participants. Staff will use new gloves between participants. All surfaces will be wiped down with disinfectant wipes. Extra attention will be paid to commonly touched surfaces like doorknobs, handles, and chairs. Participants and staff will not be allowed to eat or drink in the facilities. Bathroom use will be minimized, and the bathroom will be sanitized between use. Participants should be discouraged from touching surfaces; staff should do things like open and hold doors if possible.	Staff will clean equipment and touched surfaces prior to and after measurements of each participant.
Plan for scheduling visits to avoid overlap in appointments	All participants will be sign up for a specific time in advance. All participants must arrive at their designated time and will be asked to wait in their vehicle until we are ready for them to enter the facility, one participant at a time. No one will be allowed to enter a room where another participant is currently located or before it has been sanitized.	If participants arrive late or early to their appointment, maintain assisting only one participant at a time in the assessment area and have participants wait in their vehicle until the area is clear of any other participant.
If included in the subject population, plans for handling visits by	All participants with underlying health conditions will be instructed	Special notations will be included in participant's day-of file for any

participants in high-risk categories (older adults and anyone with serious underlying medical conditions). Refer to CDC guidance for a full list.	to contact us in advance. We will provide them with a list of conditions to notify us about. Current procedures should be enough but knowing which participants to specifically look out for will allow us to be extra cautious.	changes to procedures to best accommodate the participant. One onsite supervisor will be available to answer questions, and the project manager will oversee lab operations virtually via google meet.

Study Design

Clinical assessment protocol during COVID-19 was established to help mitigate the risk and spread of COVID-19 for NEW Soul participants. The overall percentage of assessment completion for each cohort was utilized to understand assessment participation before and during COVID-19 based on the safety measures put forth by the NEW Soul Study staff. A quasi-experimental difference-in-differences (DD) study design was utilized to compare average weight loss at 1-year assessments between Cohort 1 who was not affected by the pandemic and Cohort 2 who was affected by the pandemic.

The dependent variable for the DD estimation was average weight loss. The primary independent variable of interest was the status of the COVID-19 pandemic: before or during. Participant demographic characteristics (age, sex, education group, and employment) and intervention participation variables (class attendance and physical activity) were included in the adjusted models based on their potential to impact weight loss.[162,163]

Analytic Approach

All full (weight, blood pressure, bloodwork, dexa scan) or partial assessments (weight and blood pressure or weight only) for Cohort 1 at 1-year and Cohort 2 at 1-year

were totaled and the overall assessment completion percentages was calculated based on the total number of participants enrolled in the study for Cohort 1 (n = 67) and Cohort 2 (n = 92).

A comparison was conducted to test the statistical significance of the average weight loss for cohort 1 pre-COVID and for cohort 2 during COVID by diet group using t- tests. DD model was utilized to estimate differences in average weight loss of study participants pre COVID-19 and during COVID-19 while adjusting for patient and intervention characteristics (age, sex, education, employment, class attendance and physical activity). All analyses were completed using SAS version 9.4. This study was approved by the University of South Carolina Institutional Review Board. ***Results***

Across the two cohorts, the majority of NEW Soul participants completed assessments both pre COVID-19 and during COVID-19. Full or partial assessment completion at 1-year prior to COVID-19 and during COVID-19 fell within the 80th percentile (Table 5.7).

Table 5.7- Assessment Completion at 1-year Pre COVID-19 and During COVID-19

	Full/Partial Assessment Completion	**Full/Partial Assessment Completion Percentage**
Cohort 1: 1-year assessments (not impacted by COVID)	59/67	88%
Cohort 2: 1-year assessments (impacted by COVID)	74/92	80%

Cohort 1 (pre-COVID) experienced an average weight loss of 10.2 pounds between baseline and 12 months. Cohort 2 (during COVID) experienced an average weight loss of 3.7 pounds between baseline and 12 months (Table.5.8).

Table 5.8- Comparison of Weight Loss by Cohort for each Diet Group

Diet Group	Weight (lbs)	C1 (n=21)		C2(n=32)		Normality assumption check	Equality of Variances Tests check	t Tests
		mean ± sd	(Min, Max)	mean ± sd	(Min, Max)			
Omni	Weight at baseline	230.35 ± 52.88	(140.21 , 357.81)	216.77 ± 47.27	(129.41, 302.8)	satisfied based on Q-Q plot	F value=1.25, numerator DF/denominator DF=20/31, p=0.5619, pooled t test	t value=0.98, DF=51, p=0.3338
	Weight at month 12	220.83 ± 53.59	(139.11 , 376.77)	212.78 ± 48.06	(124.12, 318.79)	satisfied based on Q-Q plot	F value=1.24, numerator DF/denominator DF=20/31, p=0.5723, pooled t test	t value=0.57, DF=51, p=0.571
	weight change in month 12, compared to baseline	-9.51 ± 16.24	(-41.78 , 19.84)	-3.99 ± 10.15	(-36.82, 15.98)	satisfied based on Q-Q plot	F value=2.56, numerator DF/denominator DF=20/31, p=0.0182, satterthwaite t test	t value=-1.39, DF=30.28, p=0.1746
		C1 (n=19)		C2(n=33)				
Vegan	Weight at baseline	214.73 ± 45.73	(150.8 , 295.75)	229.9 ± 36.58	(165.57, 304.24)	satisfied based on Q-Q plot	F value=1.56, numerator DF/denominator DF=18/32, p=0.2637, pooled t test	t value=-1.31, DF=50, p=0.1953

	Weight at month 12	203.73 ± 43.89	(148.59 , 269.51)	226.42 ± 38.74	(161.6 , 298.95)	satisfied based on Q-Q plot	F value=1.28, numerator DF/denominator DF=18/32, p=0.5228, pooled t test	t value=-1.94, DF=50, p=0.0583
	weight change in month 12, compared to baseline	-11 ± 10.33	(-34.72 , 1.87)	-3.47 ± 13.5	(-44.75 , 28.66)	satisfied based on Q-Q plot	F value=1.71, numerator DF/denominator DF=32/18, p=0.232, pooled t test	t value=-2.1, DF=50, p=0.0408

Covariates in the models that were statistically significant with weight loss were: time, sex and the interaction of time and cohort.. Males were found to be on average, 32 pounds. heavier than female participants. The coefficients of the interaction variable in Table 5.9 indicates that the difference-in-differences of weight loss pre-COVID and during COVID between cohorts was 6.5 pounds. The difference-in-differences in weight loss pre-COVID and during COVID by diet group revealed a statistically significant change in weight loss at 12 months compared to baseline between cohorts 1 and 2 for the vegan diet group ($p=0.0408$). Pre-COVID (C1), the vegan diet group lost an average of 11 pounds. During COVID (C2), the vegan diet group lost an average of 3.47 pounds. (Table 5.10)

Table 5.9- DD Model Findings

Effect	**levels**	**Estimate**	**Std Error**	**DF**	**t Value**	**Pr > |t|**
Intercept		210.14	29.7624	94	7.06	<.0001
t	At month 12	-3.7258	1.5576	103	-2.39	0.0186
	At baseline	0	.	.	.	.
Cohort	1	4.0314	9.4131	103	0.43	0.6693
	2	0	.	.	.	.
t*Cohort	At month 12*Cohort1	-6.4926	2.5236	103	-2.57	0.0115
	At month 12*Cohort2	0	.	.	.	.
	At baseline*Cohort1	0	.	.	.	.
	At baseline*Cohort2	0	.	.	.	.
Diet Group	Vegan	1.9107	8.6658	103	0.22	0.8259
	Omni	0	.	.	.	.
Age		0.4183	0.5095	103	0.82	0.4135
Sex	Male	32.1905	12.9644	103	2.48	0.0146
	Female	0	.	.	.	.
Physical activity	High	-19.5445	12.0776	103	-1.62	0.1087
	Low	-12.77	10.0976	103	-1.26	0.2088
	Moderate	0	.	.	.	.
Class_Attendance		-0.1628	0.3219	103	-0.51	0.6142
Education	High school or equivalent, Some college	3.4694	11.9441	103	0.29	0.772
	College	19.8053	10.2925	103	1.92	0.0571
	Advanced degree	0	.	.	.	.
Employment	Unemployed	-2.2655	13.7253	103	-0.17	0.8692
	Employed	0	.	.	.	.

Table 5.10- DD COVID-19 Effect on Weight loss by Cohort and Diet Group

Diet Group	**Weight (lbs)**	**C 1 (n=21)**		**C 2 (n=32)**		**Normality assumption check**	**Equality of Variances Tests check**	**t Tests**
		mean ± sd	(Min, Max)	mean ± sd	(Min, Max)			
Omni	Weight at baseline	230.35 ± 52.88	(140.21 , 357.81)	216.77 ± 47.27	(129.41 , 302.8)	satisfied based on Q-Q plot	F value=1.25, numerator DF/denominator DF=20/31, p=0.5619, pooled t test	t value=0.98, DF=51, p=0.3338
	Weight at month 12	220.83 ± 53.59	(139.11 , 376.77)	212.78 ± 48.06	(124.12 , 318.79)	satisfied based on Q-Q plot	F value=1.24, numerator DF/denominator DF=20/31, p=0.5723, pooled t test	t value=0.57, DF=51, p=0.571
	weight change in month 12, comp. to baseline	-9.51 ± 16.24	(-41.78 , 19.84)	-3.99 ± 10.15	(-36.82 , 15.98)	satisfied based on Q-Q plot	F value=2.56, numerator DF/denominator DF=20/31, p=0.0182, satterthwaite t test	t value=-1.39, DF=30.28, p=0.1746

		C 1 (n=19)		**C 2 (n=33)**				
Vegan	Weight at baseline	214.73 ± 45.73	(150.8 , 295.7 5)	229.9 ± 36.58	(165.57 , 304.24)	satisfied based on Q-Q plot	F value=1.56, numerator DF/denomin ator DF=18/32, p=0.2637, pooled t test	t value=-1.31, DF=50, p=0.1953
	Weight at month 12	203.73 ± 43.89	(148.5 9 , 269.5 1)	226.42 ± 38.74	(161.6 , 298.95)	satisfied based on Q-Q plot	F value=1.28, numerator DF/denomin ator DF=18/32, p=0.5228, pooled t test	t value=-1.94, DF=50, p=0.0583
	weight change in month 12, comp to baseline	-11 ± 10.33	(-34.72 , 1.87)	-3.47 ± 13.5	(-44.75 , 28.66)	satisfied based on Q-Q plot	F value=1.71, numerator DF/denomin ator DF=32/18, p=0.232, pooled t test	t value=-2.1, DF=50, p=0.0408

Discussion

As measures are being taken to vaccinate the population against COVID-19, the literature revealed that quarantine and isolation has disproportionately affected individuals in the US with obesity and their ability to manage their weight and health behaviors despite COVID-19 illness status.[148] When asked, patients in health care settings and public survey respondents consistently reported: spending more time at home; hardships achieving/maintaining weight loss goals; decreased physical activity; increased stress eating; decreased dietary restraint; and an increase in anxiety and depression.[148,149,150] A systematic review of the literature that included 36 studies identified similar trends at the global level.[153] However, a critical gap in knowledge about the impact of COVID-19 on African Americans were largely underrepresented in these studies. In this study, we will provide insights on whether the pandemic had an impact on weight loss of AAs enrolled in the NEW Soul Study. Additionally, we will help inform participant levels of comfort to voluntarily complete clinical assessments (where study measures such as weight and blood pressure were collected) based on procedures implemented to mitigate the risk and spread of illness during assessment visits.

Across the two cohorts, the majority of NEW Soul participants completed assessments both pre COVID-19 and during COVID-19. Assessment participation percentages at 1-year prior to COVID-19 and during COVID-19 both fell within the 80th percentile, which may be associated with several factors that contributed to high levels of comfort. Participants received detailed communications regarding the protocol to conduct assessments in the safest way possible. These communications were delivered via phone, text message and email. Despite participants having the option to not complete

assessments, most completed either full or partial in-person assessments at the University.

Additionally, this study revealed that pre-COVID weight loss of participants not impacted by COVID (cohort 1) was greater at 12 months, as compared to weight loss of participants impacted by COVID (cohort 2) at 12 months. Furthermore, this study revealed that participants in the vegan diet group had a harder time achieving weight loss during the COVID-19 pandemic. These findings were consistent with reported weight gain during the COVID-19 pandemic in individuals (mostly with overweight and obesity) across 38 studies who reported eating and snacking more, less consumption of vegetables, fruit and legumes, and more consumption of meat, dairy, fast-food and alcohol.[153,164,165] Furthermore, household size changes, employment changes, COVID-19 diagnosis or death of individuals or their family members, and lifestyle behaviors were reported contributors of weight gain.[165]

This study is not without limitations due to assumptions related to the quasi-experimental design method. This DD analysis assumes that the composition of Cohort 1 and Cohort 2 are stable during baseline and 12 months. In a DD study design it is also assumed that: there are no spillover effects that unrelated events had on both cohorts; the amount of intervention provided is not determined by weight loss; and both cohorts have parallel trends in weight loss outcomes if no intervention was provided so that the difference between the data from the cohorts would have a consistent difference over time.[135]

Threats to the validity of the study include: attrition and measurement error. Attrition is a threat to the validity of this study, because not all participants participated in

the 12 month assessment where weight was collected. Measurement error may have also resulted during the collection of weight and/or during the entry of that data.

Significant measures were taken by the NEW Soul Staff to assure the reliability and validity of the data. These measures included: frequent communication with participants to maximize participation in assessments to collect weight; and collecting two weight measurements that were recorded and triple checked upon entering the data.

Despite these challenges, there are some strengths of this study. The DD method is flexible and will show a casual effect from experimental data when the basic assumptions are met. The DD method is a controlled pre and post analysis that focuses on changes of the cohorts at different time points and changes due to factors outside of the vegan and omni interventions of the NEW Soul Study.

Conclusion

While this study presents a DD estimation of the impact of COVID-19 on weight loss for AAs presenting with heart disease risk factors, more work is needed to fully understand this association. This study demonstrates that participants impacted by COVID experienced less weight loss than participants who were not impacted by COVID. This signifies a need to develop lifestyle interventions that include culturally-tailored curriculum to help vulnerable populations with overweight or obesity achieve weight loss during times of extended crisis.

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