2017

Let Them Eat Beef: Effects of Beef Consumption on Markers of Metabolic Syndrome

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LET THEM EAT BEEF: EFFECTS OF BEEF CONSUMPTION ON MARKERS OF METABOLIC SYNDROME

BY

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A thesis submitted in partial fulfillment of the requirement for the

Master of Science

Major in Nutrition, Exercise, and Food Science

Specialization in Nutritional Sciences

South Dakota State University

2017

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This thesis is approved as a creditable and independent investigation by a candidate for the Master of Science in Nutrition, Exercise and Food Science degree and is acceptable for meeting the thesis requirements of this degree. Acceptance of this thesis does not imply that the conclusions reached by the candidate are necessarily the conclusions of the major department.

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ACKNOWLEDGEMENTS

I would like to express my sincere gratitude to South Dakota State University and the Department of Health and Nutritional Sciences for providing my with talented and dedicated faculty and a multitude of opportunities to succeed and grow. I have been a Jackrabbit for 6 ½ years, receiving a degree in Dietetics in 2014, and now a Masters in Nutrition, Exercise, and Food Science. I have been fortunate to be part of numerous projects and experiences and cannot put into words how grateful I am. A huge thank you to my parents, Judy and Denny Olson for their unconditional love, support and unending encouragement in all of my endeavors. Thank you to my brother and sister-in-law, Darin and Marisa Olson for their love, support and encouragement. A special thank you to my grandma AnnaMarie Main for being an incredible inspiration and for instilling in me a love of cooking and life-long learning. To my committee, Dr. Jessica Meendering, Dr. Lacey McCormack, and Dr. Melissa Hauschild-Mork, I am ever so grateful for your guidance, suggestions, and all of the time you took out of your busy schedules to help me with my thesis. Thank you, Dr. Meendering, for finding gentle ways to nudge me out of my comfort zone. An extra special thank you to Mary Gengler for allowing me to be part of your Food Principles life and getting me started on my journey of teaching others to cook and feel more comfortable in the kitchen. Without that first step, I would not be here today and I will be forever in your debt. Thank you to my graduate school classmates, especially Chase Merfeld for cheering me on and never letting me quit. A special thank you to Dr. Kendra Kattelmann. You have given me so many incredible opportunities and endless support and guidance during my two years as your graduate research assistant. I will always appreciate your wisdom, insights, patience and positivity.

TABLE OF CONTENTS

ABBREVIATIONS

MetS	Metabolic Syndrome
T2DM	Type 2 Diabetes Mellitus
CVD	Cardiovascular Disease
HDL-C	High Density Lipoprotein Cholesterol
LDL-C	Low Density Lipoprotein Cholesterol
TC	Total Cholesterol
BW	Body Weight
CRP	C-Reactive Protein
DASH	Dietary Approach to Stop Hypertension
BOLD	Beef in Optimal Lean Diet
RDN	Registered Dietitian Nutritionist
TG	Triglycerides
ANOVA	Analysis of Variance
LRM	Lean Red Meat
LWM	Lean White Meat
PREDIMED	Prevención con Dieta Mediterránea
MNT	Medical Nutrition Therapy
UC	Usual Care
DRS	Diabetes Risk Score.

LIST OF FIGURES

LIST OF TABLES

ABSTRACT

LET THEM EAT BEEF: EFFECTS OF LEAN BEEF CONSUMPTION ON MARKERS OF METABOLIC SYNDROME

KRISTIN L. OLSON

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To determine the effects of a diet that provides 30% energy from protein with ½ as lean, red meat on risk factors of metabolic syndrome in humans. This pilot study was a 3-month, randomized, control, intervention trial with 33 participants (Beef-Intervention n=18; DASH-Control n=15) who displayed markers of metabolic syndrome. Registered Dietitians Nutritionists recruited and educated participants on Beef-Intervention Lean Beef Pattern, (30% of energy from protein with ½ as lean red meat, 40% carbohydrate, 30% fat) or DASH-Control dietary pattern, (15% of energy from protein, 55% carbohydrate and 30 % fat). Of the 33 participants who completed the study; 21 were female and 12 male. Bodyweight (BW), fasting serum lipoproteins [total cholesterol (TC), LDL-cholesterol (LDL-C), HDL-cholesterol (HDL-C), and triglycerides (TG)], hemoglobin A1C (HbA1C), dietary satisfaction, and general health status were assessed at baseline and post intervention**.** A three-day diet journal was collected to assess for calorie and macronutrient intake at baseline and post intervention. Repeated measures ANOVA was used to determine group differences from baseline to post-intervention. Variables were checked for normality and non-normal variables were transformed prior to analysis. Statistical significance was set at $p \leq 0.05$.

There were no significant changes in total cholesterol, LDL-C, and HDL-C. There was a significant time x group effect for TG (baseline to post; Beef-Intervention 207±88mg/dL

to 148±53; DASH-Control, 200±88 to 193±96.) Both groups had decreased BW and HbA1c from baseline to post. Both groups reported a higher level of current dietary satisfaction, a higher level of general health, increased walking minutes & total increases in physical activity minutes. Lipid parameters, BW, and HbA1C of participants with metabolic syndrome randomized to the Beef-Intervention promoting 30% energy from protein with ½ as lean, red meat had outcomes that were similar or improved to those randomized to DASH-Control diet. The implication is, although larger studies in greater numbers still need to be done, that the inclusion of LRM in calorie-reduced diets may be used short term as an alternative to the DASH diet for those with MetS for weight and TG reduction.

Chapter 1
Introduction

Metabolic syndrome (MetS), formerly known as Syndrome X or insulin resistance syndrome, is the name for a collection of risk factors that increase the likelihood for one to develop atherosclerotic heart disease and type 2 diabetes (T2DM). Although there are differing specific definitions of MetS, most researchers agree that the primary symptom is central obesity plus two or more additional risk factors that include: elevated triglyceride (TG) levels (≥150mg/dl), low high-density lipoprotein (HDL) cholesterol (<40mg/dl in men, <50mg/dl in women), high blood pressure (systolic blood pressure ≥130mmHg or diastolic blood pressure ≥85mg), and elevated fasting blood glucose (≥100mg/dl).[1-4] According to the National Health and Nutrition Examination Survey (NHANES), 2003-06, the number of adults that could be considered as having MetS was about 34.4% of total population. Obese males are more likely to experience MetS as compared to normal weight males, while obese women are just as likely to be diagnosed with MetS as obese males.[5]

Although there are many factors that fall into the metabolic, genetic and environmental categories that may determine whether one has metabolic syndrome, researchers have identified the two most important factors of influence: obesity and physical inactivity.[6] The primary risk factors that can lead to a diagnosis of metabolic syndrome are cardiovascular disease (CVD) and T2DM. Studies have shown those with metabolic syndrome experienced a significantly higher risk of cardiovascular events and death.[4] Secondary risk factors of metabolic syndrome include an increase in inflammatory markers in the body such as higher levels of C-reactive protein (CRP),

cytokine TNF-α, and chemokine IL-8.[5] Other risk factors include insulin resistance and atherogenic dyslipidemia, and an aggregation of lipoprotein abnormalities.[7,8]

Statement of the Problem

Obesity in the adult population has risen dramatically in the past five years, and the Centers for Disease Control and Prevention (CDC) estimated that approximately 1/3 of the United States adult population, nearly 72 million adults, are classified as obese, and that number is expected to continue to increase over the next decade or more.[2,5] These higher rates of obesity have been associated with greater rates of T2DM and CVD, which in turn have led to increased rates of MetS.[2,9] There are many factors that fall into the metabolic, genetic and environmental categories that may influence whether one has MetS, researchers have identified the two most important factors of influence: obesity and physical inactivity. [10,11]

Dietary modifications are one of the primary recommended therapies for MetS. There is general agreement that weight loss is the most effective tool in controlling symptoms of MetS and dietary modification is one of the best tools available.[6,7] Though there are many different types of interventions available, there has not been a general consensus as to which is the best choice. One intervention is the DASH (Dietary Approaches to Stop Hypertension) regimen, which is composed of fruits, vegetables, low-fat dairy products, and decreased consumption of saturated fat, total fat and cholesterol. This approach also includes increased whole grains and decreased refined products, red meat, and sweet items. For weight loss, the daily caloric aim of the DASH diet was generally 500 kilocalories less than needed according to the participant's Basal Metabolic Rate.[3] A second dietary approach includes a Mediterranean-type diet with

daily consumption of fruits, vegetables, whole grains, nuts, and the inclusion of olive oil instead of canola or vegetable oil. The Mediterranean-type diet provides 50% CHO, 20% PRO, and 30% fat of total daily energy needs.[12] Other dietary recommendations include reduced consumption of fats and carbohydrates.[13] These types of diets have often led to positive changes in lab values and cholesterol concentrations of those dieters, but are often times difficult to maintain in the long-term. An alternate dietary approach, the Beef in and Optimal Lean Diet (BOLD) embraces similar recommendations with the inclusion of fruits, vegetables, and whole grains as in other diets, but also allows the consumption of lean beef, in addition to other protein choices. The Adult Treatment Panel (ATP) III Guidelines and the Dietary Guidelines for Americans (DGA) noted that lean beef could be included in one's diet. The effects of a low-fat diet that includes lean beef have not been extensively evaluated and numerous studies have been conducted that looked at the effects of a DASH-type diet with the inclusion of lean beef. The BOLD approach features a macronutrient breakdown of 54% CHO, 19% PRO, and 28% total fat based on daily caloric needs. The 19% of protein recommendation includes an estimated 4 ounces (113gram) of lean beef per day.[14]

The purpose of this pilot study was to determine the effects of a dietary education intervention providing 30% energy from protein with ½ as lean, red meat on risk factors of MetS in humans. We hypothesize that those randomized to the Beef diet will show similar outcomes on serum lipid levels as those following the DASH diet.

Significance of Study

Little has been published on the benefits of a diet that includes an increased amount of protein from high quality lean beef, moderate carbohydrate consumption and moderately low-fat fat intake on the indices of metabolic syndrome in humans. It is expected that the diet that focuses on a higher percentage of protein from lean beef will control the symptoms of metabolic syndrome at least as well or better than the current DASH or Mediterranean dietary recommendations. The long-term benefit of this study will assist in defining that lean beef can be an important part of medical nutrition therapy guidelines for those who experience metabolic syndrome.

Variables

Independent variables:[13-15]

1. Intervention diet group: randomized assignment to high quality protein, moderate carbohydrate (HPMC) diet
2. Control diet group: randomized assignment to normal protein, normal carbohydrate diet following DASH guidelines

Dependent variables:[1,4]

1. Lipid levels
2. Bodyweight
3. Body mass index (BMI)

Limitations and Delimitations

Limitations:

1. Limited sample size
2. Prescribed diet compliance

These factors were addressed by obtaining a reliable and valid questionnaire that has been proven effective in testing meal consumption as well as physical activity in adults.

Delimitations:

Delimitations included the age group of those 18-65 years of age and those that resided in the Sioux Falls and Watertown, South Dakota areas, as well the use of credentialed Registered Dietitian Nutritionists (RDNs) to deliver dietary intervention education. The delimitations were addressed by randomization of the population sample. Participants were able to self-refer if they felt they were eligible for participation and the RDNs screened each participant to ensure full eligibility.

Assumptions

1. Accurate reporting of the type and quantity of foods recorded in the 3-day diet journal used for analysis.
2. It was also assumed that all participants would complete the 12-week study.

Definition of Terms

1. *Adult Obesity*: Having an excess amount of body fat and BMI above 30, which can interfere with daily living activities and/or increase the risk of disease and/or death.[7,14]
2. *Total Cholesterol (TC)*: Total cholesterol includes high-density lipoproteins (HDL), low-density lipoproteins (LDL).[1,5]
3. *Obesity-induced inflammation*: Higher levels of body fat, specifically that located in the abdominal area, is thought to lead to higher levels of C-reactive protein (CRP), cytokine TNF-α, and chemokine IL-8.[16]

4. *Body Mass Index (BMI):* One of the most accepted methods of population assessment of overweight and obesity.

Research Hypothesis

H1: It is hypothesized that those with MetS following the Beef-Intervention dietary pattern, which features the inclusion of lean red meat at ½ of 30% protein daily kilocalories will have better control of serum lipid levels than those on DASH-Control dietary intervention.

H2: Those randomized to the Beef-Intervention dietary pattern will have greater adherence to dietary recommendations than the DASH-Control group.

Chapter 2

Review of Literature

Obesity Trends and Consequences

Obesity is defined as having a disproportionately high amount of adipose tissue relative to lean tissue. If an adult has a BMI measurement of 30 or higher, they are considered obese. These higher rates of obesity have been associated with greater rates of T2DM and CVD, which in turn have led to increased rates of MetS, and related disorders.[17] This literature review will cover the definition of metabolic syndrome, trends in obesity and MetS diagnosis, contributing factors of MetS as well as possible intervention therapies.

As of 2013-14, the CDC estimated that roughly 70% of U.S. adults 20 years or older were overweight or obese.[18,19] Healthcare costs as it relates to obesity in the United States topped $147 billion in 2008, with average medical costs for obese persons an estimated $1400.00 higher when compared to those of normal weight.[20] If these trends continue to grow, it is estimated that 44% of the adult population in the United States will be obese and the number of newly diagnosed cases of T2DM, coronary artery disease, and hypertension is likely to increase exponentially.[21]

Figures 1 and 2 demonstrate the increase in the rates of obesity in the U.S. adult population from 1986 to 2014, while Figure 3 demonstrates the increasing incidence of MetS and related conditions. Aguilar and colleagues[22] conducted a review of 2003-2012 NHANES data to determine the current rate of MetS in the United States. It was found that the overall prevalence was approximately 33%, with the highest occurrence among women compared to men. This is in comparison to 1999-2006 NHANES data that

reported 34% of U.S. adults were diagnosed with MetS. Figure 3 demonstrates a visual breakdown by age and gender of the increasing incidence of metabolic syndrome in the United States among adults.

There are many factors that fall into the metabolic, genetic, and environmental categories that may influence whether one has MetS and researchers have identified the two most important factors of influence: obesity and physical inactivity.[10,11] Researchers noted that excess adipose tissue that occurs around the abdominal area and visceral fat may lead to a chronic, pro-inflammatory state that is synonymous with insulin resistance, both of which are considered risk factors for MetS and associated CVD and T2DM.[8,23-25] MetS is associated with an at least four-fold increased risk of T2DM and a two-times risk of CVD and is now considered a worldwide epidemic as it has inflicted a high socioeconomic cost.[26]

Metabolic Syndrome Background

Defining Metabolic Syndrome

MetS is thought to be a collection of risk factors that increase the likelihood for development of atherosclerotic heart disease and T2DM. In spite of divergent definitions of MetS, most researchers agree that the primary symptom is central obesity plus two or more additional risk factors that include: elevated triglyceride levels (≥150mg/dl), low high-density lipoprotein (HDL) cholesterol (<40mg/dl in men, <50mg/dl in women), high blood pressure (systolic blood pressure ≥130mmHg or diastolic blood pressure ≥85mg), and elevated fasting blood glucose (≥100mg/dl).[1-4] According to the NHANES 2003-06, the number of adults that could be considered as having MetS was about 34.4% of total

population. Obese males are 32 times more likely to experience MetS as compared to normal weight males, while obese women are 17 times more likely to be diagnosed with MetS compared to normal weight females.[5] The specific causes of MetS remain undecided, but it is thought to be a combination between hereditary, metabolic, and environmental factors. However, the greatest risk factor for the development of metabolic syndrome is being overweight or obese.[7]

The most common avenue of MetS intervention has been through weight loss and dietary modification, though a specific type of dietary modification has not been universally agreed upon. The dietary intervention listed in the Nutrition Care Manual, the evidence-based manual for therapeutic diets published by the Academy of Nutrition and Dietetics, for MetS is the DASH regimen. The DASH dietary pattern is composed of fruits, vegetables, low-fat dairy products, decreased consumption of saturated fat, total fat, and cholesterol. This approach also includes increased amounts of whole grains and decreased amounts of refined products, red meat, and sweet items.[27,29] Health professionals also agreed that dietary pattern recommendations such as the National Cholesterol Education Program (NCEP) Step I, which includes moderate fat intake (25-35% of total daily energy), higher intakes of fruits, vegetables, and whole grains may have a positive effect on the markers of MetS.[6,27] In addition, both very low carbohydrate ketogenic diets and low-fat diets have been shown to decrease markers of an inflammatory response in overweight men and women, but the response was greater in the very low carbohydrate ketogenic diets than the low-fat diet.[5] Little has been reported on the intake of dietary protein and the effects on inflammation.

As a result, there is an excess of literature focusing on the efficacy of very-low carbohydrate, low fat, DASH, and Mediterranean dietary patterns as an avenue for weight loss, treatment of insulin resistance, and control of other symptoms associated with metabolic syndrome. However, research into the incidence of MetS and how a dietary pattern, that includes lean red meat, will affect the markers of MetS has not been extensively examined.

Dietary guidelines for adults (DGA) 2015

The United States Departments of Agriculture and Health and Human Sciences publish general dietary recommendations for adults every five years in the Dietary Guidelines for Americans. The 2015-2020 edition recommends that for those consuming a 2,000 kcal/day dietary pattern, include about 2 ½ cups of vegetables, this includes legumes, per day and 2 cups of fruit per day. Recommendations also include about 5 ½ oz. protein, and 6 oz. grains per day. Limitations on sweetened foods and beverages are also encouraged.[30]

Dietary Approaches to Stop Hypertension (DASH)

The DASH dietary pattern is most often recommended and prescribed to those experiencing MetS. The DASH diet is high in complex carbohydrates, vegetables, and fruits and incorporates low-fat dairy products. DASH also includes lean protein choices such as chicken, fish, and nuts, as well as recommending reduced consumption of red meat and desserts. Studies, such as the DASH study[31] have been conducted using the DASH dietary approach resulting in lowering of blood pressure, weight loss, and reduction of some Metabolic syndrome risk factors. Azadbakht and colleagues[32] conducted a randomized controlled outpatient trial on 116 patients with metabolic

syndrome. Participants were randomized to one of three dietary patterns for six months: a control diet in which participants were instructed to consume approximately 50% CHO; 15% PRO, and less than 30% total fat; a weight-reducing diet, which was similar to the control diet but with 500 kcal/day less than daily needs; or a DASH dietary pattern that consisted of 500kcal/day less than daily caloric needs and followed the daily DASH food group recommendations. At the end of the study period, there were significant reductions in waist circumference and TG among those that were randomized to the weight reduction dietary pattern. However, those randomized to the DASH dietary pattern demonstrated higher HDL-C concentrations, lower TG, decreased body weight (BW) measurements at the end of the study period, and the incidence of MetS decreased significantly in the those following the DASH dietary pattern as compared to the other two groups.

Mediterranean Diet

A Mediterranean-style diet typically consists of larger amounts of grains, fruits and vegetables, nuts and legumes. Fat sources such olive oil, that contains higher levels of mono and polyunsaturated fats (MUFAs, PUFAs) are a hallmark of the Mediterranean-based diet. Meals are often prepared in a simple manner and often contain fresh or dried herbs for seasoning. A Mediterranean approach includes additional servings of fish and other seafood and much lower amounts of red meat and dairy products than the DASH dietary pattern. Mediterranean dietary pattern macronutrient breakdown consists of 50-60% CHO, 15-20% PRO, and 30% total fat with an emphasis on olive oil.[33]

Multiple studies have been conducted utilizing a Mediterranean-style diet as an intervention method for metabolic syndrome. A SUN prospective[34] cohort study

conducted in Spain and published in 2007 showed that as participants continued to adhere to the prescribed Mediterranean dietary pattern, they experienced marked improvement on markers of MetS. Participant's measurements of waist circumference, HDL-C, TG, systolic, and diastolic blood pressure showed improved Mediterranean Food Pattern scores over the course of the follow-up period of six years. Results showed that those participants that demonstrated a higher level of baseline observance displayed lower levels of all risk factors. Kastorini and colleagues[12] conducted a meta-analysis of the effects of a Mediterranean diet on MetS and found that this dietary pattern could be easily adopted by many population groups, and was highly effective on the markers of MetS. Improved serum lipid concentrations and lower waist circumference measurements were reported in the majority of studies analyzed.

Carbohydrate Restricted Diet versus Low-Fat Diet

Diets that are lower in carbohydrates or carbohydrate restricted are often prescribed to treat the markers of metabolic syndrome. Hu and colleagues[35] conducted a systematic review and meta-analysis comparing the effects of a low-fat diet to a low-carbohydrate diet on the effects of metabolic risk factors. Twenty-three trials from numerous countries, totaling 2,788 participants were screened to ensure eligibility. The analysis found that both dietary approaches lowered BW and showed improvement in overall lipid profiles. The low-carbohydrate method resulted in lower total cholesterol with a 4.6mg/dL reduction, a decrease in LDL levels at 2.1mg/dL and triglyceride levels decreased an average of 30.4mg/dL while HDL levels increased an average of 4.5gm/dL. Those that consumed a low-fat diet showed similar, but not statistically significant results. Reductions were noted in BW, waist circumference, and other markers of MetS

for those following a low-carb dietary pattern. The findings suggested that low-carbohydrate and low-fat diets were similarly effective in improving metabolic syndrome markers.

The Inclusion of Lean Red or White Meat and Physiological Outcomes

There are few studies that have looked exclusively at the inclusion of lean red meat on symptoms of MetS. Studies that were found that included lean red meat (LRM) or lean white meat (LWM) generally focused on cholesterol concentrations, hypertension or T2DM.

One such study, the BOLD study incorporated fruit and vegetables, whole grains, seeds and nuts, as well as legumes into a diet based on NCEP Step I recommendations The BOLD study also recommended moderate amounts of lean red meat. The ATP III Guidelines and the Dietary Guidelines for Americans noted that lean beef could be included in one's diet. This addition of red meat is recommended when the diet is already low in saturated fatty acids and cholesterol.[14] Although this dietary pattern has not been vigorously analyzed it may become an effective tool to lower one's cholesterol and subsequent metabolic syndrome symptoms.

Roussell and colleagues[14] conducted the study that compared four dietary approaches: Intervention dietary patterns - DASH, BOLD, BOLD+, and the control-healthy American diet (HAD). The macronutrient breakdown for each included: Intervention-DASH- 49% CHO, 27% total fat, 6% saturated fatty acids, and 18% PRO (includes 28g beef/day). Control-HAD-38% CHO, 33% total fat, 12% saturated fatty acids, and 17% PRO (20g beef/day). The Intervention-BOLD and BOLD+ plans both included 28% total fat and 6% saturated fatty acids. The Intervention-BOLD approach

recommended 19% PRO with 113g beef/day and 47% CHO, while the Intervention-BOLD+ plan included 27% PRO with 153g beef/day and 39% CHO. The 36 participants were assigned to their respective dietary interventions for a five-week period. Results revealed an overall total cholesterol and LDL concentration reduction of between 0.48 and 0.50 mmol/L ±0.10 for those randomized the one of the three intervention dietary patterns, while the HAD-control approach showed a much lower improvement of 0.22 mmol/L ±0.10. A greater decrease in apolipoprotein A-I, C-III and C-III bound to apolipoprotein A1 was noted in the BOLD and BOLD+ intervention when compared to HAD. Overall, it was shown through this study that a low-saturated fatty acid dietary design that includes lean beef can result in optimistic outcomes on lipid and lipoprotein risk factors that are comparable to the DASH approach.

In another study, Davidson and colleagues[36] conducted an education intervention study that compared the effects of LRM versus LWM in diets containing 15% of calories as protein on serum lipid levels of participants with hypercholesterolemia. Participants were randomized to a diet with 170g lean meat/day of either LRM or LWM, over 5-7 days/week. This amount of protein accounted for 80% of daily protein recommendations. Both groups had similar reductions in TC, LDL-C, HDL-C, and TG concentrations.

The Importance of Dietary Adherence

As with any successful dietary intervention, participant adherence to dietary instruction is essential to the success. This is often accomplished through the use of educational sessions with personalized nutrition counseling from nutrition professionals to teach participants the basics such as serving size, meal composition, menu planning, and cooking skills. Numerous studies have been conducted that allude to the

effectiveness of participant dietary pattern adherence when RDNs are involved with the study. Zazpe and colleagues[37] focused on dietary adherence in their study that utilized Mediterranean-type diets in conjunction with the Prevención con Dieta Mediterránea (PREDIMED) that was conducted in Spain. The study was a 12-month behavioral intervention that included approximately 1,500 participants who were randomized to one of three dietary patterns, which included: a control diet that was based on the NCEP Step I ATP III diet, a Mediterranean diet plus virgin olive oil, and a Mediterranean diet plus mixed nuts. Those randomized to both Mediterranean diets received motivational interviews from trained RDNs and participated in group educational classes every three months. Those randomized to the control group were given verbal instructions and a pamphlet with recommendations for their dietary guidelines, but no motivational interviews by RDN. Compliance was measured by biomarkers for specific foods. Those participants who received education intervention by trained RDNs had greater compliance.

In another study that utilized RDNs to educate participants, Parker and colleagues[38] reported that patients diagnosed with pre-diabetes displayed better clinical outcomes, specifically Hemoglobin A1c (HbA1c) and Diabetes Risk Score (DRS), than those that received Usual Care (UC) treatment which did not include education by the RDNs. Participants randomized to Medical Nutrition Therapy (MNT) treatment received 60 minutes of individualized education, a 24-hour diet recall, a pedometer and a diary to record their daily steps and minutes of physical activity (PA). Those randomized to UC were instructed to return after the 12-week period. The MNT group displayed a significant difference between groups at 12-weeks for DRS, in addition, to 95% of

participants reporting at least 30 minutes of PA compared to the UC group. Both groups displayed significant decreases in TC and LDL-C. The resulting higher level of dietary adherence as seen in the Mediterranean diet and MNT studies may have been due to the involvement of RDNs.

Chapter 3-Manuscript

Background

MetS is the name given for a collection of risk factors that increase the likelihood of developing atherosclerotic heart disease and T2DM. Although there are differing specific definitions of MetS, most researchers agree that the primary symptom is central obesity plus two or more additional risk factors that include: elevated triglyceride levels (≥150mg/dl), low HDL-C (<40mg/dl in men, <50mg/dl in women), high blood pressure (systolic blood pressure ≥130mmHg or diastolic blood pressure ≥85mg), and elevated fasting blood glucose (≥100mg/dl).[1-4] In the 2003-06 NHANES report, the number of adults that could be considered as having MetS was just over 34% of the total United States adult population. Obese males are 32 times more likely to experience MetS as compared to normal weight males, while obese women are 17 times more likely to be diagnosed with MetS compared to normal weight females.[5]

Introduction

Adult obesity has increased dramatically in the past five years, with the CDC's estimation that nearly 72 million adults are classified as obese, approximately 1/3 of the United States adult population. This estimation is expected to continue to increase over the next decade or more.[2,5] These higher rates of obesity have been associated with greater rates of T2DM and CVD, which in turn have led to increased rates of MetS.[2,9] There are many factors that fall into the metabolic, genetic, and environmental categories that may influence whether one has MetS; researchers have identified the two most important factors of influence: obesity and physical inactivity.[6] The excess adipose tissue that occurs around the abdominal area and visceral fat may lead to a chronic, pro-

inflammatory state that is synonymous with insulin resistance, which are both considered risk factors for MetS and associated CVD and T2DM.[1,2] MetS is associated with an at least four-fold increased risk of T2DM and a two-times risk of CVD.[25] MetS is now considered a worldwide epidemic as it has inflicted a high socioeconomic cost .[26]

There is limited evidence supporting specific dietary treatment for MetS. There is general agreement that weight loss is an effective tool in controlling symptoms of MetS and dietary modification is one of the primary recommendations to achieve weight loss.[1,3,27] The dietary intervention listed in the Nutrition Care Manual, the evidence-based manual for therapeutic diets published by the Academy of Nutrition and Dietetics, for MetS is the DASH regimen. The DASH dietary pattern is composed of fruits, vegetables, low-fat dairy products, decreased consumption of saturated fat, total fat, and cholesterol. This approach also includes increased amounts of whole grains and decreased amounts of refined products, red meat, and sweet items.[15,27,29]

An alternate dietary approach, the BOLD,[14] embraces similar recommendations for the inclusion of fruits, vegetables and whole grains as in other diets, but also recommends the consumption of lean beef, in addition to other protein choices. For those that are otherwise healthy, the DGA 2015 noted that lean beef could be included in one's diet. The effects of a low-fat diet that includes lean beef were evaluated in a feeding study, one of the few studies to evaluate the effects of beef on serum lipid levels. The BOLD approach featured a macronutrient breakdown of 54% CHO, 19% PRO (with an estimated 4 ounces of lean beef per day), and 28% total fat based on daily caloric needs for the BOLD arm and 45% CHO, 27% PRO (with an estimated 5 ounces of lean beef per

day, and 28% fat for the BOLD + arm. There is still a question about the inclusion of lean beef for people with MetS.

The purpose of this pilot study was to determine the effects of a dietary education intervention providing 30% energy from protein with ½ as lean, red meat on risk factors of MetS in humans. We hypothesized that those randomized to the Beef diet will show similar outcomes on serum lipid levels as those following the DASH diet.

Methods

Chapter 3 includes the detailed methodology and protocols used to complete the Beef study. The methodology chapter contains the following information: a) Study Design, b) Subjects, c) Assessments/Procedures, and e) Data Analysis.

Study Design

This was a 12-week, randomized, control, dietary education intervention with rolling enrollment. A total of 39 participants displaying markers of MetS were recruited for participation. Participants aged 18-65 years and in a rural State, were recruited by RDNs to participate through two area healthcare facilities and specialty clinics. Once qualification for the study was determined, assessments were conducted at baseline and post intervention (approximately 12 weeks from baseline).

Subjects

Participants were recruited by RDNs at two clinics (primary care and specialty) through referral from health care personnel and self-referral from informational study fliers posted in each location. Qualifications for participation in the study included the participant exhibiting central obesity (waist circumference > 35 inches in women, >40 inches in men) plus two or more additional risk factors including: elevated triglyceride

levels (≥150mg/dl), low high-density lipoprotein (HDL) cholesterol (<40mg/dl in men, <50mg/dl in women), high blood pressure (systolic blood pressure ≥130mmHg or diastolic blood pressure ≥85mg), and elevated fasting blood glucose (≥100mg/dl). Participants were randomly assigned to a group (Beef-Intervention or DASH-Control), stratified by location, by random number generator.

The costs of baseline and post-intervention study serum lipid measurements along with education meetings by the RDN were reimbursed by the study. Participants were also offered up to $100 ($25 for baseline labs, $25 upon completion of baseline dietary education, and $50 post dietary education) as gift cards from the local grocery store. Participant consent was obtained in accordance with the policy statements of Human Subjects Committee at South Dakota State University prior to enrollment.

Participants received three face-to-face education visits with the study-trained RDN. During their first face-to-face meeting, participants received education and instruction about their specific daily calorie target, as well as proper serving sizes for foods in the carbohydrate, protein, and fat groups. Participants also received information sheets that included which cuts of beef were considered lean versus those that contain higher amounts of fat and were encouraged by the RDNs to choose a leaner beef product over the fattier beef product. Those that were assigned to the Beef-Intervention group were instructed to follow a high-quality protein, moderate carbohydrate diet that provided 30% of energy from protein with ½ as lean, red meat, 40% carbohydrate and 30% fat. Those following the DASH-Control diet were instructed to follow a diet that provided 15% of energy from protein, 55% carbohydrate, and 30% fat. Participants received a second visit with the RDN at about week 7 of their participation period (about the

halfway point) to reinforce dietary pattern education. During their final visit, participants reviewed their final serum lipid values with the RDN. All participants were encouraged to include the minimum amount of 150 minutes/week of moderate activity. All education sessions included tenets of health coaching by RDN for dietary adherence. Participants were requested to set weekly goals and maintain dietary and physical activity logs to increase adherence to the prescribed interventions.

Assessments

The following measures were collected at baseline and post-intervention (12 weeks): height, weight, fasting serum lipoproteins (total cholesterol, LDL-cholesterol, HDL-cholesterol, and triglycerides), hemoglobin A1C (HbA1C), 3-day diet records, physical activity questionnaire, dietary satisfaction survey, current medications, and brief patient-reported medical history.

Anthropometric measures: Height was measured without shoes. Weight was recorded in light-weight clothing on clinical scales.

Serum lipoproteins and HgA1C: Total cholesterol, LDL-cholesterol, HDL-cholesterol, triglycerides, and HbA1C were collected via venous puncture and measurements analyzed by a CLIA-approved laboratory.

Dietary intake and adherence: All participants were instructed to record amount and type of food for 3 days at baseline and post-intervention. Diet records were analyzed for nutrient content using ESHA Food Processor SQL, (version 10.8.0, 2011, Salem, OR 97306). Dietary adherence as determined by comparing diet records with prescribed diet.

Dietary satisfaction: Dietary satisfaction was measured at baseline and post-intervention with one question “How would you describe your current satisfaction level with diet?” with Likert scale responses-a seven scale response that ranged from “terrible” to “delighted”. A higher score indicated greater satisfaction.

Medications and general health: Medication use was measured by the number of self-reported medications. Participants were queried about their general health with one question, "Would you say that in general your health is:" with six-point Likert scale responses that ranged from "excellent" to "not sure." A lower score indicated better-perceived general health of the participant.

Physical activity: The International Physical Activity Questionnaire (IPAQ) was used to assess amounts of physical activity (PA) at three intensity levels (vigorous PA, moderate PA, and walking). Physical activity minutes were converted to Metabolic Equivalents (METs or MET-minutes) per week to generate total walking, moderate activity, and vigorous activity scores.[39]

Analysis of Data

Power calculations were completed using G*Power 3 with the following assumptions[40]: power was set at 0.95, α was set at 0.05, 2-tailed tests, and effect size of 0.25. It was estimated that a sample size of 36 was sufficient. Repeated measures ANOVA (IBM SPSS Statistics, version 22.0, Armonk, New York) was used to determine group differences from baseline to post-intervention in dependent variables. Variables were assessed for normality, and logarithmic transformations were utilized for non-normally distributed variables (LDL,

HDL, Protein(g) from beef, MET minutes, and PA). Statistical significance was set at $p \leq 0.05$. Unless otherwise noted, data are presented as mean±standard deviation (SD).

Results

Subjects and Anthropometrics

Of the 39 recruited [Beef =18, 10 females; DASH=15, 11 females] Thirty-three participants completed the 12-week study period. Six were dropped from the study and data was not included in analysis. Three (Beef-Intervention = 1, DASH-Control = 1) withdrew due to illness or injury not related to this pilot study and three (Beef-Intervention = 4, DASH-Control =0) chose not to comply. At baseline, the sample was 63% female, 27% high school diploma, 73% with Associate's degree or higher, and 100% Caucasian (Table 1). Both groups demonstrated significant decreases in body weight and BMI over time.

Serum Lipoproteins and HgA1C

There were no significant changes in total cholesterol, LDL-C, and HDL-C between groups due to the intervention. There was a significant time x group effect for TG from baseline to post-intervention (Table 2).

Dietary Intake and Satisfaction

Both groups reported a higher level of current dietary satisfaction (Table 3). There were no significant differences in reported dietary intake between groups (Table 3). Mean intakes were within prescribed ranges. Participants randomized to Beef-Intervention dietary pattern displayed adherence (by analysis of dietary journals) to the inclusion of

30% protein with one-half as lean, red meat (not reported in tables).

General Health and Physical Activity

Both groups reported a higher level of general health, and walking minutes & increases in total physical activity over time (Table 4).

Discussion

Numerous studies have been conducted that measure the effects of inclusion of lean red meat (LRM), lean white meat (LWM), and fish or poultry in the diet on total cholesterol levels and occurrence of hypertension. However, there are few studies that have looked exclusively at the inclusion of lean red meat on symptoms of MetS as reported in this paper. Davidson and colleagues[36] conducted an education intervention study that compared the effects of LRM versus LWM in diets containing 15% of calories as protein on serum lipid levels of participants with hypercholesterolemia. Participants were randomized to a diet with 170g lean meat/day of either LRM or LWM, over 5-7 days/week. This amount of protein accounted for 80% of daily protein recommendations. Both groups had similar reductions in TC, LDL-C, HDL-C, and TG concentrations. Similarly, in the study reported in this paper, greater reductions in TG concentrations were observed in participants who were randomized to the Beef-Intervention pattern (30% of calories from protein with one-half from lean red meat) versus those randomized to the DASH-Control dietary pattern (15% of calories from lean meat).

The dietary patterns for the Beef study described in this paper were chosen to determine if consuming higher amounts of lean red meat affects serum lipids and body weight differently than a DASH dietary pattern. The results from the Beef study are

similar to those reported by Roussell and colleagues in their BOLD study[14] in that diets with lean red meat have similar outcomes to those of DASH Dietary pattern. The difference between the BOLD study and the Beef study reported in this paper is that the BOLD study recruited participants who were otherwise healthy, but displayed elevated LDL-C concentrations. Exclusionary criteria included T2DM, stroke, liver, kidney or autoimmune disease, as well as those that were currently prescribed cholesterol and lipid-lowering medications. While in the Beef study, participants displaying symptoms of MetS were recruited and allowed to continue with prescribed medications. The BOLD Study participants on the experimental diets of BOLD, BOLD+, or DASH dietary patterns displayed a reduction in TC and LDL-C with no differences between the groups. Comparatively, in the Beef study there were significant decreases in TG concentrations for those in the Beef-intervention group versus those in the DASH-control group, but no changes or differences between groups in TC and LDL-C. The differences in outcomes between the Roussell's BOLD study and the Beef study may be that those in our Beef study had markers of MetS, such as high TG concentrations.

Another positive outcome from this study was that both the Beef-Intervention and the DASH-Control participants lost weight and decreased BMI as expected based on the dietary prescriptions. All participants were provided dietary prescriptions within the respective macronutrient components with calorie restrictions approximately 500 less than calculated requirements. The significant weight loss from baseline to post-intervention was an indication of dietary adherence. Participant adherence to dietary instruction is essential to the success of a dietary intervention, and this is often accomplished through the use of educational sessions to teach participants fundamentals

such as serving size, meal composition, menu planning, and cooking skills. The Beef study utilized trained RDNs to provide dietary education to participants. This component may have supported a higher level of dietary adherence for both groups. Both groups received face-to-face dietary education from the RDN as well as written meal component instructions, along with a list of food item examples to refer to during the 12-week period. Those randomized to the Beef-Intervention also received a fact sheet identifying lean cuts of beef. Numerous studies have been conducted that allude to the effectiveness of participant dietary pattern adherence when RDNs are involved with the study. Zazpe and colleagues[37] focused on dietary adherence in their study that utilized Mediterranean-type diets in conjunction with the Prevención con Dieta Mediterránea (PREDIMED) that was conducted in Spain. The study was a 12-month behavioral intervention that included approximately 1,500 participants who were randomized to one of three dietary patterns, which included: a control diet that was based on the National Cholesterol Education Program (NCEP) Adult Treatment Panel (ATP) III Step I diet, a Mediterranean (Med) diet plus virgin olive oil, and a Mediterranean diet plus mixed nuts. Those randomized to both Mediterranean diets received motivational interviews from trained RDNs and participated in group educational classes every three months. Those randomized to the Control group were given verbal instructions and a pamphlet with recommendations for their dietary guidelines, but no motivational interviews by RDN. Compliance was measured by biomarkers for specific foods. Those participants who received education intervention by trained RDNs had greater compliance.

In another study that utilized RDNs to educate participants, Parker and colleagues[38] reported that patients diagnosed with pre-diabetes displayed better clinical

outcomes, specifically HbA1c and Diabetes Risk Score (DRS) than those that received Usual Care (UC) treatment which did not include education by the RDNs. Participants randomized to Medical Nutrition Therapy (MNT) treatment received 60 minutes of individualized education, a 24-hour diet recall, a pedometer, and a diary to record their daily steps and minutes of PA, while those randomized to UC were instructed to return after the 12-week period. The MNT group displayed a significant difference between groups at 12-weeks for DRS, in addition, to 95% of participants reporting at least 30 minutes of PA compared to the UC group. Both groups displayed significant decreases in TC and LDL-C. The resulting higher level of dietary adherence as seen in the Mediterranean diet and MNT studies due to the involvement of RDNs is similar to that of the Beef study which resulted in a high level of adherence in both groups, as evidenced by the significant decreases in BW and TG. In addition, participants in the Beef study reported a higher level of diet satisfaction as well as general health at the end of the study period, when compared to baseline responses.

There are limitations to the generalization of the results from the Beef study. This was a 12-week intervention period, which allowed changes in serum lipids and weight loss; however, longer trials are necessary to determine long-term adherence and outcomes. Even though the trial was conducted with the use of trained registered dietitians to deliver the education, this trial was conducted with free-living participants and dietary data was collected through self-report versus housing in a metabolic ward and/or providing the meals in a clinical institution. Although the participants were randomized to intervention or control, the recruitment occurred through convenience sampling. The participants recruited may have been more interested in changing dietary

behavior as they were recruited through health care providers and posters in respective clinics.

Conclusion

Based on the results of this pilot study, it appears that calorie reduction diets that include 30% protein with one-half as LRM have outcomes similar to the DASH dietary pattern in those with MetS. The implication is, although larger studies in greater numbers still need to be done, that the inclusion of LRM in calorie-reduced diets may be used short term as an alternative to the DASH diet for those with MetS for weight and TG reduction.

FIGURES

Figure 1: The increasing prevalence of obesity in the United States adult population.

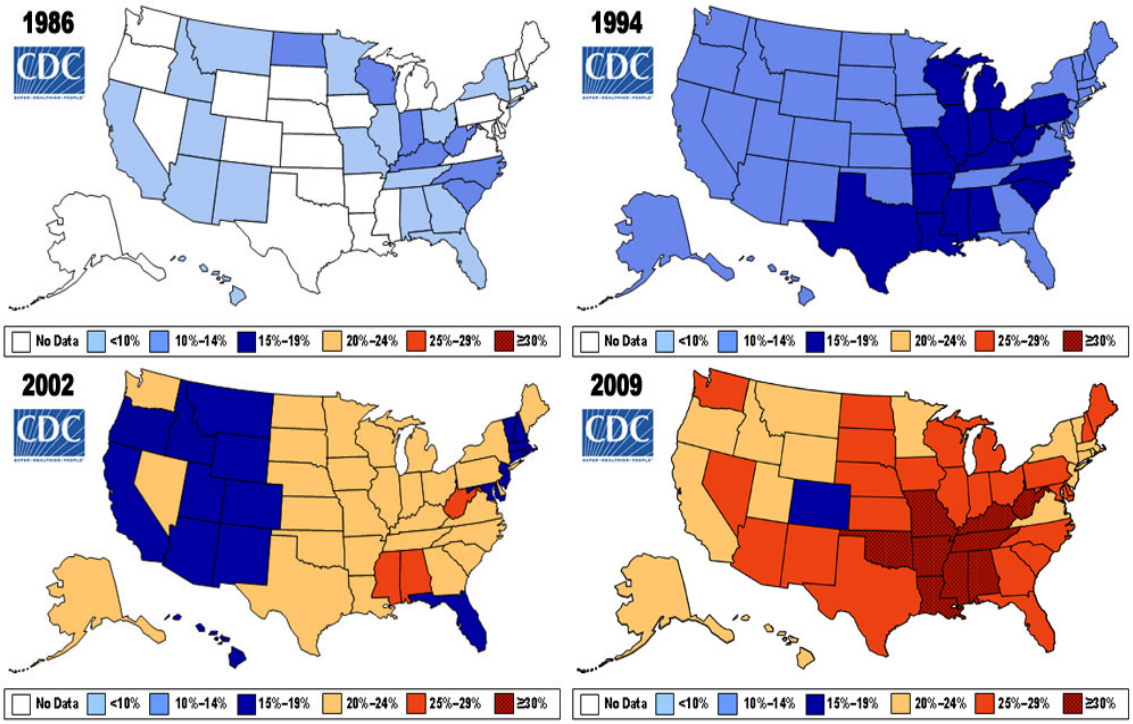


Figure 1: The increasing prevalence of obesity in the United States among the adult population from 1986 to 2009. https://publichealthwatch.files.wordpress.com/2013/07/cdc_obesity.png

Figure 2: The prevalence of obesity in the United States adult population 2014.

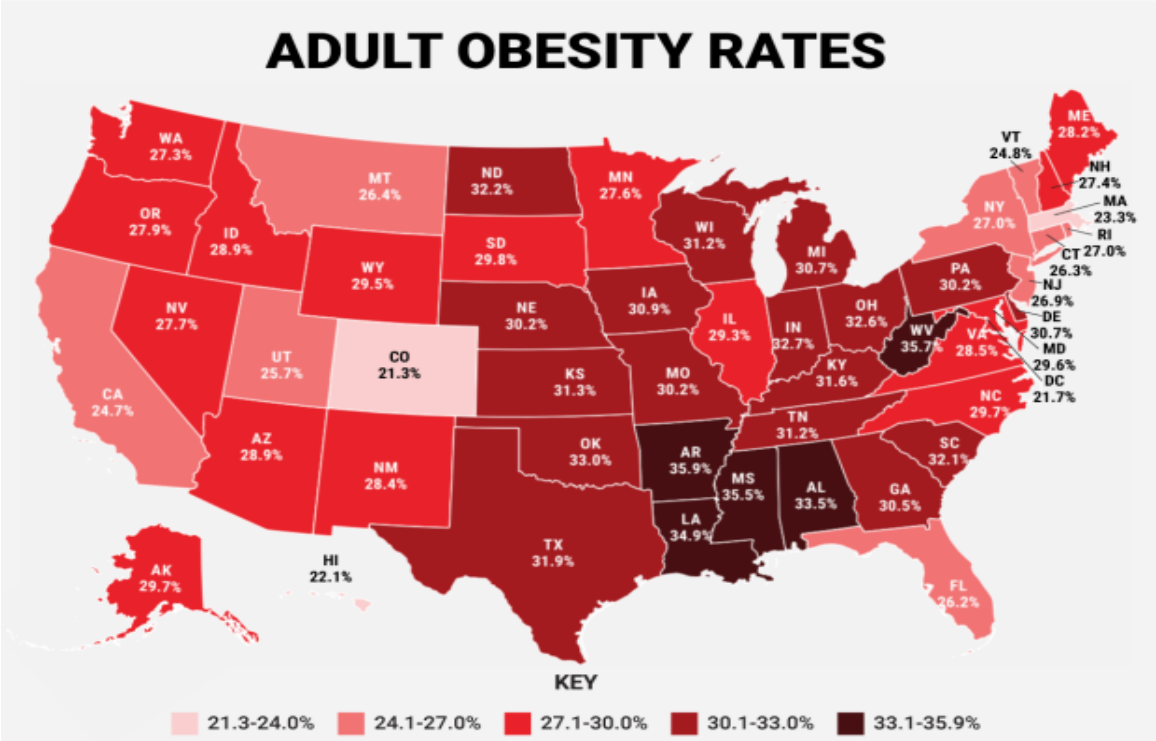


Figure 2: The prevalence of obesity in the United States among the adult population as of 2014.
http://www.businessinsider.com

Figure 3: Prevalence of Metabolic Syndrome in the United States adult population.

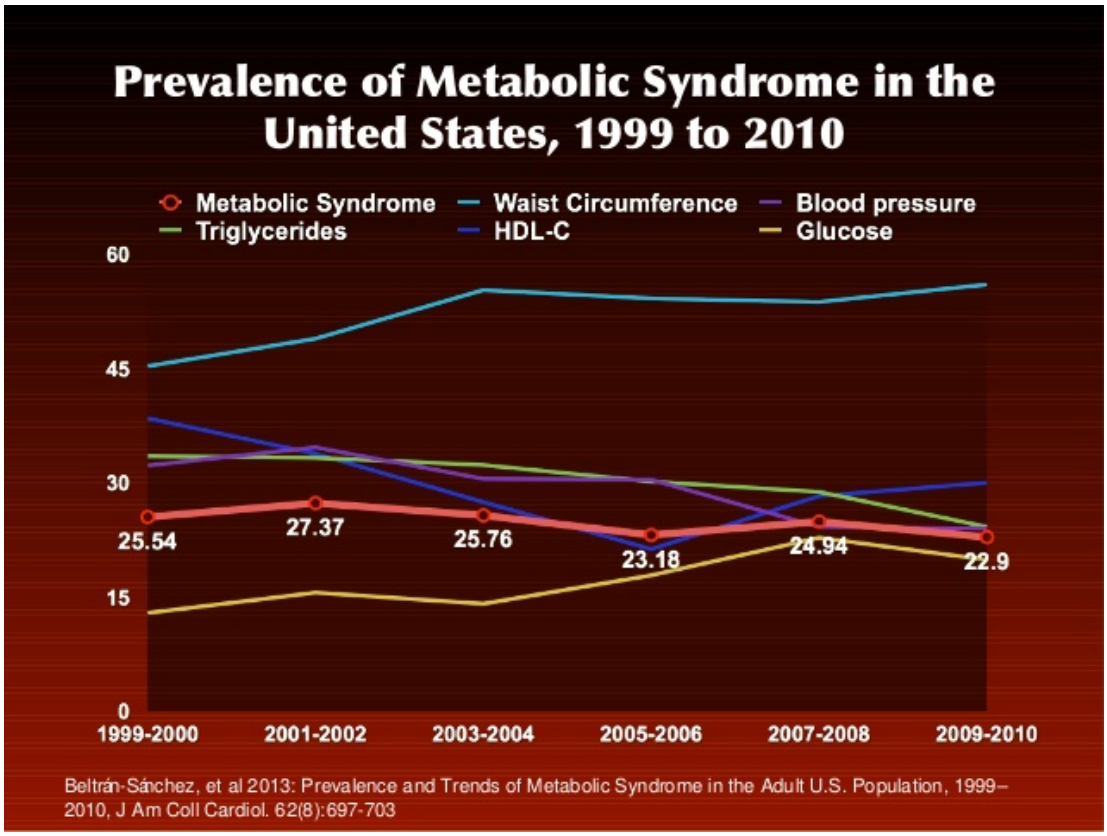
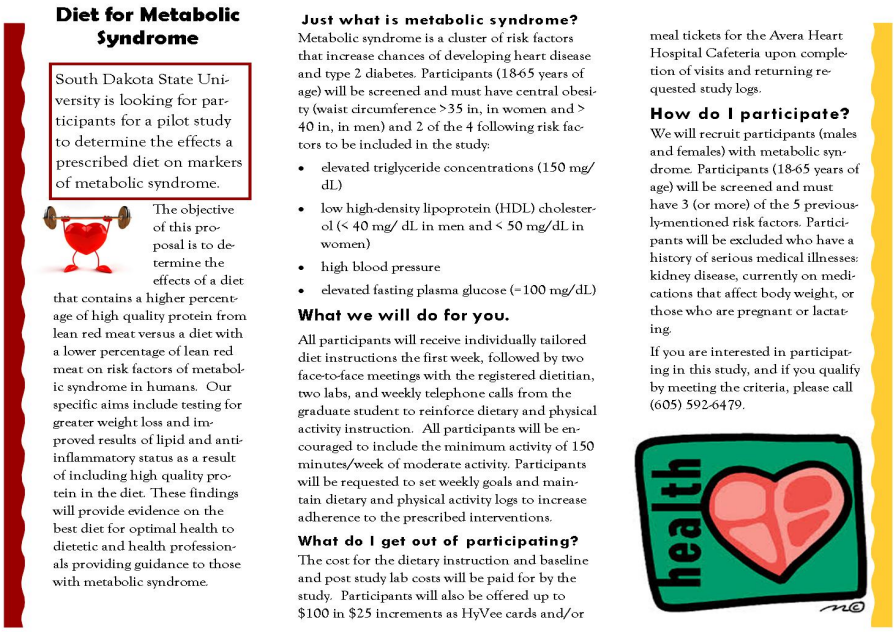


Figure 3: The prevalence percent of metabolic syndrome and corresponding markers of MetS among US adults.

APPENDICES

Appendix A: Participant Recruitment Brochure and Consent Form

- *Participant Recruitment Brochure*



- *Participant Consent Form*

Participant Consent Form

(Sign & Return to Study personnel)
Participation in a Research Project

South Dakota State University

Brookings, SD 57007

Department: Health and Nutritional Sciences
Project Director: Kendra Kattelmann
Phone No. 605-688-4045

Date: April 11, 2014
Research Assistant: Kristin Olson
Phone No. 605-515-0717
kristin.olson@sdstate.edu

Please read (listen to) the following information:

1. This is an invitation for you to participate in a research project under the direction of Health and Nutritional Sciences Department.

2. The project is entitled: The Effects of High Quality Protein on Markers of Metabolic Syndrome.

3. The purpose of the project is to determine the effects of your prescribed diet on markers of metabolic syndrome in humans.

4. If you consent to participate, you will be involved in the following process, which will take place over 3 months.

a. You will receive individually tailored diet instructions the first week followed by two face-to-face meetings. You will have appointments with the dietitian; they may measure weight, height and blood pressure at your first and last meeting.

b. You will be encouraged to follow what your physician has instructed for physical activity.

c. You will be requested to follow what your dietitian has instructed for nutrition instructions.

5. Sequence of events:

First: If you are interested in participating, sign consent form (this form) and return to dietitian. Provide a telephone number or email address to allow Kristin Olson, SDSU research graduate student to conduct a telephone interview for base-line and exit survey information.

Phone #:_____ Email: _____

Best time to contact: _____

This telephone interview will be conducted by Kristin Olson, research graduate assistant at South Dakota State University. This call should take approximately 20 minutes or less and questions will be about your diet and physical activity habits.

Second: Make an appointment with the dietitian. To schedule call Avera Heart Hospital (605)-977-7340.

Third: You will need to go to Any Lab Test Now at the beginning and about the 10th week of the study for laboratory tests. Let them know that you are with the Beef and Metabolic Syndrome Diet Study. The directions are:

Sioux Falls site:	Brookings site:
6701 South Louise Ave	3405 6th Street
Sioux Falls, SD 57108	Brookings, SD 57006
Phone: (605) 271-5757	Phone: (605) 693-3216

Fourth: Make sure you have your initial labs, have completed your telephone interview with Kristin Olson, and keep your first appointment with the dietitian to receive your first $25 gift card. The dietitian will provide you with the gift card upon completion of the first dietary appointment.

Fifth: Schedule and keep your second appointment with the dietitian. This appointment should occur at about the 4 to 6 week period. The dietitian will provide you your second $25 gift card.

Sixth: Schedule your final appointment with the dietitian. This appointment should occur at about the 10-12 week mark. **Before your last** visit with the registered dietitian you also need to complete your final set of laboratory tests at Any Lab Test Now. Please go to Any Lab Test Now to have these done. You will also complete the final telephone interview (exit surveys) with Kristin Olson. Kristin Olson will call you about 10 weeks from signing the consent form.

Last: When you have completed your final labs, your exit survey with Kristin Olson, and your final visit with the dietitian, you will receive your final $50 gift card from the dietitian.

6. Participation in this project is voluntary. You have the right to withdraw at any time without penalty. If you have any questions, you may contact the project director at the number listed above.

7. Some risks from this study may be bruising after needle pokes and slight risk for infection after blood draws. Also, blood lipid values may not improve from baseline of

study. To reduce risks CLIA-approved laboratory will be used to collect blood. A licensed health care professional and registered dietitian will be used. If blood lipid levels have not improved from baseline of study we will refer you back to your physician. Your physician visits are at your own expense.

8. Benefits to this study will include participants receiving helpful dietary counseling from a registered dietitian. HyVee grocery cards or coupons for meals at Avera Heart Hospital will be given at completion of following steps. The first $25 gift card will be given to you by the registered dietitian upon completion of the first laboratory tests from Any Lab Test Now, the telephone interview from Kristin Olson and the dietary instruction from the registered dietitian. The second $25 gift card will be provided by the registered dietitian after the completion of the second visit with the dietitian, about the 4th week. The final $50 dollar gift card will be given to you by the registered dietitian upon completion of the final labs, final telephone survey from Kristin Olson, and your final visit with the dietitian. Copies of initial and final labs will be sent to you by Kristin Olson. If you have not received, please call Kristin at 605-592-6479.

9. The compensation is limited to the gift cards as explained above. The cost for the dietary instruction and baseline and post study lab costs will be paid for by the study. Dietary instruction costs for metabolic syndrome are not normally reimbursed by medical insurance. There will be no reimbursement for travel, fees associated with physicians, and parking.

10. Your responses are strictly confidential. When the data and analysis are presented, you will not be linked to the data by your name, title or any other identifying item.

As a research participant, I have read the above, have had any questions answered, and agree to participate in the research project. I will receive a copy of this form for my information.

Participant's Signature _____ Date _____

Participant's Printed Name_____

Participant's Phone Number (and best time to contact)_____

Project Director's Signature _____ Date _____

If you have any questions regarding this study you may contact the Project Director. If you have questions regarding your rights as a participant, you can contact the SDSU Research Compliance Coordinator at (605) 688-6975 or SDSU.IRB@sdstate.edu. This project has been approved by the SDSU Institutional Review Board, Approval No.: _____

Please select type of participant stipend:
HyVee Gift Card _____
or
Avera Heart Hospital Meal Coupons _____

Appendix B: Information Collected from Participants

- *3-Day Diet Record*

3 DAY DIET RECORD

The 3-day diet record needs to be completed on three consecutive days including one weekend day

On each day you keep the record, write down the date and the day of the week in the spaces at the top of the page. Then fill out the food record section as follows.

- Column 1: Write down the time you eat.
- Column 2: Write down the amount of food eaten. Amounts should be listed in cups,
- tablespoons, teaspoons or ounces. Measuring the food is best, but if that is not feasible,
- suggestions for serving sizes are provided below.
- Column 3: Write down the name of the food eaten; be sure to include brand names
- when known.
  Remember to include any "little extras" such as sugar, margarine, mayonnaise.
- Column 4: For food that are mixed or cooked, describe the preparation. Space for recipes
- is available on the last page. For these foods simply write "see recipe" in column 4.
- At the bottom of each record page, indicate whether your appetite was typical, more
- than usual, or less than usual. Also, list any vitamin-mineral supplements taken.
- **REMEMBER:**

Measuring food is always best, but if that is not possible listed are some visual guidelines to e
stimate portion sizes.

1. A 3 oz. Piece of cooked meat is about the size and thickness of a deck of playing cards.
2. A medium piece of fruit is about the size of a tennis ball.
3. One ounce of cheese is about the size of 4 stacked dice.
4. ½ cup of ice cream is about the size of a racquetball or tennis ball.
5. 1 cup of mashed potatoes or broccoli is about the size of an adult fist.
6. 1 teaspoon of butter, margarine, mayonnaise, or peanut butter is about the size of the
7. tip of your thumb, measured from the tip of the bottom of your thumbnail.
8.

FOOD RECORD EXAMPLE

Date: July 31, 2000 Day of the week: Friday

Time	**Amount**	**Foods & Beverages** (include brand names)	**Describe Method of Preparation**
7:30am	½ cup	Kellogg's Corn Flakes	
	¼ cup	Land O'Lakes 1% Milk	
	1 slice	Kids Choice White Bread	Toasted
	¾ tsp.	I Can't Believe It's Not Butter	
	1 tsp	Jiffy Peanut Butter	
	¾ cup	Minute Maid Orange Juice	
9:45am	2 squares	Keebler Graham Cracker	
	¼ cup	Land O'Lakes 1% Milk	
12:00pm	½ cup	Kraft Macaroni & Cheese	See Recipe
	1 oz	Libby Cling Peaches	
	½ cup	Land O'Lakes Chocolate Milk	
2:15pm	1 Bite size	Snicker Bar	
	¼ cup	Musselman's Apple Juice	
5:00pm	½	Chicken breast	Fried

Day's Intake: (x) Typical ( ) More than usual ( ) Less than usual
Did you take a vitamin-mineral supplement? Yes If so, how much? One multi-vitamin

3 DAY DIET RECORD

Date: _____Name _____Day of the week: _____

Time	**Amount**	**Foods & Beverages** (include brand names)	**Describe Method of Preparation**

Day's Intake: ( ) Typical ( ) More than usual ( ) Less than usual

Did you take a vitamin-mineral supplement? _____ If so, how much? _____

Dietary Supplements & Medications:_____

Comments:_____

- *Participant Pre-and Post Study Questionnaire*

Pre-survey_____ Today's date: _____
Post-survey____

Participant Questionnaire

READ: Hello, my name is: _____. I am a research assistant helping with the Metabolic Syndrome Diet Study that you have agreed to participate in. I would like to ask you a number of questions that relate to your current diet, your current health & physical activity and then get a little bit of background information about you. Do you have time right now, or is there a better time to call you?
The first few questions will be diet and health related.
1. How would you describe your current satisfaction level with diet:
Read options, remember to pause between each one. Repeat as needed.
a. Terrible
b. Unhappy
c. Mostly Dissatisfied
d. Mixed
e. Mostly Satisfied
f. Pleased
g. Delighted

2. What type of, if any, diets have you been on or are currently on? Examples include Atkins, Weight Watchers, Jenny Craig:

3. Are you currently taking any medications and would you be willing to provide the names?

4. Would you say that in general your health is:
Read the options, and remember to pause between each one, and repeat if needed.
a. Excellent
b. Very good
c. Good
d. Fair
e. Poor
f. Not sure

5. Now thinking about your physical health, which includes physical illness and injury, during the past 30 days, are there any days that you would describe your physical health as not good? And if so, how many days?
a. Number of Days _____
b. None
c. Not sure

6. Now thinking about your mental health, which includes stress, depression, and problems with emotions, during the past 30 days, are there any days that you would describe your mental health as not good? And if so, how many days?
a. Number of Days _____
b. None
c. Not sure

7. During the past 30 days, were there any days in which you were not able to perform your normal or usual daily activities, such as work, caring for yourself or recreation? If so, how many days?

a. Number of Days _____
b. None
c. Not sure

Next Set of questions is about your physical activity.

READ: Now, think about all the vigorous activities which take hard physical effort that you did in the last 7 days. Vigorous activities make you breathe much harder than normal and may include heavy lifting, digging, aerobics, or fast bicycling. Think only about those physical activities that you did for at least 10 minutes at a time.

8. During the last 7 days, on how many days did you do vigorous physical activities?

_____ Days per week
Don't Know/Not Sure (Skip to question 10)

9. How much time did you usually spend doing vigorous physical activities on one of those days?

__ __ Hours per day
__ __ __ Minutes per day
Don't Know/Not Sure

READ: Now think about activities which take moderate physical effort that you did in the last 7 days. Moderate physical activities make you breathe somewhat harder than normal and may include carrying light loads, bicycling at a regular pace, or doubles tennis. Do not include walking. Again, think about only those physical activities that you did for at least 10 minutes at a time.

10. During the last 7 days, on how many days did you do moderate physical activities?

____ Days per week
Don't Know/Not Sure (Skip to question 12)

11. How much time did you usually spend doing moderate physical activities on one of those days?

__ __ Hours per day
__ __ __ Minutes per day
Don't Know/Not Sure

READ: Now think about the time you spent walking in the last 7 days. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.

12. During the last 7 days, on how many days did you walk for at least 10 minutes at a time?

____ Days per week
Don't Know/Not Sure (Skip to question 14)

13. How much time did you usually spend walking on one of those days?

__ __ Hours per day
__ __ _Minutes per day
Don't Know/Not Sure

READ: Now think about the time you spent sitting on week days during the last 7 days. Include time spent at work, at home, while doing course work, and during leisure time. This may include time spent sitting at a desk, visiting friends, reading or sitting or lying down to watch television.

14. During the last 7 days, how much time did you usually spend sitting on a week day?

__ __ Hours per weekday
__ __ __ Minutes per weekday
Don't Know/Not Sure

15. What is the total amount of time you spent sitting last Wednesday?

__ __ Hours on Wednesday
__ __ Minutes on Wednesday
Don't Know/Not Sure

Next set of questions is about your Demographics.

16. Gender (circle one):
Female
Male
Age: _____ Date of birth: _____
Height: _____ Weight: _____

18. May I ask your primary ethnic identity?

A. African American
B. Asian American
C. White, non-Hispanic
D. White, Hispanic
E. Middle Eastern
F. Other: _____

19. What is the highest degree or level of school you have completed?

A. High School Degree (for example: GED)
B. Associate degree (for example: AA, AS)
C. Bachelor's degree (for example: BA, AB, BS)
D. Master's degree (for example: MA, MS, MEng, MEd, MSW, MBA)
E. Doctorate Degree (for example: MD, DDS, DVM, LLB, JD, PhD)

➢ *Participant Individualized Meal Plan Information*

My Meal Plan

Weight (lb):_____ **Height (in):**
Ideal Body Weight (lb):_____ IBW in Kilograms (IBW/2.2):

(Women: 105 for 1st 60 inches, 5 pounds for each additional inch) (Men: 106 for 1st 60 inches,

Total Calories Per Day (IBW x 30kcals/kg):

Meal Plan: Plan A Plan B% Carbohydrates:_____% Protein:_____% Fat: __**%**

Grams Carbohydrates:_____**Grams Protein:**_____**Grams Fat:** _____

Exchanges

Breakfast:

_____ Carbohydrate Choices
_____ Protein Choices
_____ Fat Choices

Afternoon Snack:

_____Carbohydrate Choices
_____Protein Choices
_____Fat Choices

Morning Snack:

_____ Carbohydrate Choices
_____ Protein Choices
_____ Fat Choices

Dinner:

_____Carbohydrate Choices
_____Protein Choices
_____Fat Choices

Lunch:

_____ Carbohydrate Choices
_____ Protein Choices
_____ Fat Choices

Evening Snack:

_____Carbohydrate Choices
_____Protein Choices
_____Fat Choices

Carbohydrate Choices

A carbohydrate choice is a serving of food that has about 15 grams of carbohydrate and varying amounts of protein and fat.

Grains / Beans / Starchy Vegetables	Amount	Carb Choices
Beans, Baked	1/2 Cup	1 1/2
Beans (Black, Garbanzo, Pinto, Red), Cooked	1/2 Cup	1
Bread, Wheat	1 Slice (1 oz.)	1
Bun, Hamburger or Hot Dog, Whole Wheat	1 Bun (2 oz.)	2
Old Fashioned Oats, Cooked	1/2 Cup	1
Cereal, Unsweetened (High Fiber)	3/4 Cup	1
Corn	1/2 Cup or 5-6" Cob	1
Whole Wheat Dinner Roll	1 Roll (1 oz.)	1
English Muffin, Whole Wheat	1 Muffin (2 oz.)	2
Whole Wheat Pancake, 4" across	1 Pancake	1
Whole Wheat Pasta (Macaroni, Noodles, Spaghetti), Cooked	1/3 Cup	1
Peas, Green	1/2 Cu	1
Potato, White, Baked or Boiled, Medium (about 4" long)	1 Potato (6 oz.)	2
Potatoes, Sweet or White, Mashed, Plain	1/2 Cup	1
Rice, Brown, Cooked	1/3 Cup	1
Squash, Acorn or Butternut, Cooked	1 Cup	1
Whole Wheat Flour Tortilla (8" across)	1 Tortilla	1 1/2

Fruits / Fruit Juices	Amount	Carb Choices
Apple, Orange, Peach or Pear, Small	1 Whole	1
Banana, Medium	1 Whole	2
Berries (Blueberries, Raspberries, Strawberries)	1 Cup	1
Fruit, Canned	1/2 Cup	1
Fruit, Dried	1/4 Cup	1 1/2-2
Grapefruit	1/2 Medium	1
Grapes or Cherries	12-15	1
100% Juice (Apple, Cranberry, Grape, Pineapple)	1/3 Cup (3 oz.)	1
100% Juice, Grapefruit or Orange	1/2 Cup (4 oz.)	1
Melon (Canteloupe, Honeydew, Watermelon)	1 Cup	1
Raisins or Cran-Raisins	1/4 Cup (1 1/2 oz.)	2

ilk / Yogurt	Amount	Carb Choices
Milk, Skim or 1%	1 Cup (8 oz.)	1
Soymilk, Plain or Flavored	1 Cup (8 oz.)	1-2
Yogurt, Low-Fat, Artificially Sweetened or Plain	3/4-1 Cup (6-8 oz.)	1
Yogurt, Low-Fat, Sweetened, with Fruit	3/4-1 Cup (6-8 Oz.)	2-3

1 Choice = 15 Grams Carbohydrate
2 Choices = 30 Grams Carbohydrate
3 Choices = 45 Grams Carbohydrate
4 Choices = 60 Grams Carbohydrate

Combination Foods	Amount	Carb Choices
Asian Entreé (No Rice)	1 Cup	1
Burrito, Bean, Flour Tortilla, Frozen, 7" Long	1 Burrito	3
Burrito, Meat, Flour Tortilla, Frozen, 7" Long	1 Burrito	2
Casserole or Hot Dish	1 Cup	2
Chili	1 Cup	1-2
Frozen Dinner, 8-11 oz.	1 Dinner	2-3
Hamburger, with Bun, Regular	1 Hamburger	2
Lasagna, 3" x 4" Piece	1 Piece	2-2 1/2
Mixed Vegetables with Corn, Pasta, or Peas	1 Cup	1
Pasta or Potato Salad	1/2 Cup	1-1 1/2
Pizza, Frozen, Thick Crust, Medium	1 Slice (1/8 Pizza)	1 1/2-2
Pizza, Frozen, Thin Crust, Medium	1 Slice (1/8 Pizza)	1
Sauce, Tomato or Marinara, Canned	1/2 Cup	1
Soup (Bean, Noodle, Rice or Vegetable	1 Cup	1
Soup, Cream	1 Cup	1
Sub Sandwich, 6" Long	1 Sandwich	3
Taco, Corn Shell, 5" Across	1 Taco	1/2

Snacks / Sweets	Amount	Carb Choices
Brownie or Cake, Frosted, 2" x 2"	1 Piece	2
Candy, Hard, Round	3 Pieces (1/2	1
Candy Bar, Chocolate, Snack Size, About 2"	1 Bar (1 oz.)	1
Chips, Potato or Tortilla, Regular	10-15 Chips (1	1
Cookie, 3" Across	1 Cookie	1
Crackers, Snack	4-5 Crackers	1
Doughnut, 3" Cake or 4" Raised	1 Doughnut (2	2
Frozen Yogurt, Nonfat or Low Fat	1/2 Cup	1 - 1 1/2
Gelatin, Regular	1/2 Cup	1
Granola Bar	1 Bar (1 oz.)	1
Honey or Table Sugar	1 Tbsp.	1
Ice Cream, Light or Regular	1/2 Cup	1
Jam or Jelly, Regular	1 Tbsp.	1
Popcorn, Microwave, Light, Popped	1/2 Bag	2

Pretzel Twists, Mini	15 Pretzels (3/4	1

Name:

Calorie Range:

Suggestions: Three balanced meals spread evenly throughout the day. (i.e. 8 am, 12 Noon, 5:30 pm) If more than 4-5 hours between meals, then choose a snack.

Breakfast:

_____ Carbohydrate Choices
_____ Protein Choices
_____ Lean Protein Choices
_____ Fat Choices

Afternoon Snack:

_____Carbohydrate Choices
_____Protein Choices
_____Fat Choices

Lunch:

_____ Carbohydrate Choices
_____ Protein Choices
_____ Lean Protein Choices
_____ Fat Choices
_____ Vegetable

Evening Snack:

_____Carbohydrate Choices
_____Protein Choices
_____Fat Choices

Dinner:

_____ Carbohydrate Choices
_____ Protein Choices
_____ Lean Protein Choices
_____ Fat Choices
_____ Vegetable

Goals:

1.
2.
3.

THESIS TABLES

Table 1: Comparison of Age and Anthropometric Measurements at Baseline and Post-Intervention

Table 1. Comparison of Age and Anthropometric Measurements at Baseline and Post-Intervention

				Significance[1]	
		Baseline mean±SD	**Post Intervention mean±SD**	**Group x time**	**Time**
Age, Years (mean±SD)	Beef	56.2±11.6	57.6±11.5	0.68	0.1
	Dash	49.4±12.0	50.7±15.0		
Weight, kg (mean±SD)	Beef	97.6±19.6	92.6±19.4	0.41	<0.0001
	Dash	107.2±23.0	103.4±21.6		
BMI, kg/m2 (mean±SD)	Beef	34.5±6.5	32.7±6.5	0.31	<0.0001
	Dash	36.7±6.3	35.5±6.1		
Body Mass Index Category					
Overweight/Obese, %	Beef	100%	94%	--	
	Dash	93%	93%		

[1] Repeated measures ANOVA was used to determine group differences from baseline to post-intervention. Statistical significance was set at $p \leq 0.05$.

Table 2. Serum Lipid Concentrations from Baseline and Post-Intervention

Table 2. Serum Lipid Concentrations from Baseline and Post-Intervention						
				Significance[1]		
Characteristic		**Baseline mean±SD**	**Post Intervention mean±SD**	**Group x time**	**Group**	**Time**
Serum Lipid Values						
Total Cholesterol (mg/dL)	Beef	194.0±35.6	190.4±41.2	0.87	0.91	0.30
	Dash	196.3±33.9	190.0±46.5			
LDL (mg/dL)	Beef	117.7±29.2	117.4±32.2	0.88	0.70	0.80
	Dash	122.5±25.9	120.6±37.2			
HDL (mg/dL)	Beef	43.0±12.5	45.5±10.9	0.21	0.30	0.27
	Dash	39.7±9.8	39.5±11.0			
Triglycerides (mg/dL)	Beef	202.9±86.9	148.5±53.2	0.04	0.40	0.01
	Dash	199.9±88.2	193.4±95.9			
HbA1C (%)	Beef	6.0±0.9	5.9±0.9	0.24	0.40	0.21
	Dash	6.2±0.9	6.1±0.7			

[1] Repeated measures ANOVA was used to determine group differences from baseline to post-intervention. Statistical significance was set at $p \leq 0.05$.

Table 3: Comparison of Dietary Satisfaction and Intake

Table 3: Comparison of Dietary Satisfaction and Intake						
				Significance[1]		
Characteristic		**Baseline[2]**	**Post Intervention[2]**	**Group x time**	**Group**	**Time**
Current Diet Satisfaction[3]	Beef	4.0±1.1	5.1±1.4	0.62	0.40	<0.0001
	Dash	4.2±1.2	5.5±0.8			
Dietary Intake						
Total Calories (kcal/day)	Beef	1739±309	1660±358	0.48	0.21	0.81
	Dash	1453±448	1554±275			
Protein (g/day)	Beef	94±28	103±34	0.22	0.03	0.83
	Dash	85±33	78±21			
Protein from Beef (g/day)[2]	Beef	32 (18,48)	37 (9,65)	0.53	0.18	0.97
	Dash	23 (-8,54)	19 (6,32)			
Carbohydrates (g/day)	Beef	184±46	165±37	0.41	0.54	0.60
	Dash	173±52	192±46			
Fat (g/day)	Beef	71±21	66±20	0.28	0.07	0.95
	Dash	58±17	59±12			

[1] Repeated measures ANOVA was used to determine group differences from baseline to post-intervention. Statistical significance was set at $p \leq 0.05$.

[2] mean±SD or mean (95%CI)

[3] Measured with one question "How would you describe your current satisfaction level with diet?" with 7 scale response that ranged from "terrible" to "delighted", higher score indicates greater satisfaction

Table 4: Physical Activity and Health and Daily Activities of Participants

Table 4. Physical Activity and Health and Daily Activities of Participants at Baseline and Post-Intervention						
				Significance[1]		
Characteristic		**Baseline mean±SD**	**Post Intervention mean±SD**	**Group x time**	**Group**	**Time**
Medications and General Health						
Number of Medications	Beef	3.0±1	3.7±1.3	0.35	0.86	0.35
	Dash	3.8±2.7	3.8±2.7			
Current General Health[2]	Beef	1.25±0.4	1.00±0.0	0.63	081	0.03
	Dash	1.42±0.5	1.00±0.0			
IPAQ[3]						
Walking minutes per week (MET)	Beef	505±396	912±1297	0.61	0.16	0.09
	Dash	831±916	1310±934			
Moderate PA minutes per week (MET)	Beef	649±1407	1523±3433	0.68	0.85	0.85
	Dash	1076±2238	1160±1515			
Vigorous PA minutes per week (MET)	Beef	307±503	679±992	0.31	0.57	0.05
	Dash	289±428	901±2168			
Sitting Hours	Beef	278±193	320±190	0.06	0.49	0.19
	Dash	362±110	287±131			
Total PA	Beef	1552±1395	3168±4914	0.95	0.63	0.002
	Dash	2198±2928	3372±3158			

[1] Repeated measures ANOVA was used to determine group differences from baseline to post-intervention. Statistical significance was set at $p \leq 0.05$.

[2]Participants queried about general health, "Would you say that in general your health is:" with six-point Likert scale responses that ranged from "excellent" to "not sure", lower score indicates better general health.

[3]International Physical Activity Questionnaire (IPAQ) was used to assess amounts of physical activity (PA) at three intensity levels (vigorous PA, moderate PA and walking). Physical activity minutes were converted to Metabolic Equivalents (METs or MET-minutes) per week to generate total walking, moderate activity, and vigorous activity scores.

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