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Sobia Sattar Date

Grant proposal to study the effects of dietary modifications in pre-hypertensive African-Americans aged 18-35.

By

Sobia Sattar

MPH

Prevention Science

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Thesis Advisor

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M.B.B.S
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2005

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An abstract of
A thesis submitted to the Faculty of the
Rollins School of Public Health of Emory University
in partial fulfillment of the requirements for the degree of
Master of Public Health
in Prevention Science
2017

Abstract

Grant proposal to study the effects of dietary modifications in pre-hypertensive African-Americans aged 18-35.

By Sobia Sattar

According to the Centers for Disease Control and Prevention (CDC), African Americans develop high blood pressure at a younger age and more often than any other ethnicity. Complications of High blood pressure can prove debilitating and range from blindness, kidney diseases and stroke, as well as putting an individual at risk for other illnesses such as diabetes and heart disease. Pertinent to this fact, is the high incidence of cardiovascular disease among African Americans compared to other races. The disproportionately high rate of hypertension among blacks poses a unique challenge for researchers to explore race-specific guidelines targeting social, economic or environmental or habitual factors, which can help prevent the onset of hypertension in these individuals. This grant proposal seeks to identify the consequences of differential dietary habits and aims to seek any correlation between a modified diet regimen and incidence of high blood pressure among African Americans aged 18-35.

By using a quasi-experimental two group pre-post design, we will examine whether patients who are pre-hypertensive that receive standard prevention guidelines plus dietary based interventions will show improvements in clinical and patient reported outcomes versus a control group receiving only standard prevention guidelines and no dietary advice. The population selection will be based on the criteria of being African American and between the ages of 18-35 residing in the Greater Atlanta area with documented pre-hypertensive readings with a systolic pressure from 120 to 139 mm Hg or a diastolic pressure from 80 to 89 mm Hg at least 3 times in the past 6 months.

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Table of Contents

Chapter I

Introduction

Introduction and Rationale

Hypertension is one of the preventable causes of early morbidity and mortality among males and females. It is estimated that about 75 million American adults (32%) have high blood pressure—that's 1 in every 3 adults (CDC, 2012). It is a major risk factor for stroke, coronary heart disease, chronic kidney disease and can lead to morbidities associated with vascular system, vision and cognition. According to the Centers for Disease Control and Prevention (CDC), African Americans develop high blood pressure at a younger age and more often than any other ethnicity. About 43% and 45.7%of African-American men and women vs. 33.9% and 33.1% of white men and women have Hypertension (Dariush Mozaffarian & Subcommittee, 2015). Dietary factors play an important role in the development of Hypertension and the progress can be halted or reversed if significant dietary modification and lifestyle changes are adapted (Patricia J. Elmer, 2006). However, if unchecked, complications of high blood pressure can prove debilitating especially among African Americans, leading to high incidences of cardiovascular and kidney diseases, compared to other races. Moreover, the high cost of managing hypertension is a significant consideration for the healthcare expenditure in the United States. According to The Agency for Healthcare Research and Quality (AHRQ), in 2010, about 58.6 million persons or 25.1% of adults age 18 and older were treated for hypertension and the mean expenditure per person for the treatment of hypertension was higher for Hispanics and non-Hispanic blacks ($981 and $887, respectively), than for non-Hispanic whites ($679) and non-Hispanic others ($661). Direct health care spending to treat hypertension totaled $42.9 billion in 2010, with almost half ($20.4 billion) in the form of prescription drugs.

The disproportionately high rate of hypertension among African Americans poses a unique challenge for researchers as well as healthcare providers and health educators to explore race-specific guidelines targeting social, economic or environmental or habitual factors, which can help prevent the onset of hypertension in these individuals as well as treat those with diagnosed hypertension. This grant proposal seeks to identify the consequences of differential dietary habits and aims to seek any correlation between a modified diet regimen, lifestyle change and incidence of high blood pressure among African Americans aged 18-35.

Problem Statement

In an analysis of burden of disease done in 2008, the worldwide burden of disease attributable to high blood pressure (≥115 mm Hg systolic) was estimated for groups according to age (≥30 years). The results indicated that 7·6 million premature deaths (about 13·5% of the global total) and 92 million Disability Adjusted Life Years (DALYs) (6·0% of the global total) were attributed to high blood pressure. About 54% of stroke and 47% of ischemic heart disease worldwide were attributable to high blood pressure. About half this burden was in people with hypertension; the remainder was in those with lesser degrees of high blood pressure. Overall, about 80% of the attributable burden occurred in low-income and middle-income economies (Carlene MM Lawes, 2008). These results are consistent with findings from the WHO world report 2002, which estimated that 62% of cerebrovascular disease and 49% of ischemic heart disease are attributable to suboptimal blood pressure (systolic > 115mm of Hg), with little variation among sex. The report also found the modifiable factors for prevention of blood pressure include diet (specifically salt intake), level of physical activity, obesity and alcohol consumption (WHO, 2002).

In light of the facts stated already, there is significant importance of exploring effective strategies which can be implemented particularly among vulnerable individuals, in order to

reduce the burden of disease and also to suggest cost effective remedies in achieving the goal.

Purpose Statement

This grant proposal will aim to identify and help to implement specific dietary guidelines for reducing blood pressure catering to the African American community with individuals who are pre-hypertensive and within the ages of 18-35.

Furthermore, the grant proposal will also explore the following sub-objectives:

1) To establish the effectiveness of a modified dietary regimen in preventing incidence of high blood pressure among this subgroup.

2) To establish the role of community education efforts coupled with technological component in delivering health education.

3) To improve upon current dietary guidelines for African Americans to a comprehensive diet management plan in order to replicate best practices for prevention of hypertension and subsequently cardiovascular disease among these individuals.

Significance Statement

At the conclusion of the study, the findings can be replicated in the form of specific dietary guidelines for pre-hypertensive African American individuals aiming for optimal control of blood pressure and in order to prevent subsequent complications from cardiovascular disease.

Definition of Terms

Pre-Hypertension: According to the American Heart Association (AHA), Prehypertension is defined as "a systolic pressure from 120 to 139 millimeters of mercury (mm Hg) or a diastolic pressure from 80 to 89 mm Hg".

Co-morbid conditions: Comorbidity is the presence of one or more additional diseases or disorders co-occurring with (that is, concomitant or concurrent with) a primary disease or disorder.

Quasi – Experimental Design: One that is an experimental design but lacks the key ingredient of a true experimental design which is random assignment.

DASH Diet: DASH stands for Dietary Approaches to Stop Hypertension. The DASH diet is a lifelong approach to healthy eating that's designed to help treat or prevent high blood pressure (hypertension). The DASH diet encourages you to reduce the sodium in your diet and eat a variety of foods rich in nutrients that help lower blood pressure, such as potassium, calcium and magnesium. The standard DASH diet meets the recommendation from the Dietary Guidelines for Americans to keep daily sodium intake to less than 2,300 mg a day.

Salt Sensitivity: Defined as an abnormal increase in blood pressure in response to increased salt intake. People are either salt-sensitive or salt-resistant. Those who are sensitive to salt are more likely to have high blood pressure than those who are resistant to salt.

MANOVA: The multivariate analysis of variance (MANOVA) is used to determine whether there are any differences between independent groups on more than one continuous dependent variable.

Disability Adjusted Life Years (DALYs): The sum of years of potential life lost due to premature mortality and the years of productive life lost due to disability.

Chapter II

Review of the Literature

Introduction

The systolic and diastolic blood pressures have a strong, continuous and significant effect on the development of cardiovascular disease in the future. This significant association has been proven in many epidemiological studies done on patients with optimal or high blood pressure (Dariush Mozaffarian & Subcommittee, 2015) (Gerd Assmann MD, 1988) (Peter W. F. Wilson, 1998). A study done on patients categorized into three categories of optimal, normal or high normal blood pressure found that men and women with high-normal blood pressure at base-line examination had a higher incidence of cardiovascular disease on follow-up than those with optimal blood pressure. These relationships were consistent in both men and women and in both age groups, and they persisted after adjustment for multiple cardiovascular risk factors (Ramachandran S. Vasan, 2001). This significant correlation highlights the importance of preventing high blood pressure and subsequently prevent heart disease in patients who might not be otherwise susceptible of developing any cardiovascular event. The effects of pre-hypertension on risk factors for heart disease as well as high cholesterol and Diabetes Mellitus were also explored in another study which included 39% of persons who were normotensive, 31% who were pre-hypertensive, and 29% who were hypertensive. The age-adjusted prevalence of prehypertension was greater in men (39.0%) than in women (23.1%). African Americans aged 20 to 39 years had a higher prevalence of prehypertension (37.4%) than whites (32.2%) and Mexican Americans (30.9%). The probabilities of above-normal cholesterol levels, overweight/obesity, and diabetes mellitus, which are common conditions leading to cardiovascular disease, were also greater for persons with prehypertension vs normotension (Kurt J. Greenlund, 2004).

The Disease Burden

A report published by the National Center of Health Statistics (NCHS) found that the overall prevalence of hypertension among U.S. adults aged 18 and over was 29.1% in 2011–2012, similar to the prevalence in 2009–2010 (Tatiana Nwankwo, 2013). The same report also found that the prevalence was comparable among sexes with men at 29.7% and women at 28.5% and that the highest rate of hypertension was among non-Hispanic black adults, at 42%. This means that despite progress in prevention, treatment, and control of high blood pressure during the past few years, hypertension remains a major public health challenge, especially among the African American group. Also, the control of hypertension has neither met the goal of the Healthy People 2020 (61.2% by 2020) nor the Million Hearts Initiative (65% by 2017). These results provide evidence for continued efforts to improve the management of hypertension in order to attain these goals.

Furthermore, there is significant cost associated with the management of Hypertension in the US. Total costs associated with high blood pressure in 2011 in the US were $46 billion in health care services, medications, and missed days of work (Tatiana Nwankwo, 2013). According to a report published by the Agency of Healthcare Research and Quality (AHRQ), in 2010, 58.6 million adults or 25.1% of the U.S. community population age 18 and older received treatment for hypertension (Davis, 2013). The percentage with reported treatment for hypertension in age groups, 45–64 years was 32.4% and for 18–44 years was 6.1%. A higher percentage of non-Hispanic African Americans were treated for hypertension (30.4%) than those who were non-Hispanic white (26.7%) (Davis, 2013). The mean expenditure per person for the treatment of hypertension was higher for adults age 65 and older ($778) than for adults ages 45–64 ($715) or ages 18–44 ($636). Although the cost is lower than older adults, this number is still significantly high for a disease that's supposed

to manifest during the later years of life. The same study found that the mean expenditure per person for the treatment of hypertension was higher for Hispanics and non-Hispanic African Americans ($981 and $887, respectively), than for non-Hispanic whites ($679) and non-Hispanic others ($661) (Davis, 2013).

Hypertension among African-Americans

The potential causes for the higher rate of Hypertension in African Americans can include either biological differences in the mechanism of blood pressure control or differences in the environment and habits of African Americans and other races. The higher prevalence of hypertension in African Americans living in the United States as compared to black patients living in Africa demonstrates that environmental and behavioral characteristics are the more likely reasons for the higher prevalence in African Americans living in the United States (Richard S CooperEmail author, 2005). Another interesting finding among several studies has been the linkage of salt sensitivity to race. Salt sensitivity is a measure of how one's blood pressure responds to salt intake. People are either salt-sensitive or salt-resistant and those who are sensitive to salt are more likely to have high blood pressure than those who are resistant to salt. African Americans have been consistently shown to have a greater frequency of salt sensitivity than whites. One study observed that 73% of African American hypertensive patients were salt sensitive compared with 56% of a white hypertensive group; but in the normotensive population, the frequency of salt sensitivity among African Americans (36%) was similar to that seen among whites (29%) (Weinberger, 1996), while another found that normotensive salt sensitivity may also be higher in African Americans and less frequent in Caucasian Americans (whites), but only when dietary potassium is deficient (R. Curtis Morris, 1999).

However, one genetic hypothesis is insufficient to explain the difference in Hypertension among races and research suggests that dietary habits are also important in the salt sensitivity-blood pressure relationship. According to a National Health and Nutrition Examination Survey (NHANES) study (2009–2010), it was reported that compared with whites, African Americans consumed on average lower amounts of whole grains, fruits, and vegetables (0.8, 1.2, 1.3 servings/day for black men, respectively, vs. 1.1, 1.6, 2.1 servings/day for white men) (CDC, 2012). Data from a previous NHANES 2007–2010 showed that there was a significant difference between African Americans and whites in the percentage of calories consumed from fast foods (defined as foods usually sold at eating establishments for quick availability or takeout. Young adults aged 20–39 consumed the highest percentage of calories from fast foods (21 % in African Americans vs. 15 % in whites) (Frayar, 2013). Another study showed that less favorable multiple nutrient intake by African Americans than non-Hispanic white Americans accounted, at least in part, for higher blood pressure among African Americans. Multiple linear regression, standardized data from four 24-hour dietary recalls per person, two 24-hour urine collections, and 8 blood pressure measurements were used to quantitate the role of foods, nutrients, and metabolites in higher African American blood pressure. The extensive data collected showed that compared with non-Hispanic white Americans, African American's average systolic/diastolic pressure was higher by 4.7/3.4 mm Hg (men) and 9.0/4.8 mm Hg (women). Lesser intake of vegetables, fruits, grains, vegetable protein, glutamic acid, starch, fiber, minerals, and potassium, and higher intake of processed meats, pork, eggs, and sugar-sweetened beverages, along with higher cholesterol and higher Na/K ratio, related to in higher African American's blood pressure. Control for 11 nutrients and 10 non-nutrient correlates reduced higher systolic/diastolic pressure in African Americans (52% and 33% reduction in men) and (21%

and 27% reduction in women) (Stamler J1, 2013). One important reason for over-consumption of fast food can be due to the fact that African Americans tend to be within the low-income range category and thus simply cannot afford healthy food such as fresh or organic fruits and vegetables. The National Poverty Center estimates that over 25% of African Americans are poor compared with 9.4% of whites. Poverty can lead to hypertension, perhaps mediated by chronic stress as an added factor and this can serve as a reasonable explanation for the high rates of Hypertension among this race.

Diet affects Blood Pressure

Substantial evidence points towards the fact the blood pressure can be controlled through diet. Documented dietary modifications include, reduced salt intake, weight loss, physical activity and reduced alcohol consumption. Over the past decade, increased potassium intake and consumption of dietary patterns based on the "DASH diet" have emerged as effective strategies that also lower blood pressure. Specifically, African Americans are especially sensitive to the BP-lowering effects of reduced salt intake, increased potassium intake, and the DASH diet (Lawrence J. Appel, 2006) (Laura P. Svetkey, 1999) (George A Bray, 2004). There is plenty of evidence, multifactorial dietary modifications help to reduce blood pressure (A Ziv, 2013). One study determined the effects on blood pressure and other cardiovascular disease risk factors of a comprehensive lifestyle intervention (sodium reduction, calorie reduction and physical activity). It found that among hypertensive overweight adults already on antihypertensive medication, a comprehensive lifestyle intervention can substantially lower blood pressure and improve blood pressure control (Edgar R. Miller, 2002). However, salt remains the most important dietary component causing significant reductions in blood pressure when its intake is even moderately reduced. And this result holds true irrespective of age, sex or ethnicity (Feng J He, 2013).

The above-mentioned studies all show effects of dietary modifications in individuals with high blood pressure. However, there is a small research gap in exploring effects of dietary modification among individuals with pre-hypertension. Some studies in the past have provided mixed results. One showed that moderate dietary sodium restriction does not lower blood pressure in patients with this degree of hypertension (G C Watt, 1983). This study was only done on 18 participants and out of them 5 failed to follow the reduced sodium diet. Also notable is the fact that the study implied only a moderate decrease in sodium in the diet of the participants. Another study done one year later, showed some decrease in blood pressure when a moderate reduction in salt intake was coupled with beta blocker given to individuals with mild hypertension (T M Erwteman, 1984). A study which explored the effects of reduced salt intake as well as weight loss found some effectiveness in altering both factors but concluded that further studies were needed to establish a clear connection (Paul K. Whelton, 1992). A randomized study on stage I Hypertensive patients concluded that individuals with above-optimal BP, including stage 1 hypertension, can make multiple lifestyle changes that lower BP and reduce their cardiovascular disease risk (Patricia J. Elmer, 2006), but the study participants were only followed for 6 months and thus the results cannot be deemed conclusive for long term efficacy. A randomized trial conducted in 2006, involving pre-hypertensive individuals showed statistically improved results when the individuals were followed for a period of almost 18 months and given low sodium diet along with comprehensive lifestyle modification plan and showed improved blood pressure measurements (Patricia J. Elmer, 2006). Interestingly enough a European study done in 2011, concluded that high salt intake did not have any long term effects on reducing blood pressure and eventually preventing cardiovascular events (Katarzyna Stolarz-Skrzypek, 2011). The study however is limited to Europeans and relatively young people and it notes that the

results cannot be generalized to any other population especially African Americans due to their increase salt sensitivity. A similar study done in Boston, used data from 2,632 normotensive subjects, ages 30–64 years, in the Framingham Offspring Study, to address the question of the long-term effect of dietary sodium in particular on systolic (SBP) and diastolic blood pressures (DBP) over 16 years of follow-up. They concluded that the long-term data from the Framingham Study provide no support for lowering sodium intakes among healthy adults to below 2.3 g/day as recommended (Lynn L. Moore, 2017). However, in this particular study sodium was not the only element that was being manipulated but potassium calcium levels were also taken into account and thus the combined effect of these nutrients had a significant role in lowering blood pressure.

One study done in 2014 incorporated a technological component in addition to the DASH diet and asked the participants to record body weight, steps taken and through weekly newsletters, participants engaged in electronic reporting and goal setting and received feedback on progress. The study found that electronic reporting led to more feedback, more steps taken and greater reduction in systolic blood pressure compared to the control group. Although the sample size was small with only 23 participants this study highlights the importance of concentrating efforts not only toward adoption and initiation of innovative risk-reduction strategies but also toward the provision for long-term maintenance of a healthy lifestyle which the participants can follow (Dorough, 2014).

Health status is influenced by individual characteristics and behavioral patterns (lifestyles) but continues to be significantly determined by the different social, economic and environmental circumstances of individuals and populations. The relationships between these social factors and health, although easy to observe, are less well understood and much more difficult to act upon. Also, given the widespread variation in research already

published, it is necessary to test dietary modification interventions in individuals with a broad range of demographic and clinical characteristics. This would help to further explore the relationship between dietary factors and results of the modified diet among African American individuals of a relatively younger age group, before their pre-hypertensive status evolves further and leads to Hypertension that would traditionally require not only vigorous lifestyle change but also prescription drugs.

Chapter III

Methodology

Funding Agency – American Heart Association

American Heart Association (AHA) offers research funding programs to eligible investigators and institutions across the U.S. The AHA generally has two funding cycles per year and research awards are limited to non-profit institutions, including medical, osteopathic and dental schools, veterinary schools, schools of public health, pharmacy schools, nursing schools, universities and colleges, public and voluntary hospitals and others that can demonstrate the ability to conduct the proposed research. AHA continues to offer a variety of grant opportunities for scientists and researchers from many different fields of study to accomplish their goals to reverse and prevent cardiovascular diseases and stroke. Other funding agencies that sponsor these types of grants include the Centre of Disease Control (CDC) and National Institute of Health (NIH) which have extensive funding opportunities to combat and prevent chronic disease especially cardiovascular disease. The AHA was chosen specifically because of the direct correlation between hypertension and cardiovascular disease rates (Ramachandran S. Vasan, 2001). The grant covers research for the prevention of cardiovascular disease due to any cause and offers an opportunity for early investigators with supportive mentoring relationships to conduct introductory pilot studies that will guide future strategies for reducing cardiovascular disease and stroke. This pilot study will provide a basis for further investigation into the fact that by modifying dietary intake in pre-hypertensive patients, it can have a profound effect on the development of hypertension that may require medication in the future.

Grant Announcement

The grant announcement includes all clinical and population research broadly related to cardiovascular disease and stroke. The award amount is $154,000 divided into two year grants of $77,000 and is limited to Healthcare professional with a masters or post-baccalaureate doctoral degree with the inclusion of a sponsor for the proposal. The work is to be done at an accredited institution within the United States and research awards are limited to non-profit institutions, including: medical, osteopathic and dental schools, veterinary schools, schools of public health, pharmacy schools, nursing schools, universities and colleges, public and voluntary hospitals and other institutions that can demonstrate the ability to conduct the proposed research.

The complete grant announcement can be found at: https://professional.heart.org/professional/ResearchPrograms/ApplicationInformation/UCM_443302_Mentored-Clinical-and-Population-Research-Award.jsp

Grant Proposal Reviewers

1. **Janice Irene Lea, MD, Msc, FASN**

   Dr. Lea is a professor of medicine at Emory University and is board-certified in nephrology and hypertension. She is the chief medical director of Emory Dialysis and is a nationally renowned expert in hypertension - designated a "Clinical Specialist in Hypertension" by the American Society of Hypertension. Dr. Lea's research and clinical interests are in hypertension, chronic kidney disease, and dialysis, with numerous publications. Dr. Lea has served as the Emory principal investigator for the NIH study "African-American Study of Hypertension and Kidney Disease" and the National Medical Spokesperson for the National Kidney Disease Education Program (NKDEP), sponsored by the National Institutes of Health.

2. **Rebecca Filipowicz, MPH, MS, MCHES**

Before working for PRISM supporting AIDSVu, HIVContinuum, and HepVu projects in the Department of Epidemiology at Emory University, Rebecca has worked at the Texas Department of State Health Services at DSHS in the field of HIV, STD, and TB surveillance and for the Florida Department of Health in Duval County as the Coordinator for the Center for Health Statistics at the Institute for Health Policy, Evaluation, and Research. In addition, she has held positions as the Region 1 Coordinator for Chronic Disease, Heath Promotion and Education in Florida and worked as a program evaluator and instructional designer for the Rollins School of Public Health at Emory University. Her background in chronic disease prevention and education will prove valuable to the grant proposal project.

3. **Johanna M. Hinman, MPH, MCHES**

   Johanna M. Hinman is Associate Director of Education for the Department of Surgery in Emory University's School of Medicine. Johanna has 18 years of experience in public health education, health communication, program planning and project management. She spent 10 years at the RSPH, working in tobacco control and environmental health, then the Emory Prevention Research Center (EPRC). Johanna oversaw EPRC administration, managed supplemental funding applications, led communication and dissemination efforts, supervised project staff, and coordinated partnership activities. Johanna is active in the Georgia Public Health Association (GPHA) and the American Public Health Association (APHA). She is a Past Chair of APHA's Public Health Education and Health Promotion Section and the GPHA Health Education and Health Promotion Section.

4. **Lisa M. Carlson, MPH, MCHES**

Lisa Carlson joined the Emory Global Health Institute in April, 2015 to provide administrative leadership for the rapid start-up and implementation of the CHAMPS Network. She has served at Emory since 2002, primarily as the first principle Director of the academic programs of the Emory Transplant Center (ETC). Prior to joining the ETC, Carlson served as Director of Operations for the Tobacco Technical Assistance Consortium at the Rollins School of Public Health. Carlson is a past president and honorary lifetime member of the Georgia Public Health Association (GPHA), a past chair of the Executive Board of the American Public Health Association (APHA), was a Fellow in the 2013 class of the Emory Woodruff Leadership Academy, and is serving her third term on the Emory Alumni Board. Carlson is on the adjunct faculty at RSPH, teaching public health ethics and qualitative methods in the distance-based Executive MPH program. Her expertise in the research field as well as Public Health Ethics will be invaluable for this proposal.

5. **Laura M.D. Gaydos, PhD**

Dr. Gaydos is a highly-respected researcher and educator in Public Health, serving as an Associate Professor in the Department of Health Policy & Management and the Associate Chair for Academic Affairs for the Executive MPH Program at the Rollins School of Public Health. Dr. Gaydos received her undergraduate degree in Public Policy from Brown University and her PhD in Health Policy & Administration from the University of North Carolina at Chapel Hill. She then completed a postdoctoral fellowship with the Women's and Children's Center at Emory before joining the faculty at the Rollins School of Public Health in 2007. On the research side, Dr. Gaydos is a mixed-methods researcher with a focus on women's, reproductive and maternal/child health issues. In addition to mixed-methods inquiries across a variety

of topics, Dr. Gaydos has also charted a new, innovative path of inquiry examining the intersections of religion and reproductive health. Dr. Gaydos has published over 35 peer-reviewed journal articles, book chapters and commissioned works and has made dozens of public presentations on her work. Dr. Gaydos has received numerous awards for her work, including the Noah Krieger Memorial Prize for Excellence in Public Policy, The Delta Omega Professional Development Award, a Woodrow Wilson Fellowship, the McMahon Young Investigator's Award from The Center for Women's Health Research, and a STAR (Science Translated to Action and Results) award.

Protection of Human Subjects

Human subject's involvement, characteristics, and design

The study plans to recruit approximately 200 participants from the Metro Atlanta area. The participants must be between 18-35 years of age, African American by race and should be English speaking. The participants need to be diagnosed as being Pre-Hypertensive and without any co-morbid condition such as Diabetes or Heart Disease. The exclusion criteria are put into place since the study aims to identify the effects of a modified diet on the development of hypertension. Patients with co-morbid conditions such as Diabetes or Heart disease may already be on a modified diet and thus would skew the results of the study. The rationale for the specific age-group is due to the fact that pre-hypertension is mostly a disease of a relatively younger age and also the fact that the study aims to analyze if diet control can prevent the pathway of pre-hypertension to full blown hypertension requiring medication for its management. The participants in the experiment group will be provided smartphones as incentives for enrolling in the study while the participants in both groups will be provided with monetary incentives in the form of gift cards for their time during each

follow-up visit so as to aim to maintain at least 80% retention rate for increasing validity of the study. The IRB and the funding agency which is the American Heart Association (AHA) will approve the above-mentioned criteria before proposal implementation.

Human subject materials collected

The following data/specimens will be collected during the course of the study:

- Demographic data including name, age, address, race.
- General health data on health form to identify any pre-existing conditions as well as either physician's records relating to high blood pressure to establish the diagnosis of pre-hypertension.
- Current dietary habits in the form of a questionnaire for ensuring similar characteristics while assigning groups.
- Blood pressure recordings which will be done on-site during follow-up visit, pre and post intervention as well as at 3,6,9,12 and 18 months' interval during the course of the study.
- Spot-Urine test which will be done on-site during follow-up visit.

The demographic data as well as participant health data will be encrypted and the participants will be assigned a numerical code for identification. This will be done personally by the researchers and all data will be converted into an electronic form. This way the data will only be available to researchers in the study and will not be made available to any students or volunteers hired for help during the follow-up visits. The blood pressure and spot urine results will be conducted by students or volunteers recruited for this purpose who will enter it manually into an electronic form assigned to each person with their unique numerical I.D. code.

Recruitment and Informing subjects of study

At the initial visit, all participants will be given a consent form which will be personally administered by the researchers to all participants on the initial visit at different sites throughout the Metro Atlanta area. The participants will fill out the form and hand it over to the researchers who will then convert the data into electronic format where it will be encrypted. The participants will be explained fully the process of the study, risks and benefits as well as an explanation of incentives and requirements for the follow-up visits. A unique numerical I.D. code will be assigned to each participant which will be used to identify the participants at each follow-up visit. The students and volunteers conducting the follow up visit will only have access to the unique I.D. of the participants and will submit blood pressure recordings and results of the spot-urine test electronically to the researchers.

Potential Risks to Human Subjects

The only risk in the study is for the participants in the control group in that they will not get specific advice on how to lower sodium in their diet in order to prevent development of high blood pressure by receiving modified recipes and steps to shop smart to avoid buying high sodium content food coupled with the eDiet app with even more specific dietary advice that goes beyond just the DASH diet plan. However, the participants will be provided with written pamphlets and generalized version of the "DASH" diet which does include advice on lowering sodium as well as advice on how to eat a healthy balanced diet for lowering blood pressure. Thus, the risk is minimal to the study participants in this group.

Benefits of the Research or Program to Human Subjects and Society

The study will provide great benefit to the participants as it will provide access to specific dietary advice as well as sodium lowering ways in conjunction with the use of a smartphone app which is both convenient and practical in everyday usage. The community health education sessions will also provide participants with a chance to meet people and influence

as well as be influenced by persons dealing with high blood pressure and wanting to make healthy choices for a healthier future.

Chapter IV

Incorporation of Reviewer Comments

I would like to thank the reviewers for the thoughtful and insightful comments that made this proposal stronger and led to great improvements in the final version. Detailed responses to the comments are given below:

Reviewer 1 Comments:

- **Comment 1:** On "Disease Burden" - It's difficult to grasp the relevance of these figures in this format. Putting them into tables might help. Your key points get lost here.

  Response to comment 1: Figures were made simpler by taking out lengthy numbers. Paragraph 1 in the 'Disease Burden' section as well as paragraph 1 under 'Hypertension among African Americans' was re-written to simplify numbers and summarize results instead.

- **Comment 2:** You use both "%" and "percent" – choose one and be consistent

  Response to comment 2: Percent was replaced with % throughout the document.

- **Comment 3:** On African Americans, not being able to afford healthy food - This is a major generalization and not true for the majority of people. It is true for more AAs than whites. Be careful of your wording. Probably also needs more context – fast food is cheaper than fresh food, etc.

  Response to comment 3: More context was added in the last paragraph of 'Hypertension among African Americans' section to indicate that African Americans tend to consume more fast food compared to fresh food.

- **Comment 4:** Define DASH diet.

Response to comment 4: Definition of DASH diet was included in the "Definition of Terms" section.

- **Comment 5:** On Exclusion Criteria - Any co-morbid condition would rule out of a lot of people. The two you list seem important – are they enough?

  Response to comment 5: Including more intense Exclusion criteria was considered, but that would mean excluding a large population of people and recruitment might not yield sufficient numbers. The two main co-morbid conditions which have a connection with dietary control have already been included.

- **Comment 6:** Is it possible to use a stronger sampling method? This will attract a particular kind of participant – how will you control for bias?

  Response to comment 6: The recruitment section was modified to clarify more on participant recruitment and selection. Given the time-frame and the budget allocation for the study, a true randomization is not possible for this kind of study. However, it is recommended to duplicate the study with true randomization in the future to further elaborate on a connection between diet and its effects on pre-hypertensive individuals.

- **Comment 7:** On Phase IV, Follow-up- What incentives will you provide for them to do this? Seems like there could be a lot of no-shows over 18 months. Will you communicate with them in between visits?

  Response to comment 7: Monetary incentives will be provided as indicated in the Initial Introductory paragraph of the study design. The participants will be given a number to call and schedule follow-up visit. Reminder calls will also be given before the upcoming visit. These points were added in the same section for clarification.

Reviewer 2 Comments:

- **Comment 1:** There is no information given about the investigator.

  Response to comment 1: Investigator information has been included in the revised document.

- **Comment 2:** There is no information given about the scientific environment in which the study will take place.

  Response to comment 2: Environment information included and elaborated in the revised document.

- **Comment 3:** A potential difficulty in the recruitment – if the study is publicized at area health centers and hospitals, it may be harder to find participants who do not have co-morbidities, so the exclusion rate may be high.

  Response to comment 3: The study plans to cover the Metro Atlanta Area and recruitment will be done in community centers and area hospitals. Recruitment section was modified to include widespread advertisement in area hospitals and doctor's offices. The age limit is relatively young and thus it might be possible to find patients without any co-morbid conditions.

- **Comment 4:** It is unclear whether or not recruitment will include any screening for possession of an appropriate smartphone, nor is it clear whether or not the study will reimburse participants for data usage while running the app on their personal smartphones.

  Response to comment 4: Incentives section was added in the proposal to clearly define what sort of incentives will be offered to patients. For the study group, smartphone with pre-installed blood pressure and dietary advice app will be provided as an incentive and the option of keeping the smartphone if the participants

complete the study and follow-up regularly. For both groups, monetary incentives in the form of gift cards will be provided for each follow-up visit.

- **Comment 5:** The description of the dietary advice session (page 8) is somewhat concerning in its assumption that participants all have easy and affordable access to supermarkets that stock fresh fruits and vegetables.

  Response to comment 5: Since the participants are being recruited from Metro Atlanta area, it is assumed that they will have access to fresh fruits and vegetables as opposed to someone who lives in a food dessert area. The provision of monetary incentives at each follow-up visit can also serve to somewhat offset the cost of buying fresh produce.

- **Comment 6:** The discussion of potential difficulties and limitations is somewhat hard to follow.

  Response to Comment 6: The whole section was modified and re-written to better address the difficulties and limitations of the study.

- **Comment 7:** Discussion of poverty and relation to hypertension is too broad and lacks sufficient reference data to support the overarching statement "Poverty can lead to hypertension." This argument needs more detail and substance; it seems like an afterthought, and the implications of the link between poverty and hypertension are not clarified.

  Response to comment 7: The over-arching statement was re-worded to better address the issue of the linkage between poverty and race. The statement used to make the said generalization was also removed.

- **Comment 8:** The paragraph about health status being influenced by individual as well as social circumstances is somewhat confusing and difficult to follow. It is

unclear if this is meant to tee up a behavioral intervention, further study on environmental factors, or some other focus. There are no citations in this section, so the specific scientific links are not only implied but not well documented.

Response to comment 8: The paragraph was re-worded in an attempt to better clarify the importance of social factors as well as individual behaviors in chronic disease development especially hypertension.

Reviewer 3 Comments:

- **Comment 1:** There isn't enough information about the scientific environment given. The proposal indicates that subjects will be recruited from area hospitals and community health centers but would want to see letter of support from those that specifically agreed to have recruitment efforts there. Also, it is not clear regarding where the participants will go for testing, classes, etc. after recruited.

  Response to comment 1: Environment information included and elaborated in the revised document.

- **Comment 2:** The investigator does a good job at outlining the burden but should spend more time defining implications for future approaches to address the problem.

  Response to comment 2: As indicated in the study, it is only meant to be a pilot study for future exploration and development into a randomized trial and a longer follow up time since only then the link between diet and lowering Blood pressure at a pre-hypertensive stage can be established.

- **Comment 3:** Recruitment site information is vague.

  Response to comment 3: Recruitment section was re-written to further clarify recruitment and advertisement methods for the study.

- **Comment 4:** Coming from a Behavioral Science background, would like to have seen a behavioral theory included to support the methodology for this type of disease.

Response to comment 4: The inclusion of behavioral theory was optional and thus was not discussed in the document. However, the concluding paragraph in the Literature Review section addresses the topic to some extent.

Reviewer 4 Comments:

- **Comment 1:** Certainly can add info about my being your mentor and vast experience in Hypertension in African-Americans- Principal Investigator of NIH-AASK trial.

  Response to comment 1: Information added in the Reviewers section as well the Biography section.

- **Comment 2:** Unclear how participants will be recruited. Would not recruit at hospitals as likely to have sicker patients and hard to compare them to those from community centers who are healthier. Would use community settings- health fairs, churches, etc.

  Response to comment 2: Recruitment section was modified to include widespread advertisement in area hospitals and doctor's offices as well as health fairs and local area churches. The age limit is relatively young and thus it might be possible to find patients without any co-morbid conditions.

- **Comment 3:** Also 24-hour urine will need to be done before study and after to know if the intervention made a difference-i.e.- salt intake may have already been low. Are you going to do this on all patients, even those without intense education on salt restriction? Doing 24 hour urines may be problematic if they do not collect it for appropriate period of time. Would need to measure creatinine in order to determine if sample is adequate. There is formula that can be used to estimate sodium intake based on a spot urine sodium which will be much easier.

  Response to comment 3: Due to budget restrictions for this kind of study it seemed more appropriate to adapt the spot-urine method for estimating sodium content. The study was modified overall to include this approach instead of using the

more cumbersome process of 24-hr urine collection. Accompanying limitations in using this method instead of the more reliable 24-hr urine collection along with creatinine measurement were also added in the Limitations section of the document.

- **Comment 4:** Certainly the association of salt intake and BP is not very innovative but the use of a smartphone to help with dietary compliance is novel. Problem is what to do with those who may not have smartphone- thus if exclude those without one that is biasing your sample some in that those with smartphones are likely more educated and able to comply with specific diet.

  Response to comment 4: The incentives section was added detailing the supply of smartphones for the study purpose and keeping them as an incentive for enrolling and follow-up during the study time frame. This will control for bias as it will attract participants with or without a smartphone.

Reviewer 5 Comments:

- **Comment 1:** In "Specific Aims" section: Again, for whom? What population? In what setting? Because you don't provide any intro about how/where this will take place, this is all out of context and not detailed enough.

  Response to comment 1: Specific aims were re-written to reflect the population under study.

- **Comment 2:** Who do dietary guidelines come from? Are you in a position to "enhance" them yourself or to make recommendations to a key organization regarding enhancements?

  Response to comment 2: Dietary guidelines were defined in the "Specific Aims" section and recommendations will be provided to the American Heart Association (AHA).

- **Comment 3:** On Literature Review, Line 4: There should be tons of citations on this. I recommend using numerical format so you can say (1-8).

  Response to comment 3: Appropriate references were included.

- **Comment 4:** On Literature Review, Line 9: Rather than describing a particular study here, it would make more sense to use some general statistics (easily available) about what groups have highest prevalence.

  Response to comment 4: General statistics were included in the beginning of the Introduction section to show the pathway of Cardiovascular disease among patients of high blood pressure.

- **Comment 5:** On Literature Review, Line 13: Not sure why you included this level of detail here. Focus on the results of the studies you discuss unless there is something

about the methods (good or bad) that you want to delve into. Just providing the descriptive background doesn't help, so take it out.

Response to comment 5: The detail of study methods was provided to signify the use of normotensive as well as pre-hypertensive patients in the study which showed a correlation of elevated blood pressure to heart disease. High incidence of diabetes and high cholesterol were included since they were also observed in pre-hypertensive patients subsequently leading to heart disease.

- **Comment 6:** Every study you include should have findings that link to the "story" of why you are proposing the study you are. Based on this, Men and AA patients have higher risk – so would it make sense to focus on them? Or one of them? (each likely has some unique needs for dietary guidelines).

  Response to comment 6: The study aims to address the dietary needs for both men and women. The DASH diet being used for study purposes applies to both genders and recommendations are the same for both men and women in terms of lowering blood pressure.

- **Comment 7:** On Literature Review, last paragraph of "Disease Burden": But that's not your focus group. So, if you are providing this info, how does it support the story of why you are proposing what you are proposing? Ok to include, but you need some language along the lines of "although the highest costs are for older adults, targeting younger, pre-hypertension adults is more cost-efficient over the lifetime." Or something along those lines.

  Response to comment 7: Edited as recommended in the comment.

- **Comment 8:** On Literature Review, Line 9 under "Hypertension among African Americans: This is interesting – It would help if you could talk about exactly how

this is defined – is it physiological/congenital or is it a reaction to higher salt in diet over time that the body reacts to. These are different things and it's not clear to me which this refers to.

Response to comment 8: Definition of salt sensitivity added in the same line as well as under "Definition of Terms".

- **Comment 9:** On Literature Review, last paragraph of "Disease Burden": I think you could probably streamline this section, by making general statements (e.g. Young Adults are most likely to get a significant (20% or more) of calories from fast food (multiple refs)) This is easier to read/follow and space saving rather than describing each study in detail – unless there is aa specific reason to discuss a specific study.

  Response to comment 9: The studies all relate to either the methodology used in the current proposal or findings are relevant for the current recommendation, thus the studies in detail were included in this section. For example, including the methodology for using 24-hr urine collection and 8 blood pressure measurements, implies that the study followed gold standards of monitoring accurate blood pressure readings and thus the findings can be deemed reliable.

- **Comment 10:** On Literature Review, Line 13 under "Diet effects Blood Pressure": Are these the only studies? Seems unlikely. If you are making the argument that this is understudied, be sure that is the case. Can you cite something showing that is the case? From my own work on obesity in AA women, I know there are lots of interventions that are multifactorial.

  Response to comment 10: The statement regarding understudied was removed since it was mistakenly written as such.

- **Comment 11:** On Literature Review, Line 54 under "Diet Effects Blood Pressure": This is interesting but if you are not proposing something relevant, don't put it in.

  Response to comment 11: The said study was included to show the importance of technology in changing study participants' behavior.

- **Comment 12:** On Literature Review, closing paragraph: This should be your theoretical framework, but I don't see one discussed formally. And how? I'm not sure that's true. There is a large literature on the social ecological model that should be referenced here.

  Response to comment 12: The closing paragraph was re-written as discussed in response to previous reviewers.

- **Comment 13:** On Research Design, Line 7: Is this consistent with the current guidelines? If not, not clear to me how you will answer research Q3.

  Response to comment 13: The guidelines were defined to include DASH diet in accordance with AHA recommendations.

- **Comment 14:** On Research Question 4: I don't see anything about this in your research design.

  Response to comment 14: Research design was updated to show how educational sessions will be held in a community setting each week for 3 consecutive weeks.

- **Comment 15:** On consent/confidentiality: This would not be sufficient for an IRB/grant review. How will it be done (written/oral), where will it happen? Who will conduct the consent?

  Response to comment 15: Consent/confidentiality section was updated and details included to reflect how and when consent will be obtained. Consent Form included in Appendix.

- **Comment 16:** On Inclusion and Exclusion criteria: Be more specific here.

  Response to comment 16: Exclusion and Inclusion criteria made more specific and specific details added about places of recruitment as addressed in comments from other reviewers.

- **Comment 17:** On Phase I of study design: Who will you work with? How will this be accomplished? Also, there are lots of existing apps for this. A funder would want you to use an existing app so they don't have to pay for its development. My recommendation here is that you research some existing and propose to use it. At a minimum, propose to adapt something existing.

  Response to comment 17: Phase I uodated to reflect working in conjunction with Emory students to develop specific dietary guidelines adapted from DASH diet, for both groups. Since the guidelines have to be study specific and have the ability to send alerts to participants for follow-up time period, it makes sense to develop a new app for the said purpose.

- **Comment 18:** On Phase III of study design: I would suggest that the educational content be similar, but the mode of training/education be different.

  Response to comment 18: The educational content is somewhat similar but the addition of strong emphasis on how to reduce sodium in the diet among the experiment group and the ability of the participants to follow instructions and the subsequent result is the main question of the study which needs to be evaluated.

- **Comment 19:** On Phase IV of study design: In reality, it is very hard to get patients to do this after the study. I would suggest you build in incentives or ongoing activities to help make this possible.

Response to comment 19: Incentives section was added to the study design. Details on how the participants will be contacted and reminded of the upcoming visit were also added in the same section.

- **Comment 20:** On Data Analysis section: Need some specifics here. What will you measure? What kinds of tests will you use? Will you control for any patient demographics?

  Response to comment 20: Data analysis section was updated to reflect the exact method for data analysis.

- **Comment 21:** On Difficulties/Limitations section: Please review the concept and discuss more accurately.
- **Response to comment 21:** The whole section was updated to clarify the difficulties and limitations of the study.

Chapter V

Grant Proposal

Specific Aims

1) To identify and recommend specific dietary guidelines for reducing blood pressure catering to the African American community with individuals who are pre-hypertensive and within the ages of 18-35.
2) To assess the effectiveness of a modified dietary regimen in preventing incidence of high blood pressure among this subgroup.
3) To assess the role of community education efforts coupled with technological component in delivering health education.
4) To make recommendations in conjugation with American Heart Association (AHA) to enhance current dietary guidelines for African Americans to a comprehensive diet management plan in order to replicate best practices for prevention of hypertension and subsequently cardiovascular disease among these individuals.

Null Hypothesis*:* Dietary modifications with focus on a low sodium diet, has no effect on lowering blood pressure for pre-hypertensive African American individuals between the ages of 18-35.

Alternative Hypothesis*:* Dietary modifications with focus on a low sodium diet, has effect on lowering blood pressure for pre-hypertensive African American individuals between the ages of 18-35.

Background and Significance

Introduction

The systolic and diastolic blood pressures have a strong, continuous and significant effect on the development of cardiovascular disease in the future. This significant association has been proven in many epidemiological studies done on patients with optimal or high blood pressure (Dariush Mozaffarian & Subcommittee, 2015) (Gerd Assmann MD, 1988) (Peter W. F. Wilson, 1998). A study done on patients categorized into three categories of optimal, normal or high normal blood pressure found that men and women with high-normal blood pressure at base-line examination had a higher incidence of cardiovascular disease on follow-up than those with optimal blood pressure. These relationships were consistent in both men and women and in both age groups, and they persisted after adjustment for multiple cardiovascular risk factors (Ramachandran S. Vasan, 2001). This significant correlation highlights the importance of preventing high blood pressure and subsequently prevent heart disease in patients who might not be otherwise susceptible of developing any cardiovascular event. The effects of pre-hypertension on risk factors for heart disease as well as high cholesterol and Diabetes Mellitus were also explored in another study which included 39% of persons who were normotensive, 31% who were pre-hypertensive, and 29% who were hypertensive. The age-adjusted prevalence of prehypertension was greater in men (39.0%) than in women (23.1%). African Americans aged 20 to 39 years had a higher prevalence of prehypertension (37.4%) than whites (32.2%) and Mexican Americans (30.9%). The probabilities of above-normal cholesterol levels, overweight/obesity, and diabetes mellitus, which are common conditions leading to cardiovascular disease, were also greater for persons with prehypertension vs normotension (Kurt J. Greenlund, 2004).

The Disease Burden

A report published by the National Center of Health Statistics (NCHS) found that the overall prevalence of hypertension among U.S. adults aged 18 and over was 29.1% in 2011–

2012, similar to the prevalence in 2009–2010 (Tatiana Nwankwo, 2013). The same report also found that the prevalence was comparable among sexes with men at 29.7% and women at 28.5% and that the highest rate of hypertension was among non-Hispanic black adults, at 42%. This means that despite progress in prevention, treatment, and control of high blood pressure during the past few years, hypertension remains a major public health challenge, especially among the African American group. Also, the control of hypertension has neither met the goal of the Healthy People 2020 (61.2% by 2020) nor the Million Hearts Initiative (65% by 2017). These results provide evidence for continued efforts to improve the management of hypertension in order to attain these goals.

Furthermore, there is significant cost associated with the management of Hypertension in the US. Total costs associated with high blood pressure in 2011 in the US were $46 billion in health care services, medications, and missed days of work (Tatiana Nwankwo, 2013). According to a report published by the Agency of Healthcare Research and Quality (AHRQ), in 2010, 58.6 million adults or 25.1% of the U.S. community population age 18 and older received treatment for hypertension (Davis, 2013). The percentage with reported treatment for hypertension in age groups, 45–64 years was 32.4% and for 18–44 years was 6.1%. A higher percentage of non-Hispanic African Americans were treated for hypertension (30.4%) than those who were non-Hispanic white (26.7%) (Davis, 2013). The mean expenditure per person for the treatment of hypertension was higher for adults age 65 and older ($778) than for adults ages 45–64 ($715) or ages 18–44 ($636). Although the cost is lower than older adults, this number is still significantly high for a disease that's supposed to manifest during the later years of life. The same study found that the mean expenditure per person for the treatment of hypertension was higher for Hispanics and non-Hispanic

African Americans ($981 and $887, respectively), than for non-Hispanic whites ($679) and non-Hispanic others ($661) (Davis, 2013).

Hypertension among African-Americans

The potential causes for the higher rate of Hypertension in African Americans can include either biological differences in the mechanism of blood pressure control or differences in the environment and habits of African Americans and other races. The higher prevalence of hypertension in African Americans living in the United States as compared to black patients living in Africa demonstrates that environmental and behavioral characteristics are the more likely reasons for the higher prevalence in African Americans living in the United States (Richard S CooperEmail author, 2005). Another interesting finding among several studies has been the linkage of salt sensitivity to race. Salt sensitivity is a measure of how one's blood pressure responds to salt intake. People are either salt-sensitive or salt-resistant and those who are sensitive to salt are more likely to have high blood pressure than those who are resistant to salt. African Americans have been consistently shown to have a greater frequency of salt sensitivity than whites. One study observed that 73% of African American hypertensive patients were salt sensitive compared with 56% of a white hypertensive group; but in the normotensive population, the frequency of salt sensitivity among African Americans (36%) was similar to that seen among whites (29%) (Weinberger, 1996), while another found that normotensive salt sensitivity may also be higher in African Americans and less frequent in Caucasian Americans (whites), but only when dietary potassium is deficient (R. Curtis Morris, 1999).

However, one genetic hypothesis is insufficient to explain the difference in Hypertension among races and research suggests that dietary habits are also important in the salt sensitivity-blood pressure relationship. According to a National Health and Nutrition

Examination Survey (NHANES) study (2009–2010), it was reported that compared with whites, African Americans consumed on average lower amounts of whole grains, fruits, and vegetables (0.8, 1.2, 1.3 servings/day for black men, respectively, vs. 1.1, 1.6, 2.1 servings/day for white men) (CDC, 2012). Data from a previous NHANES 2007–2010 showed that there was a significant difference between African Americans and whites in the percentage of calories consumed from fast foods (defined as foods usually sold at eating establishments for quick availability or takeout. Young adults aged 20–39 consumed the highest percentage of calories from fast foods (21 % in African Americans vs. 15 % in whites) (Frayar, 2013). Another study showed that less favorable multiple nutrient intake by African Americans than non-Hispanic white Americans accounted, at least in part, for higher blood pressure among African Americans. Multiple linear regression, standardized data from four 24-hour dietary recalls per person, two 24-hour urine collections, and 8 blood pressure measurements were used to quantitate the role of foods, nutrients, and metabolites in higher African American blood pressure. The extensive data collected showed that compared with non-Hispanic white Americans, African American's average systolic/diastolic pressure was higher by 4.7/3.4 mm Hg (men) and 9.0/4.8 mm Hg (women). Lesser intake of vegetables, fruits, grains, vegetable protein, glutamic acid, starch, fiber, minerals, and potassium, and higher intake of processed meats, pork, eggs, and sugar-sweetened beverages, along with higher cholesterol and higher Na/K ratio, related to in higher African American's blood pressure. Control for 11 nutrients and 10 non-nutrient correlates reduced higher systolic/diastolic pressure in African Americans (52% and 33% reduction in men) and (21% and 27% reduction in women) (Stamler J1, 2013). One important reason for over-consumption of fast food can be due to the fact that African Americans tend to be within the low-income range category and thus simply cannot afford healthy food such as fresh or

organic fruits and vegetables. The National Poverty Center estimates that over 25% of African Americans are poor compared with 9.4% of whites. Poverty can lead to hypertension, perhaps mediated by chronic stress as an added factor and this can serve as a reasonable explanation for the high rates of Hypertension among this race.

Diet affects Blood Pressure

Substantial evidence points towards the fact the blood pressure can be controlled through diet. Documented dietary modifications include, reduced salt intake, weight loss, physical activity and reduced alcohol consumption. Over the past decade, increased potassium intake and consumption of dietary patterns based on the "DASH diet" have emerged as effective strategies that also lower blood pressure. Specifically, African Americans are especially sensitive to the BP-lowering effects of reduced salt intake, increased potassium intake, and the DASH diet (Lawrence J. Appel, 2006) (Laura P. Svetkey, 1999) (George A Bray, 2004). There is plenty of evidence, multifactorial dietary modifications help to reduce blood pressure (A Ziv, 2013). One study determined the effects on blood pressure and other cardiovascular disease risk factors of a comprehensive lifestyle intervention (sodium reduction, calorie reduction and physical activity). It found that among hypertensive overweight adults already on antihypertensive medication, a comprehensive lifestyle intervention can substantially lower blood pressure and improve blood pressure control (Edgar R. Miller, 2002). However, salt remains the most important dietary component causing significant reductions in blood pressure when its intake is even moderately reduced. And this result holds true irrespective of age, sex or ethnicity (Feng J He, 2013).

The above-mentioned studies all show effects of dietary modifications in individuals with high blood pressure. However, there is a small research gap in exploring effects of dietary modification among individuals with pre-hypertension. Some studies in the past have

provided mixed results. One showed that moderate dietary sodium restriction does not lower blood pressure in patients with this degree of hypertension (G C Watt, 1983). This study was only done on 18 participants and out of them 5 failed to follow the reduced sodium diet. Also notable is the fact that the study implied only a moderate decrease in sodium in the diet of the participants. Another study done one year later, showed some decrease in blood pressure when a moderate reduction in salt intake was coupled with beta blocker given to individuals with mild hypertension (T M Erwteman, 1984). A study which explored the effects of reduced salt intake as well as weight loss found some effectiveness in altering both factors but concluded that further studies were needed to establish a clear connection (Paul K. Whelton, 1992). A randomized study on stage I Hypertensive patients concluded that individuals with above-optimal BP, including stage 1 hypertension, can make multiple lifestyle changes that lower BP and reduce their cardiovascular disease risk (Patricia J. Elmer, 2006), but the study participants were only followed for 6 months and thus the results cannot be deemed conclusive for long term efficacy. A randomized trial conducted in 2006, involving pre-hypertensive individuals showed statistically improved results when the individuals were followed for a period of almost 18 months and given low sodium diet along with comprehensive lifestyle modification plan and showed improved blood pressure measurements (Patricia J. Elmer, 2006). Interestingly enough a European study done in 2011, concluded that high salt intake did not have any long term effects on reducing blood pressure and eventually preventing cardiovascular events (Katarzyna Stolarz-Skrzypek, 2011). The study however is limited to Europeans and relatively young people and it notes that the results cannot be generalized to any other population especially African Americans due to their increase salt sensitivity. A similar study done in Boston, used data from 2,632 normotensive subjects, ages 30–64 years, in the Framingham Offspring Study, to address the

question of the long-term effect of dietary sodium in particular on systolic (SBP) and diastolic blood pressures (DBP) over 16 years of follow-up. They concluded that the long-term data from the Framingham Study provide no support for lowering sodium intakes among healthy adults to below 2.3 g/day as recommended (Lynn L. Moore, 2017). However, in this particular study sodium was not the only element that was being manipulated but potassium calcium levels were also taken into account and thus the combined effect of these nutrients had a significant role in lowering blood pressure.

One study done in 2014 incorporated a technological component in addition to the DASH diet and asked the participants to record body weight, steps taken and through weekly newsletters, participants engaged in electronic reporting and goal setting and received feedback on progress. The study found that electronic reporting led to more feedback, more steps taken and greater reduction in systolic blood pressure compared to the control group. Although the sample size was small with only 23 participants this study highlights the importance of concentrating efforts not only toward adoption and initiation of innovative risk-reduction strategies but also toward the provision for long-term maintenance of a healthy lifestyle which the participants can follow (Dorough, 2014).

Health status is influenced by individual characteristics and behavioral patterns (lifestyles) but continues to be significantly determined by the different social, economic and environmental circumstances of individuals and populations. The relationships between these social factors and health, although easy to observe, are less well understood and much more difficult to act upon. Also, given the widespread variation in research already published, it is necessary to test dietary modification interventions in individuals with a broad range of demographic and clinical characteristics. This would help to further explore the relationship between dietary factors and results of the modified diet among African

American individuals of a relatively younger age group, before their pre-hypertensive status evolves further and leads to Hypertension that would traditionally require not only vigorous lifestyle change but also prescription drugs.

Preliminary Studies

None

Research Design and Methods

Research Design

The study will use a Quasi Experimental research design study with African American participants who are already pre-hypertensive and between the ages of 18-35. The two group pretest posttest design will assign the participants into two groups; a study group and a control group. One group will receive detailed dietary advice in a community educational setting with special emphasis on sodium reduction in diet by following the "DASH" diet, advice on how to lower sodium in food and ways to modify recipes and shop smart to include less sodium in the diet coupled with a technological component with a smartphone app called the "eDiet" app which they can use to monitor dietary sodium levels and receive recommendations for dietary modifications. The control group will receive general hypertension prevention advice coupled with dietary recommendations according to the "DASH" diet plan, of how to eat a healthy and balanced diet. The information will be distributed in the form of study material and pamphlets without any specific sodium reduction means or any technological component associated to it. The two groups will be monitored throughout a period of 18 months at 3,6,9,12 and 18 month intervals for changes in blood pressure and results will be analyzed at the end of the experiment.

The rationale for focusing African-American individuals is the high incidence of Hypertension and cardiovascular disease amongst them and by focusing on pre-hypertensive

individuals, the study will explore how significant of a role diet can play in the prevention of developing Hypertension in the future.

Research Questions

1. Does specific dietary advice focusing on sodium reduction in diet, help to lower blood pressure in pre-hypertensive individuals?
2. Do community education efforts play a part in modifying behavior of individuals to adapt healthy practices?
3. Can current dietary guidelines on hypertension be modified and improved upon to cater to the African-American community in order to reduce incidence of developing Hypertension?
4. Can a technological component like a smartphone app be useful in helping to modify behavior to adapt healthy practices among the African American community?
5. Can pre-hypertensive individuals reverse the blood pressure increase through dietary control only and without medication?

Objectives

The objectives of this study are:

- To decrease the incidence of developing hypertension among high risk group i.e. African American individuals who are already pre-hypertensive.
- To reduce the incidence of developing Hypertension which will subsequently prevent Cardiovascular compilations in the long term.
- To educate the African American community about best practices and altering lifestyle in order to prevent early disease incidence.
- To demonstrate the use of everyday technology in improving health status of individuals.

- To increase awareness among African American individuals regarding the adverse effects of high blood pressure and subsequent complications arising from cardiovascular issues.

Consent/Confidentiality

After obtaining IRB and Ethics approval, informed consent would be obtained from all participants and the study procedure and timeline explained to the participants. Written consent will be obtained while recruiting participants at Emory University during the initial phase. In addition, procedures will be put in place to encrypt identifiable data as well as protocols for storing data.

Participant Recruitment

Inclusion Criteria: African American participants with age 18-35, both males and females with diagnosed pre-hypertension (Systolic pressure from 120 to 139 millimeters of mercury (mm Hg) or a diastolic pressure from 80 to 89 mm Hg based on the average of two or more blood pressure readings taken on separate occasions in a consistent manner).

Exclusion Criteria: Otherwise healthy individuals without a co-morbid condition in addition to high blood pressure, such as diabetes or any cardiovascular event. Also, individuals taking any medication to lower blood pressure or on NSAIDs (Non-steroidal Anti-Inflammatory Drugs) other than on occasional basis.

Recruitment/Advertisement: The participants will be recruited using convenience sampling from the Metro Atlanta area. The study will be publicized in local area hospitals and community health centers to recruit willing participants. Apart from these locations, participant recruitment will also be done through local area churches and health fairs. The study will also be advertised in local physician office's, all major area hospitals as well as predominantly African-American churches to encourage participants to enroll in the study.

Incentives: For recruiting in the study, a smartphone will be provided to each participant in the study group, with the eDiet app pre-installed and data usage paid for up to 5MB of use. The participants will get to keep the smartphone on successful completion of all follow-up visits. Furthermore, monetary incentives in the form of gift cards will be provided to participants in both study groups for their time and commitment at each visit to ensure participant retention in the study and subsequent follow up every 3 months during the course of the 18-month period.

Sample Size

Approximately 200 participants will be recruited to be divided into two groups of 100 each comprising the study and the control groups. The participants will be assigned using the non-equivalent group design to ensure as similar characteristics as possible among the participating individuals. An expectation of at least an 80 % participant retention rate till the end of the study will enhance the study validity.

Methodology

Phase I*:* Phase I of the study will include preparation of the study material including the development of the smartphone app in collaboration with Emory University public health students.

1. Study material will comprise of:
    - ***Experiment Group:*** DASH diet plan (1500 mg. sodium) + Specific advice on sodium reduction in diet + Smart shopping by reading labels + Sodium reduced version of common recipes and exercise.
        - Teaching material will be developed for three weekly sessions of one-hour duration each for the study group, delivered in a community health education setting at a local community center or local area church.

- First session will be a general introductory session, followed by introduction to specific dietary guidelines to reduce sodium in the diet by explaining DASH diet regimen. Second session will comprise of emphasis on eating healthy and reducing sodium in the diet as well as including more fresh fruits and vegetables in the diet. Third session will deal with modified recipes, how to shop smart by effectively reading labels pertaining to sodium content in food and how to use the eDeit app for utilization and reference to the study material.

- *Control Group:* Generalized DASH diet plan (2300 mg. sodium) + Advice on importance of eating a balanced diet and exercise.
    - The study material will be printed in the form of educational pamphlets and distributed to the participants during recruitment and consent phase.

2. Smartphone app will contain information about the dietary guidelines emphasized in the study sessions and will also contain modified recipes for preparing commonly consumed foods, using low salt content. Volunteer student from Emory University will be hired to develop the smartphone app according to study requirements with special emphasis on easy to use interface so that people with no knowledge or experience of a smartphone can also use the app with ease.

Phase II*:* Second phase of the study will include recruiting participants by visiting local community centers, physicians' offices, local churches and hospitals. The participants will be selected based on the inclusion and exclusion criteria and will be explained fully the requirements for participating in the study as well as offered monetary incentives for each visit for follow-up to ensure participant compliance and retention.

Participants will be divided into two groups. One group will be selected to receive the dietary advice educational sessions in a community setting with special emphasis on DASH diet and reduced salt intake and will be provided with a smartphone with the app pre-installed. The second (control) group will only receive general advice in compliance with DASH diet regarding blood pressure and eating healthy.

Both groups will be provided with demographics and general health forms to complete as well as a diet form with general questions about their existing diet. This information will be used to ensure as similar characteristics of participants as possible while assigning study groups.

Phase III*:* After recruitment and initial processing, the participants in the study group will be enrolled to participate in the weekly sessions for receiving dietary advice and education material. The educational sessions will be held in a community education setting in local community centers or churches. Multiple sessions will be held around Metro Atlanta area so as to avoid participants having to travel long distances. The participants will be required to attend three sessions, once every week, of one-hour duration each and will be provided with educational material regarding dietary modification in the diet. The participants will be trained to utilize the eDiet smartphone app in an effective way to use it to get modified recipes with low sodium content and to ensure healthy eating habits by incorporating more fresh fruits and vegetables in the diet and to avoid purchasing foods with high sodium content as well as the importance of exercise.

The control group will be given general advice regarding blood pressure, risk factors and complications. They will be provided with pamphlets encouraging regular monitoring and general advice on eating healthy foods in accordance to the DASH diet and limiting sodium intake up to 2300 mg. daily intake as well as exercise.

The content of the three sessions for the study group will include the following:

1. ***Introductory session.*** This session will familiarize the participants with the objectives of the study as well as general information about hypertension, cardiovascular disease and how being pre-hypertensive can have an effect on the blood pressure later on. The session will also familiarize participants with the DASH diet regimen and the importance of reducing sodium in everyday diet, limiting it up to 1500 mg. daily.
2. ***Dietary advice.*** Specific dietary advice will deal with educating individuals on how to reduce sodium content in their diet (Cooking, eating out, shopping smart), to maintain daily recommended sodium intake levels, how to incorporate more fruits and vegetables, to avoid cooking with canned products and replace canned goods with fresh ingredients, all of which are readily available and fairly common in supermarkets. The importance of a healthy lifestyle including exercise and monitoring blood pressure regularly will also be emphasized. The participants will also be instructed on how to estimate sodium content in the food that they cook at home and read labels and shop smart to get an estimate of the sodium contained in the foods.
3. ***Technology component.*** The final sessions will deal with the technological component on how to effectively use the smartphone app to have access to recipes of commonly prepared foods, but with reduced sodium content. In addition, they will be instructed on how to utilize the app for estimating sodium content in the food that they are preparing or buying from outside.

Data Collection Phase*:* This phase will consist of monitoring blood pressure and collecting data from both groups in order to have comparison. After collecting data at the baseline

level, the monitoring will be done every three months at 3,6,9,12 and 18 months. The monitoring will consist of the following tests:

- Blood pressure readings.
- Spot urinary sodium test.

The participants will be instructed to visit the local community center or a local church on a specified date for follow up. Multiple data collection centers will be setup for two consecutive days for the convenience of the participants and incentives will be provided for each follow-up visit. The participants will be given a phone call as a reminder to attend their follow up visit and courtesy alerts through the eDiet app will also be provided to the participants in the study group.

The collection of spot urine sodium will give an idea of the compliance of the participants to a low-sodium diet. The participants will be instructed to eat their usual/normal diet before the spot urine test so as not to risk skewing the result by eating either too much fast food or too much fruits and vegetables the day before. To prevent this from happening, participants will be instructed to log 24-hr food intake before the scheduled visit to ensure a balanced diet before the test. The 24-hr sodium will be estimated from the spot urine test by using Tanaka's formula: (T Tanaka, 2001)

$$\textbf{Estimation of Na24h (mEq) excretion} = 21.98 \times \text{NaUr}^{0.392}$$

A final survey will be given to the participants to fill out which will include their thoughts on the study and the ease of following dietary advice as well as modified recipes and the smartphone app.

Date Analysis Phase*:* The analysis phase will consist of analysis using the data obtained from both groups to compare the contrast the differences, if any, among the blood pressure readings of the two groups. Analysis will be done using SPSS software. MANOVA analysis

will be used to compare means between groups pre and posttest as well as at 3,6,9,12 and 18 months' intervals during the course of the study.

Phase IV*:* The fourth phase will be dissemination of results in the form of PDF document along with the results of the analysis and will be shared with all participants as well as distributed to all stakeholders.

Phase V*:* The final phase of the study will consist of translating the data in the form of dietary recommendations for African Americans with slightly elevated blood pressure. The recommendations will serve as a future tool in the prevention of this chronic disease and help to either reverse or slow it progression and will cater to the specific needs of the sub-group.

Difficulties/Limitations

The limitation of the study can be as follows:

1. Participant bias – Regarding following low sodium diet, recipes, healthy lifestyle choices in both groups. The participants who are self-reporting on the diet might have a tendency to agree to following the advice but might not be doing so in practice. This will be dealt with by measuring 24-hr sodium content by using the spot urine sodium test to assess if the sodium was actually reduced in the diet or not and how sodium levels relate to an increase or decrease in blood pressure.
2. Selection bias – Since the study will aim to recruit at select recruitment locations, selection bias can be introduced and this will undermine the external validity of the study. This bias can be removed by a pre-screening of the participants with careful data collection to ensure participants have as similar characteristics and dietary habits as possible.

3. Participant loss – Since the study is 18 months long and requires follow up multiple times, some participant drop out or loss of follow up will occur. But it can be prevented by offering incentives for each visit and the smartphone app will help to motivate participants to stick to healthy lifestyle choices.
4. Internal Validity – Since this study is not a randomized study, the threat of internal validity is present. If the results of the study are statistically significant, it is recommended to do a large scale study with true randomization and a larger sample size to establish causality.
5. Participant cross-over – Participants may have a tendency to talk to each other and discuss study details and adapt modified dietary aspects. This can be dealt with by carefully analyzing biographic data from participants and taking care to not assign participants from the same family into the two different groups.
6. Availability of healthy affordable options – Although there are no food deserts in the metro Atlanta area, affordability is still an issue with fresh fruits and vegetables and the widespread availability of these options instead of junk food which is much more readily available. This can be combatted by education patients on the importance of fresh fruits and vegetables in the diet as well as using recipes made with simple ingredients and commonly available fruits and vegetables from all seasons to ensure the participants can comply to the dietary regimen.
7. Limitations of smartphone usage and app utilization – The study will compensate participants for the data usage during the study period to effectively use the smartphone app but this can also lead to limitation of usage after the study period has ended or using smartphone data excessively for purposes other than using the eDiet app. For dealing with this issue, it is recommended to emphasize the usage and

importance of the technology for the betterment of health. The app will have a user-friendly simple software that will not require learning beyond the community education lessons so that the participants can use the app at home with ease and effectively use it for the purpose that it is intended.

Ethical Aspects of the Proposed Research

The first aspect of Ethics will deal with protection of the participants. The individual's medical records and information will be encrypted and made accessible to researchers only and for the sole purpose of the study. Providing limited access to identifiable data will also be ensured so as to maintain privacy of the participants. Furthermore, detailed informed consent will be taken from the participants dealing with how and where the information will be used and disseminated and how their information will be protected. Second aspect of ethics will deal with ensuring the best interest of individuals in both arms of the study. While the control group may not be given specific dietary advice but will still be provided with information regarding hypertension risk factors and be advised to adapt a healthy lifestyle. The final aspect of ethical consideration will take into account the fact that the participants are not put in any risk or have to deal with complications arising as a result of the study, by ensuring the participants have access to researcher information and can contact the researchers anytime they have a question of face an issue. Thus, Transparency will be ensured in a way that is beneficial to both the researchers and the participants.

Biographical Sketch

Name: Sobia Satta**r**

Position Title: Student Researcher/Principal Investigator

Education/Training:

INSTITUTION & LOCATION	DEGREE	COMPLETION DATE (MM/YYYY)	FIELD OF STUDY
NUST Medical College Islamabad, Pakistan	M.B.B.S. (Bachelor of Medicine, Bachelor of Surgery)	01/2005	Medicine
PIMS Hospital Islamabad, Pakistan	Residency in Medicine &Nephrology	01/2006	General Medicine & Nephrology
Emory University Atlanta, GA	M.P.H Master of Public Health	07/2017	Public Health

1. Personal Statement

Sobia Sattar is a second year graduate student currently earning a Master of Public Health degree at Rollins School of Public Health with a focus on prevention science and will graduate in the summer of 2017. Sobia Sattar was trained as a Physician overseas where she worked in an urban area public hospital and completed her residency in Medicine with a focus on Nephrology. She has been a presenter in many Hypertension preventive workshops throughout her career. She is currently working with "Innovative Solutions for Disadvantage and Disability" (ISDD), to develop a Mental Health Literacy Curriculum for Veteran parents with a focus on PTSD. Her work for this project will be mentored by Dr. Lea Janice who has extensive experience in hypertension and Nephrology.

2. Positions and Honors

- Medical Doctor: PIMS Hospital, Medicine and Nephrology Department
- Medical Doctor: AFIC Hospital, Cardiology Department
- Student Researcher: TEACH study, Emory University
- Student Intern: ISDD, Curriculum Developer

3. Contribution to Science

None

4. **Research Support**
   - **TEACH Research study – Emory University.**
     - Served as HIV/AIDS counsellor for the Faith-based TEACH P4 study in African American women in Metro Atlanta churches. The study aimed to assess the usefulness of P4 program for preventing HIV/AIDS among the African American women and to practice safe sex techniques.
     - Also served as Quality Insurer for administering the TEACH P4 program among African American women.
   - **Grant proposal to study the effects of dietary modifications in pre-hypertensive African-Americans aged 18-35.**
     - Principal Investigator

AHA Research Project Environment

Applicant's Name: Sobia Sattar

FACILITIES:

- Emory University School of Public Health – Development of education material, Storage, Data processing/analysis
- Community Health Centers, Metro Atlanta – Consent, Initial visit as well as follow-up visits.
  - Neighborhood Union Health Center
  - Healing Community Center
  - Good Samaritan Health Center
- Local Churches, Metro Atlanta Area – Consent, Initial visit as well as follow-up visits.
  - New Hope AME Church
  - Cascade United Methodist Church
  - Beulah Missionary Baptist Church

LABORATORY:

- Emory University Hospital Laboratory – Spot Urine Sodium Content

COMPUTER:

- Emory University School of Public Health – Data processing, storage and analysis

OFFICE:

- Emory University School of Public Health

MAJOR EQUIPMENT:

- Computers – Emory University School of Public Health

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Bernauer, PhD; Patricia Borhani; Carlos de la Cruz; Andrew Ertl; Doug Heustis; Marshall Lee, MD; Wade Lovelace; Ellen O'Connor; Liz Peel; Carolyn Sugars, RD; James O. Taylor, MD; Beth Walker Corkery, MPH; Denis A. Evans, MD; Mary Ellen Keough, MPH; Martha Clare Morris, MPH; Eleanor Pistorino, RN; Frank Sacks, MD; Mary Cameron, MS; Sheila Corrigan, PhD; Nancy King Wright; William B. Applegate, MD; Amy Brewer, RD; Laretha Goodwin, RN; Stephen Miller, MD; Joe Murphy, PhD; Judy Randle; Jay Sullivan, MD; Norman L. Lasser, MD; David M. Batey, PhD; Lee Dolan; Sheila Hamill; Pat Kennedy, RD; Vera I. Lasser, MA; Lewis H. Kuller, MD; Arlene W. Caggiula, PhD; N. Carole Milas, MS; Monica E. Yamamoto, DrPH; Thomas M. Vogt, MD; Merwyn R. Greenlick, PhD; Jack Hollis, PhD; Victor Stevens, PhD; Jerome D. Cohen, MD; Mildred Mattfeldt-Beman, RD; Connie Brinkmann, RN; Katherine Roth, RD; Lana Shepek, RD; Charles H. Hennekens, MD; Julie Buring, ScD; Nancy Cook, ScD; Ellie Danielson, MIA; Kim Eberlein, MPH; David Gordon, MAT; Patricia Hebert, PhD; Jean MacFadyen; Sherry Mayrent, PhD; Bernard Rosner, PhD; Suzanne Satterfield, MD; Heather Tosteson, PhD; Martin Van Denburgh; Jeffrey A. Cutler, MD; Erica Brittain, PhD; Marilyn Farrand, RD; Peter Kaufmann, PhD; Ed Lakatos, PhD; Eva Obarzanek, PhD.; John Belcher; Andrea Dommeyer; Ivan Mills; Peggy Neibling; Margo Woods, ScD; B.J. Kremen Goldman, RD, MS; Elaine Blethen, RD. (1992). The effects of nonpharmacologic interventions on blood pressure of persons with high normal levels. Results of the Trials of Hypertension Prevention, Phase I. *JAMA Internal Medicine, 267*(9), 1213-1220. doi:10.1001/jama.1992.03480090061028

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Appendix:

Appendix A: Assent and Consent Form

We are asking you to participate in a research study. This form is designed to give you information about this study. We will describe this study to you and answer any of your questions.

Project Title: Study the effects of dietary modifications in pre-hypertensive African-Americans aged 18-35.

Principal Investigator: Sobia Sattar
Executive Masters of Public Health, Emory University
sobia.sattar@emory.edu

Faculty Advisor: Rebecca Filipowicz. MPH, MS, MCHES
Emory University
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Lea Janice, M.D.
Emory University Hospital Midtown
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What the study is about
The purpose of this research is to determine if limiting the amount of sodium taken in everyday diet can have an effect on lowering blood pressure for pre-hypertensive individuals of African American descent.

What we will ask you to do
We will ask you to attend educational sessions in a community based classroom setting to educate about the importance of lowering blood pressure and ways and means to reduce dietary sodium. The weekly sessions will be of one-hour duration each for three weeks. They will be accompanied by learning through an educational smartphone app which will aid in furthering the teachings of the study material. After the educational sessions are over, you will be required to visit a local community center or a local church reserved for your area, to provide a urine sample and blood pressure measurements to be recorded by research study volunteers. The visits will be scheduled at 3,6,9,12 and 18 months after recruitment. Transport will not be provided however the visits can be scheduled at a convenient time within a 3-day timeframe.

For control group:
We will ask you to read and self-educate yourself about the importance of lowering blood pressure and ways and means to reduce dietary sodium. The information will be given to you in the form of printed materials. After that you will be required to visit a local community

center or a local church reserved for your area, to provide a urine sample and blood pressure measurements to be recorded by research study volunteers. The visits will be scheduled at 3,6,9,12 and 18 months after recruitment. . Transport will not be provided however the visits can be scheduled at a convenient time within a 3-day timeframe.

Risks and discomforts
While there are no physical risks of the study, study participants sometimes might find it hard to follow a low sodium diet that is being recommended or to follow the modified recipes available to reduce sodium in the diet, thus some feelings of anxiety are to be expected.

Benefits
Direct benefits of the study will be in the form of improved overall health due to healthy eating practices as well as lowering of blood pressure due to following a low sodium diet. Some other benefits through educating oneself about the risks of hypertension in the future and self-control by refraining from eating unhealthy foods are also to be expected. Added benefit of learning about smartphones and using smartphone technology for health benefits will also be emphasized.
Information from this study will benefit people in similar situations and we hope to learn more about how to reverse a chronic disease such as hypertension and manage it without depending on medication.

Cost of participating
The costs could include transportation costs for the follow-up visits and costs of buying fresh fruits and vegetables in order to follow the recommended diet.

Payment for participation
You will be given incentives for participating in the study. Since the study also requires a smartphone and data plan, both will be provided to you and you will have the option of keeping the smartphone at the end of the study. Furthermore, for each follow-up visit gift cards of $50 will be provided to offset the transportation costs as well as a payment for the visit.

For control group: You will be given incentives for participating in the study. For each follow-up visit gift cards of $50 will be provided to offset the transportation costs as well as a payment for the visit.

Use of Tissue Samples/DNA for Future Studies
A urine sample will be taken from each participant at each follow-up visit. Each sample will be taken to a lab and analyzed to assess sodium content in the sample. There are no plans to further store the sample for future and will be destroyed after the results are obtained. The sample will have a unique identifier number attached to it and the information of true identity will only be available to the principal investigators of the research and will not be made available to the student volunteers collecting the samples. Future access to the stored samples will not be provided.

Abnormal Test Results

In the event that we get back any abnormal results from urine test and blood pressure recording, we will inform you about these results within 2 days and recommend you contact your private medical provider for follow-up. Please be advised that as researchers we are not trained to diagnose or treat medical conditions. You or your insurance company will be responsible for payment of any treatment of medical conditions.

If you are injured by this research
In the event that any research-related activities result in an injury, treatment will be made available including first aid, emergency treatment, and follow-up care as needed. Cost for such care will be billed in the ordinary manner to you or your insurance company. No reimbursement, compensation, or free medical care is offered by Emory University. If you think that you have suffered a research-related injury, contact Sobia Sattar right away at sobia.sattar@emory.edu.

Privacy/Confidentiality
Please note that email communication is neither private nor secure. Though we are taking precautions to protect your privacy, you should be aware that information sent through e-mail could be read by a third party.

Data Sharing
De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Taking part is voluntary
It must be made clear that your involvement is voluntary and you may refuse to participate before the study begins, discontinue at any time or skip any questions/procedures that may make you feel uncomfortable with no penalty and no effect on the compensation earned before withdrawing.

Withdrawal by investigator, physician, or sponsor

The investigators, physicians or sponsors may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so, if you experience a study-related injury, if you need additional or different medication/treatment, or if you do not comply with the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

If you have questions
The main researcher conducting this study is Sobia Sattar a student at Emory University. Please ask any questions you have now. If you have questions later, you may contact Sobia Sattar at sobia.sattar@emory.edu. If you have any questions or concerns regarding your rights as a subject in this study, you may contact the Institutional Review Board (IRB) for Human Participants at 607-255-6182.

You will be given a copy of this form to keep for your records.

Statement of Consent
I have read the above information, and have received answers to any questions I asked. I consent to take part in the study.

Your Signature_____ Date_____

Your Name (printed)_____

Signature of person obtaining consent_____ Date_____

Printed name of person obtaining consent_____

This consent form will be kept by the researcher for at least five years beyond the end of the study.

Appendix B: Health Insurance Portability and Accountability Act Of 1996

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 requires all physicians and health care facilities to provide patients with a notice describing how an individual's medical information may be used and disclosed, and how a patient may obtain access to their personal health information.

Please note that there is an attached copy of HIPAA to this consent form, for the participant receiving medical or educational health services at Emory University. You must sign below, indicating that you have received a copy of our HIPAA policies, prior to receiving services.

I certify that a copy of the Health Insurance Portability and Accountability Act of 1996 was provided with the general consent form.

Appendix C: General Health Pre-Screening Form

Name:

DOB:

Age:

Sex:

Address:

Phone number:

Weight:

Height:

Participant Health Questionnaire

PLEASE NOTE:

This is a confidential record of your medical history and will be kept in this office.
Information contained here will not be released to any person except when you have authorized us to do so.

Marital Status*:*

- Single
- Married
- Divorced
- Widowed

Occupation: ***(if retired, previous occupation):*** **_____**

If disabled, Nature of disability: _____

Do you exercise routinely?

- No
- Yes

If *Yes*, what exercise/how often?

Have you ever smoked?

- No
- Yes

If *Yes*: No. cigarettes/day: _____

Tell us a little about your home environment: _____

(e.g. live alone, with family, single parent, house, apt., etc.)

Medical Information

1. Are you allergic to any drugs?

- No
- Yes

Please list: _____

2. List all medications you are taking regularly. ***(Include over the counter, herbal or natural remedies):*** **_____**

3. List any chronic conditions which you have been diagnosed to have:
_____

4. Have you ever had or been diagnosed to have:

Cataracts	Heart Disease	Ulcers	Anemia	Depression
Glaucoma	Heart Murmur	Digestive Disorder	Bleeding Disorders	Frequent Infection
Asthma	High Blood Pressure	Hemorrhoids	Bone or Joint Disease	Cancer (type)
Allergies	Pneumonia	Kidney Disease		
Stroke	TB/Lung Disease	Kidney Stone(s)	German Measles	High Cholesterol
Seizures/Epilepsy	Pleurisy	Diabetes or PreDiabetes	Rheumatic Fever	Prostate Enlargement
Heart Attack or Angina	Jaundice or Liver Disease		Chicken Pox	
		Thyroid Disease	Syphilis	

Dietary Information

1. Are you currently following any sort of restricted diet (including calorie, salt or sugar restriction)?

- No
- Yes

2. How many servings of fruits do you take daily? _____

3. How many servings of vegetables do you take daily? _____

4. How many servings of whole grains do you take daily? _____

5. On an average how many times per week do you eat a home cooked meal? _____

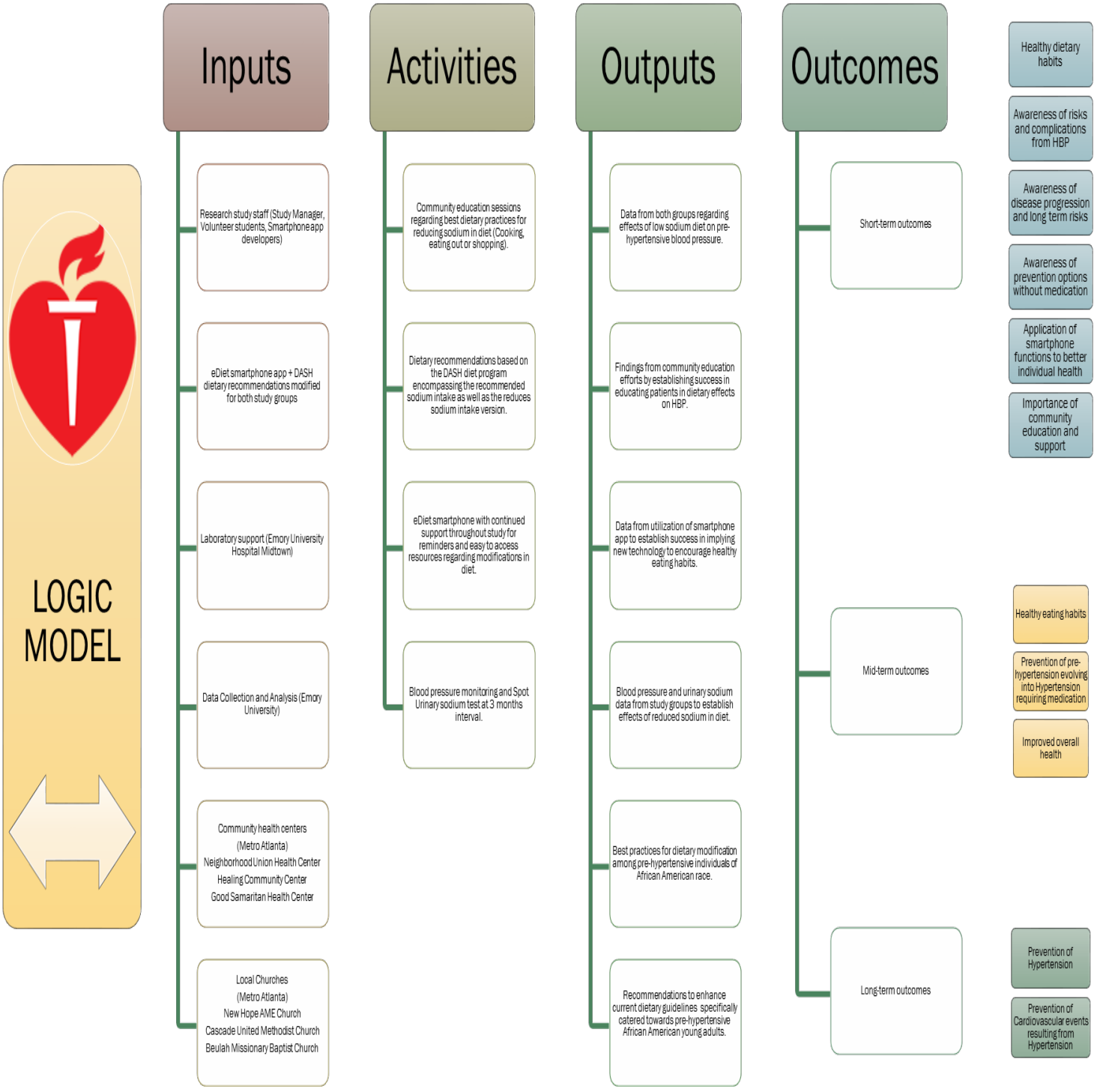
6. On an average how many times do you eat out per week? _____

7. When shopping for food from a grocery store, do you ever look at sodium content of the food? _____

8. Have you ever in the past followed ot attempted to follow a sodium/salt restricted diet?

- Yes
- No

Appendix D: Logic Model



Assumptions:

- Complete all study sessions and attend follow-ups for maximum benefit.
- Participants will continue to follow the healthy dietary recommendations even after conclusion of study.
- Aim to reduce sodium from diet and keep it at or around the recommended daily intake.
- Utilize smartphone app in an effective way and continuously monitor blood pressure.

External Factors:

- Availability of resources (transport) etc. to participate in study
- Support for smartphone usage after conclusion of study.
- Widespread availability of affordable healthy food choices to replace current diet.