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Kids Playing For Keeps: A Feasibility Study of Coronary Heart Disease Intervention in a Rural African American Community

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KIDS PLAYING FOR KEEPS: A FEASIBILITY STUDY OF CORONARY HEART DISEASE INTERVENTION IN A RURAL AFRICAN AMERICAN COMMUNITY.

by

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(Under the Direction of R. Greg Evans)

ABSTRACT

The prevalence of Coronary Heart Disease (CHD) and the associated modifiable risk factors, combined with the known health disparities that exist in the African American (AA) community, increases the significance of prevention exponentially. Theories involving genetic and environmental factors and their interaction are gaining popularity as relevant influences on both modifiable and fixed risk factors for CHD. Innovative and targeted strategies of health promotion and preventative measures are needed to combat the growing trend of modifiable risk factors for CHD within the southern rural AA population. The aim of this pilot study was to evaluate the feasibility and effectiveness of an after school diet and exercise intervention and the results within the community. A quantitative, quasi-experimental, pre and post-test design was used to examine the feasibility in recruiting rural, school-age AAs participants (n=58), their parents (n= 21) and community members (n= 26) and the effectiveness of the intervention program. The findings of this pilot study features the significance of an intervention provided to meet specific aspects of southern rural AA communities with a high prevalence of CHD. This research describes the rationale and methods used in an individual level intervention, within a rural AA community, with children as the proponents for change.

Continued research is needed to elucidate pathways by which promising strategies can be implemented to reduce the prevalence of modifiable risk factors and therefore close the gap of CHD disparities in southern, rural AA communities.

INDEX WORDS: Coronary heart disease, Modifiable risk factors, Hypertension, Health disparities, Culturally comprehensive, Youth empowerment.

KIDS PLAYING FOR KEEPS: A FEASIBILITY STUDY OF HEART DISEASE INTERVENTION IN A RURAL AFRICAN AMERICAN COMMUNITY.

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DEDICATION

To my Heavenly Father, with whom all things are possible. To my family for all of their love and support during what seems impossible. I also dedicate this work to my family and friends who know the devastating effects of coronary heart disease.

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In all things, I give thanks to God. To my wonderful, awesome, and spectacular family, who has been a blessing every day of my life, I say thank you. My parents, my husband and my children have sacrificed so much and I am truly grateful. I am especially blessed by the prayers and well wishes of those in my community, and again I am thankful. Thank you to my mentor, Dr. Vera Thurmond for her many years of support. I must also thank Mrs. Tessie Brown, who exemplifies the true meaning of friendship, every day of this journey.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

Kids playing for KEEPS: A feasibility study of coronary heart disease intervention in a rural African American Community.

Chapter 1: Background and Significance

Introduction

Coronary Heart Disease (CHD) is the leading cause of death in the United States. Although public health interventions have been effective in slowing the death rate among some segments of the U.S. population, African Americans (AAs) living in the rural Southern region[1] of the U.S. have not experienced similar slowing in the death rate. The CHD risk factors, hypertension, lack of physical activity, and high calorie, high sodium diets are especially problematic in southern rural AA communities. The increase in these modifiable risk factors for CHD with rural AA residents is the main area of concern when addressing the health disparities existing in this community. The socio-ecological model for behavioral change related to the different modifiable risk factors for chronic diseases has been repeatedly employed in community interventions. In order to improve health promotion interventions, it may be necessary to consider what makes the southern rural AA community different in their response to traditional public health initiatives. Research in the area of gene by environment (GxE) interactions, shows promise in delaying or preventing the onset of CHD and other chronic diseases. The opportunity to use information on modifiable risk factors and genetic influence relative to health promotion programs may provide a focused, culturally comprehensive approach to designing interventions. There has been little research on the involvement of genetics, environment, and behavior when planning interventions in southern rural communities,

[1] Southern region states, Florida, Georgia, Alabama, Mississippi, Kentucky, Louisiana, South Carolina, Tennessee

which are predominately AA. Compiling GxE interaction and the behavioral research that is available on southern rural AA populations, which is relevant to specific areas of concern for coronary heart disease is a strategy that needs to be explored.

The purpose of this pilot study is to determine the efficacy of an intervention that uses an innovative and focused strategy to combat the increased prevalence of modifiable risk factors for CHD within the southern rural AA population. Normally, studies of behavioral modification for diet and exercise interventions report only the change in behavior for the participants receiving an educational and physical activity component. The two specific aims of this research are to evaluate (1) the efficacy of a diet and exercise intervention in an after school program and (2) the ability of program participants to effect behavior change among members of their community. The education and exercise modules of the intervention concentrate on the modifiable risk factors for CHD, specifically, hypertension, diet, and physical inactivity. The intervention program is the Kids Educational Exercise Program Study (KEEPS). The study population is children and adolescences, 5 to 17 years of age, residing in rural communities.

Background

Coronary Heart Disease (CHD) is an umbrella term, which covers several conditions affecting the heart and blood vessels of the heart (CDC, 2010). Most commonly, CHD refers to a narrowing of the blood vessels caused by the buildup of plaque, reducing the flow of blood and oxygen to the heart. In the United States, heart disease is a major cause of illness and the leading cause of death in each of the following categories in European Americans (EAs) and African Americans (AAs) of both genders (Kochanek, 2011). According to the Center for Disease Control (CDC), CHD health care costs are 108.9 billion dollars each year. Each year in the United States, 935,000 people suffer heart attacks and 600,000 people die from heart disease

(CDC, 2010). To illustrate of the severity of CHD, more people die each year from heart disease than from lower respiratory diseases, stroke, and accidents combined; the number three, four, and number five leading causes of death in the U.S. (Kochanek, 2011). The frequency of heart disease in the Southern U.S. is double that in the Northern region (CDC, 2010). Deaths attributed to heart attacks in the south have consistently remained above the national average. The six adjacent states, Alabama, Arkansas, Mississippi, Oklahoma, Louisiana, and Georgia had age-adjusted heart failure mortality rates 69% higher than the national rate (Mujib, 2011).

The burden of CHD in the U.S. is immeasurable. The prevalence of risk factors for CHD is expected to rise due to an aging and increasing minority population in the U.S. Consequently, an increase in the burden of the disease will be seen (Heart Disease, 2010). Although, the national mortality rate for heart disease has experienced a decrease over the past sixty years, the prevalence of heart disease has increased (Washington, 1999). The 66% national decrease in CHD appears to be masking the increase in CHD in some regions and among AAs (Barnett, 1996; Oliver, 2005).

Statement of the problem

According to the 2010 Census, 55 percent of AAs lived in the South and the population of AAs in the South doubled from 2000 to 2010(Census Bureau, 2010). This information on the large concentration of AAs is critical in any attempts to target high-risk individuals for participation in CHD research. EAs residing in the Southern U.S. have a higher risk for CHD as compared to EAs in other parts of the country, but do not have the same clinical outcomes as AAs. Appropriate preventative therapies or adequate control of risk factors is less often used in treating AAs. To follow ethnicity further, the available research shows AAs who reside in rural communities have the highest mortality rates of any group in the U.S. (Taylor, 2002). It is

believed that the combination of minority status and rural residence has a negative impact on heart disease risk factors and thus is one of the major rationales used to explain the following statistic. Rural AAs have the highest rate of mortality from heart disease than any other group in the world (Taylor, 2002).

The modifiable risk factors for CHD generating the most concern in rural AA communities are hypertension, smoking, lack of physical exercise, and unhealthy diets (CDC, 2010). The number of rural AAs with risk factors for heart disease is significant due to the disparities that exist in the treatment this group receives when compared to EAs. There is a deficiency on many levels in the assessment and treatment of CHD within the southern rural AA community. The discrepancy, disproportion, inconsistency and inequality are normal components for AAs in the battle against CHD. Systematic barriers and disproportionate burden of disease are facts substantiated by research conducted in minority populations on access to health care and the treatment received (Agency for Healthcare Research and Quality, 2012; U.S. Department of Health and Human Services, 2011). The prevalence of CHD and the associated modifiable risk factors, combined with the known health disparities that exist in the AA community, increases the importance of disease prevention. Public health professionals must find innovative and targeted strategies for health promotion and preventative measures to combat the growing trend of modifiable risk factors for heart disease within the southern rural AA population. The purpose of this research is to evaluate the efficacy of an intervention focused on the main areas of concern for the modifiable risk factors for CHD in the southern rural AA community. An intervention introducing fruits and vegetables to replace high fructose snacks and drinks in an after school program will serve as diet modification education. The implementation of a physical activity module (play) will teach the importance of physical fitness

and disease prevention. Each of the diet and exercise modules will concentrate on teachable, sustainable activities. Pre and post surveys will be used to assess behavioral change within the community.

Significance

The KEEPS research explores several significant aspects of intervention design not currently addressed in the literature. Intervention planning in ethnic communities has been built upon the importance of "culturally appropriate" and "culturally competent" components, but has not included any genetically specific information in the design. A "culturally comprehensive" strategy would combine genetics, environmental, and behavioral information into the design phase of a community intervention. Planning interventions for rural AA youth, focusing on the identifiable differences in a targeted community is a significant addition to the literature.

The final significant aspect of this study is the break from using the multilevel, socio-ecological model approach to influence the change in behavior at the individual level. The current research seeks to examine an individual level intervention and any change in behavior upstream. The influence of rural AA youth on the upper levels on the ecological model is currently absent from the literature.

Specific Modifiable Risk Factors

Hypertension is the main precursor to the development of CHD. Hypertension is defined as having a systolic blood pressure(SBP) $\geq$ 140 mm Hg or a diastolic blood pressure(DBP) $\geq$ 90 mm Hg or the use of antihypertensive medications (Kessler, 2010; Aronow W. F., 2011; Bravo, 2013). Normal blood pressure is a SBP lower than 120 mm Hg and a DBP lower than 80 mm Hg. A prehypertension designation has been developed for people with SBP levels from 120 to 139 mm Hg or 80 to 89mmHg DBP (National Heart, Lung, and Blood Institute, 2003).

Hypertension is responsible for a structural change in the walls of the left ventricle of the heart. This condition, known as Left Ventricular Hypertrophy (LVH), can be influenced by age, race and gender (Agabiti-Rosei, 2005).

Research has shown that AAs develop hypertension at earlier ages and experience a greater severity of the disease compared to EAs. The increased prevalence and severity of the hypertension is due to environmental and genetic factors (Ferdinand K., 2007). Hypertension is associated with increased levels of dietary cholesterol and sodium intake. Diet modification has been successful in the control of hypertension and is recommended in early intervention for high-risk populations. The genetic factor of hypertension has to do with the heritability of salt sensitivity. Sodium within the body is vital for maintaining cellular health and the efficient working of the cardiovascular system (Franco, 2006). Salt sensitivity is the change in sodium balance and extracellular fluid homeostasis, which results in a change in blood pressure (Weinberger, 2001). Salt sensitivity increases the development of LVH and therefore is a major concern in the assessment of risk factors for CHD. The manner in which AAs load and excrete sodium is thought to be the important distinguishing factor (Campese, 1996); explaining the higher prevalence of salt sensitivity in AAs as compared to EAs (Svetkey, 1996).

Studies show cigarette smoking is a risk factor in the increased incidence of deaths due to CHD. The CDC and the American Heart Association (AHA) report individuals who smoke cigarettes are 2 to 4 times more likely to develop CHD than nonsmokers (Roger V. G.-J., 2011). Smoking is linked to the formation of plague in Atherosclerosis and decreased coronary blood flow and reduced myocardial oxygen supply. Cigarette smoking impacts all phases of atherosclerosis from endothelial dysfunction to acute clinical events. Vasodilatory function impairment is one of the earliest signs of changes in the heart vessels (Ambrose, 2004). The

increase in systolic blood pressure and heart rate limits an individuals' ability to exercise and reduce their risk of CHD (Alemu, 2011).

Physical inactivity is a detriment to many systems of the body. The impact of physical inactivity is comparable to other established risk factors for CHD. Positive adjustments in CHD risk factors have been observed with increased physical activity or the implementation of a structured exercise program (Kokkinos, 2012). Physical exercise aids in the control of lipid levels in the blood and helps to maintain a healthy blood pressure. There is substantial research on the association of increased physical activity and the reduction of hypertension and CHD. A limited number of studies, however, have included AAs and their response to increased exercise (Bell, 2013).

Poor diet is a behavioral concern in the prevalence of CHD. Larger portions of food, the greater availability of fast food, the convenience of pre-packaged meals, and the enticement of high fructose beverages, all play a role in the increase in obesity in the U.S. An unhealthy diet and obesity are modifiable risk factors linked together in many health conditions that are a precursor to CHD. Researchers have detailed obesity as a multifaceted interaction between genetic and environmental elements. Obesity produces elevated blood pressure, elevated cholesterol levels, and lipoprotein ratios, which lead to atherosclerotic lesions being seen in children, adolescents, and adults (Ratner, 2005). Modifiable risk factors are interrelated and the prevalence of the co-occurrence of multiple risk factors for CHD is highest for AAs (Baruth, 2011).

Chapter 2: Literature Review

Previous Studies

There has been little research in the development of CHD in southern rural AA communities. The 1948 Framingham Heart Study is the most expansive work on the precursors of heart disease and is credited with the identification of the risk factors for the disease. The research, a 30-year longitudinal study, followed participants from the Framingham community in Massachusetts to determine the correlation between certain factors and the development of heart disease (Oppenheimer, 2005). The Framingham study was composed almost entirely of EAs, with results generalized to the U.S. population. One of the most important findings generated from a follow-up of Framingham study patients, determined hypertension was the main precursor to heart failure in 70% of the cases.

Later studies, to include data from both EAs and AAs from the period of the mid-1960s through the mid-1970s, reported a national decline in the mortality and morbidity rates for EAs and AAs of both genders (Liao, 1995; Barnett, 1996; Gillum, 1985). These studies attributed the decline in CHD in part to factors relating to increased urbanization, the increased affluence of both races and better hypertension control. Richard Gillum, the principal investigator in studies of AAs and heart disease, points to the lack of data to describe trends in diagnostic accuracy and the inability to gather statistics to properly compare the rates of mortality with AAs (Gillum, 1985). After the mid-1970s, the declining trend in CHD rates for AAs began to slow significantly as compared to EAs. In the 1980s, mortality rates for EA males declined sharply, but these rates were still above those for AAs. Studies funded by the National Heart, Lung, and Blood Institute in the late 1980s, aggressively worked to effect both individual and community changes in risk behaviors with more focused intervention strategies. These interventions

succeeded in improving health behaviors, but were implemented in predominantly middle-class EA populations (Plescia, 2008). For the first time in 1989, reports indicated that CHD mortality rates for AAs exceeded those for EAs. The gap in the mortality rates continued increasing from 19 percent to 33 percent from the 1980s to the 1990s (Liao, 1995).

More recent CHD research involving AAs as study participants, found increased prevalence of CHD persisted for AAs when compared to EAs (Francis, 1997). Although, limited by the lack of comprehensive data compiled on AAs, researchers presented discrepancies in the use of diagnostic, clinical and therapeutic methods. The sensitivity and specificity of diagnostic tests established in the EA population would be different for use in AA populations. The reliability of the available cardiac tests could not be validated for AAs to the degree it could be in EAs (National Heart, Lung and Blood Institute, 1994).

Health disparities among AAs are substantial, with no one culprit being identified as creating or perpetuating the occurrence of chronic diseases, such as CHD (Low, 2007). Researchers have noted that insufficient scientific data and the lack of research focused on minority populations are some of the reasons for the continued gap in outcomes. Sizable challenges have been recognized in the recruitment and retention of AAs in research studies. Personal experiences with racial discrimination and the knowledge of AA exploitation in medical trials have perpetuated the mistrust AAs harbor for research studies.

The CDC recognized major disparities in the burden of heart disease among different racial and ethnic groups. Relevant information for some ethnic groups was scarce because data that would effectively address heart health concerns had not been collected. As part of a commitment by the federal government to reduce health disparities, Healthy People 2010 addressed the implementation of heart health among high-risk populations (Holmes J, et. al.

Heart disease and prevention). Medical researchers view the continuation of extreme conditions; such as the development of coronary atherosclerosis at earlier ages; and the high prevalence and severity of hypertension; as the drivers of CHD disparities in the AA community (Clark, 2001). In research from the Reasons for Geographic and Racial Differences in Stroke (REGARDS) study, researchers found that AAs were about twice as likely to die from CHD compared to their EA counterparts (Safford, 2012). Research conducted by investigators at the University of Alabama at Birmingham confirms that disparity in the rate of death caused by CHD is due to an excess burden of known risk factors found in the AA community. The Alabama study found that death is more likely to be the first sign of CHD in AAs than in EAs (Daviglus.M., 2012).

Intervention Studies

The vast majority of interventions developed for AAs in the area of heart health are those that initiate change in the social, educational, cultural, and physical environment, as opposed to interventions to improving access to health care services and health screenings (Shaya, 2006). However, professionals in health promotion have been criticized for focusing on lifestyle change and negating the power of contextual factors that influence health (Golden, 2012). Contextual factors are the characteristics of the physical and structural environment within a community, i.e., any set of forces, situations, and/or circumstances that have the probability of influencing the effectiveness of a program (Iwasiw, 2009). Physical health and health care are therefore strongly influenced by cultural and social-environmental factors.

Researchers Sonia Caprio et. al. describes race and ethnicity as social factors that permeate every aspect of life and can have a cumulative and many times a generational effect on health status (Caprio, 2008). The social ecological models that describe the interactive characteristics of individuals and environments, that motivate health outcomes, have long been

recommended to guide public health practice (Sallis, 2008). Conversely, there is a deficient amount of guidance on designing and focusing interventions for an effective reduction in modifiable factors (Appel, 2005). The underlying conclusion of contextual researchers suggests individual-level interventions are less likely to have significant or sustained effects on a community at large.

In a review of articles published from 1996 through 2006, researcher from The University of South Alabama used inclusion criteria focusing on heart disease, AAs, and interventions. Of 524 abstracts identified, only 33 articles contained health disparities research, and half of those designed interventions were in high-risk populations addressing hypertension, nutrition and physical activity (Crook, 2009).

In a study of southern AA adults and three behavioral risk factors for heart disease, low fruit and vegetable consumption, low physical activity, and cigarette smoking were part of an intervention in North Carolina. Using a multi-level socio-ecological approach involving policy and community environment, researchers implemented change strategies in a community of 20,000 AAs in 2001 to 2005. Health behavior questions from the Behavioral Risk Factor Surveillance System (BRFSS) survey were administered annually to a cross-section of the community. The results were compared with AAs' responses from a statewide survey. In the study population, all three health behaviors improved. Statistically significant improvements were seen in the areas of physical activity, smoking and fruit and vegetable consumption among middle-aged adults (Plescia, 2008). The authors of the study recommended community environment change strategies and community participation as ways to improve health behaviors in AA communities and therefore reduce health disparities.

It has been established that AAs bear a disproportionate burden hypertension-associated heart disease (Center for disease control and prevention, 2010). The current knowledge of the risk factors for CHD and the disparities that exist is expanded by the addition of promising details in targeted interventions. Public health initiatives have sought improved health and worked to reduce disparities. By providing an understanding of individual-level risk factors and appropriate interventions, a positive change may occur in the major contributors of morbidity and mortality (Hillemeier, 2003).

There continues to be an attempt to explain the biological differences of AAs and the best route to proceed to effectively suspend increasing rates of CHD. The issue of race and ethnicity has surfaced again in the twenty first century and is salient to disease vulnerability, an argument that was dismissed over five decades ago as biological fantasy (Frank, 2007). The importance of race, genetics and environmental influences on heart disease and the disparities between AAs and EAs in the United States has not fully been outlined (Kuzawa, 2009). Although "race" is not considered to be a scientific term, its definition has origins in race-based genomics and has proven to be a reliable way to differentiate population groups (Fine, 2005). Medical research benefits from the use of race as population-specific patterns of genetic variation, paralleled with geographical ancestry (Krimski, 2012). The clustering of CHD risk factors has been shown to differ by race; therefore a concentrated effort to analyze the combined effects clustering and the genetics of race has become prudent (Hernandez, 2006). In epidemiological studies of hypertension, researchers have focused in on the impact of salt sensitivity as a genetic factor in the development of CHD (Ferdinand, 2010).

Public health scientists have focused on the category and distribution of disease or illness within the AA population. The social environmental influences and the application of the

appropriate theoritical/ conceptual frameworks have been significant in disproving certain assumption base on race. Literature has previously been published, explaining that the prevalence of CHD among AAs can be attributed to shared ancestry (Curtin, 1992). However, later studies explain that CHD among people of African decent, residing in other countries, have not developed the disease in levels experienced in the U.S (Cooper, 1997; Grim, 2003; Forrester, 2004).

Researcher Frank Hu contends that diet and lifestyle are environmental factors, which increase the risk of CHD within a population. He also asserts that risk factors of smoking, obesity, and limited physical activity causes CHD; but agrees with other researchers that the development of CHD is determined by the encounters between genetic factors and environmental factors (Hu, 2009). Several analyses by researchers, completed post-Human Genome Project, support Gene by Environment (GxE) Interaction studies, acknowledging this research provides innovative opportunities in combating the prevalence certain diseases, like CHD (Aschard, 2012). Interventions incorporating genetic information and environmental studies are a priority due to the disease characteristics of CHD. The pervasiveness and the severity of CHD in the southern rural AA community demonstrate the need for a more robust approach to designing interventions.

Amid the studies of genetic and ethnic differences emerges another group generating alarming statistics in preventable risk factors for heart disease, children in the Southern U.S. It has been found that many of the modifiable risk factors for heart disease start in childhood (Washington, 1999). In 1972, the Bogalusa Heart Study examined children from the township of Bogalusa, located in the Washington Parish, Louisiana. The goal of the study was to provide an understanding of biological and behavioral risk factors in youth and their link to heart health as

adults. The study began with an initial cross-sectional survey of just over 3,500 children ranging in ages from 5 years to 14 years of age. This study was compromised of 63% EA children and approximately 37 % AA children. Additional, between 1976 and 1985, five cross-sectional surveys were completed. The research found there was a positive correlation with children ranking in the upper percentiles for CHD modifiable risk factors (blood pressure, cholesterol, and body mass index) and abnormal levels of the same risk factors as adults. The research also indicated that CHD risk factors cluster at early ages.

Research has shown that the prevalence of the risk factors for CHD is higher in rural counties than that of urban counties in southern states (Jackson, 2005). As a result of the steady upsizing in portions of unhealthy meals and the increase seen in this nation's waistlines, the youth in this country have been the recipients of behaviors contrary to healthy outcomes. Obesity is an inheritable as well as a behavioral risk factor in the development of CHD (Walley, 2006). Rural AA youth are in an especially difficult position as it relates to diet and exercise. Ironically, rural AA youth inhabit housing that is more likely situated in the midst of farm land, but the resulting agriculture is not for distribution to local retail outlets. Grocery stores willing or large enough to stock a supply of fruits and vegetables are located outside rural communities (Blanchard, 2007). Therefore, food deserts are a real concern for this population of youth. Moreover, the rural area is not conducive for individual or organized physical activity due to the lack of safe built environments for young people to participate and sustain a regular exercise regimen. The paradox of rural living is the abundant, unused property and open spaces creates obesogenic environments, which negatively impacts heart health (Lovasi, 2011).

The field of knowledge that exists contends young people must increase their rate of physical activity and have healthier foods available for their consumption. Rural youth are quite

dependent on their caregivers to provide food and activities. This dependence is not currently being addressed in the reduction of modifiable risk factors for heart disease. The introduction of health education components can influence the reduction of modifiable risk factors for heart disease (Zuniga, 2003).

CHD research is paramount, but not unique in the attempts made to explain the large discrepancies, which exist in certain U.S. populations. The nature versus nurture debate finds researchers promoting methods, which incorporate biology, environment, and behavior, due to inability of either argument, nature or nurture alone, to adequately elucidate the human disease process (Kaput, 2004). Conversely, racial disparities failed to be justified solely on the existence of factors such as poverty and the type of access or lack of access to health care. Behavior and environment are important variables to be added to any CHD disparity inquiry, but their addition is needed in combination (Olden, 2005). Interactions between all aforementioned factors plus the inclusion of genetics, creates a synergistic effect. The contemporary argument gaining support maintains there is a significant genetic function serving as a contributor to health disparities (Braun, 2006; Fine, 2005). There remains a crucial need to examine the confounding effects of genetics and the environment in studies of health disparities and interventions.

Previous study recommendations

Studies, with a focus on health disparities and/or modifiable risk factors involving AAs, recommend several approaches to aid in the research of CHD. The CDC as a part of the organizations' nationwide initiative to reduce deaths from CHD, suggest the development of focused strategies targeting identified areas of a subpopulation with greater prevalence of CHD (Fang, 2011). Increasing cultural and evidence-based interventions will assist in eliminating health disparities (Low, 2007). Researchers recommend a push to identify the relationship

between genetics/race and disease and involve these factors in the elimination of disparities (Fine, 2005). The discovery of certain genotypic variants, which occur with different frequencies in AAs than in EA, may help to explain differences in susceptibility to CHD. To highlight aspects of AAs' response to treatment may facilitate the development of tailored interventions (Gibbons, 2004).

Previous studies, designed to target high risk populations for hypertension, have depended heavily on extrapolated information from studies of EAs (Weinberger, 2001). AA communities are in need of initiatives with specific information about salt sensitivity and hypertension. A start to this initiative can be achieved by designing interventions with information based on the Dietary Guidelines for Americans, released in 2010, it will remain current until the publication of the 8th edition in 2015. The government guidelines call for the reduction of sodium intake to an amount less than 2,300 milligrams a day. However, the guide specifically calls for further reduction of sodium intake for AA, of any age, to an amount less than 1,500 milligrams a day (U.S. Department of Agriculture and U.S. Department of Health and Human Services, 2010). Community- based interventions designed for reducing salt consumption have been successfully implemented in the U. S. and evaluated as feasible and acceptable for participants (Mugavero, 2012). To better understand overall health disparities and the work needed to reduce them, researchers studying subgroups of AAs in the U.S. recommend future studies of diet and health should consider cultural differences (Lancaster, 2006).

Summary

The prevalence of CHD among AAs has steadily increased over the past three decades. The lack of scientific data on minority populations and contextual factors are cited as primary reasons for the existing disparities in southern rural AA communities. Due to the pattern of

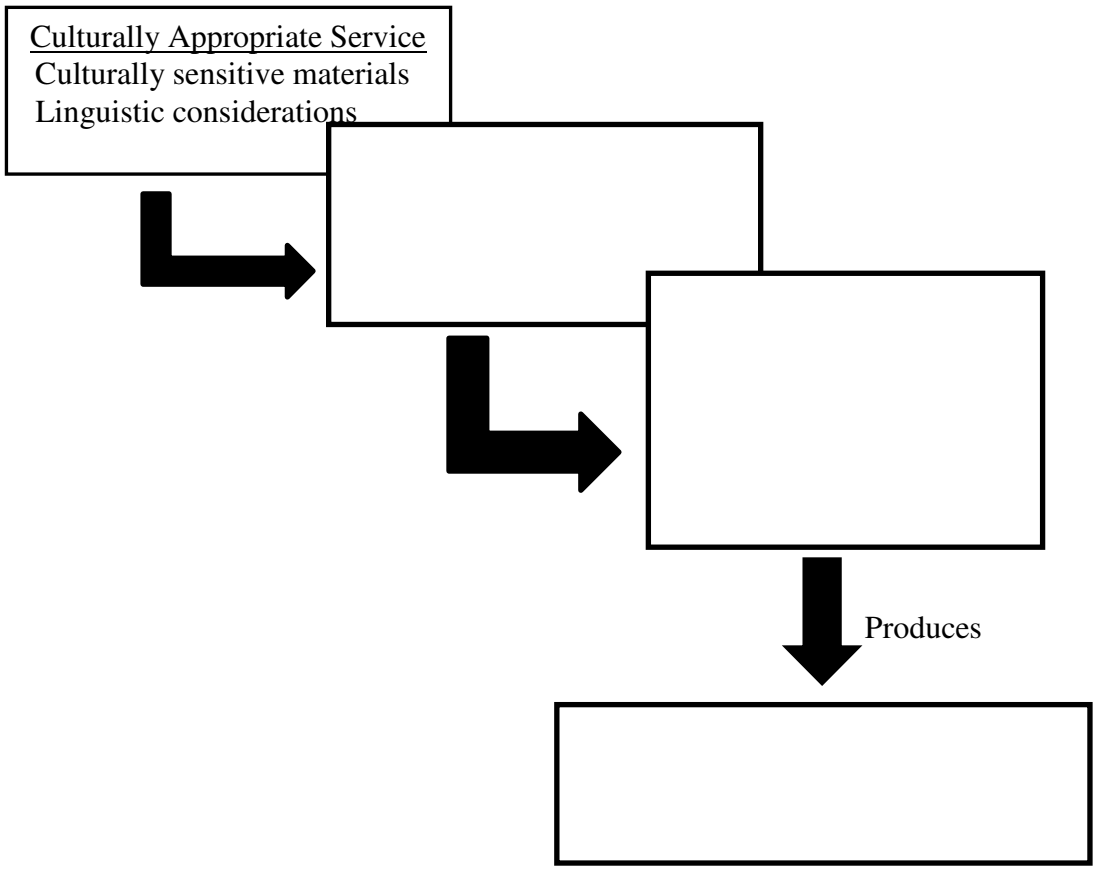
onset and the severity of CHD among southern rural AAs, prevention strategies are a must. Researchers attribute 80% of CHD events to lifestyle factors and have shown modest adjustments in lifestyle can result in achievable and substantial effects on heart health (Mozaffarian, 2008). In the designing of interventions, evidence is now emerging to consider inherit biological characteristics of AAs, alongside diet and inactivity as risk factors for CHD (Hernandez, 2006). By considering an added genetic component, such as salt sensitivity in AAs, as part of the risk factors for CHD, interventions become more focused, improving the sustainability of successful programs within a community. Understanding the variables at work in the AA community and addressing the influence of these variables on diet and physical activity is crucial to developing effective public health interventions to reverse the upward trend of CHD (Caprio, 2008).

Chapter 3: Theoretical Framework and Methodology

Being equipped with new statistics relating to heart disease and AAs, well-structured interventions are pivotal to implementing successful preventative measures to effectively change the trajectory of CHD within southern rural communities. Culturally appropriate and culturally competent elements are important to intervention planning, but more structure was needed for the current KEEPS research. While "culturally appropriate" deals with the linguistics of a targeted population, it may fall short in integrating pertinent preventative measures for a specific population. "Culturally competent" interventions prove to be different, in that they address more abstract characteristics of a targeted group. Culturally competent as a process, addresses the beliefs and attitudes of a culture but may not provide enough of a foundation to build an intervention. Designing a community intervention consisting of genetics and environmental components is missing from the current literature. A "culturally comprehensive" strategy in this present research, combining genetics, environmental, and behavioral information, was necessary to the design phase of this community intervention. Values, attitudes, preferences, and expectations are relative terms used in culturally appropriate and culturally competent intervention design. Absent from the literature is the adherence to conduct relevant research to include genetics when targeting vulnerable populations. Therefore, the appropriate progression may be the shift from culturally appropriate interventions, moving beyond culturally competent interventions to "culturally comprehensive" interventions. It is necessary that research deemed "culturally comprehensive" includes the physiological characteristics of the group or groups targeted during an intervention. The term, "culturally comprehensive" serves to go beyond just the inclusion of the psychological and the investigation of congruent behaviors, beliefs and attitudes; but progress to include disease manifestations, which are different in certain groups of

people. The introduction of genetically relevant information during intervention design can serve to narrow the focus and provide customized, well- executed public health initiatives as outlined in the Culturally Comprehensive schematic (see figure 1).

Figure 1. Culturally Comprehensive Schematic



The present study examines tailoring research toward a target population using a "Culturally Comprehensive" schematic. One goal of this study is to add the term "Culturally Comprehensive" to the landscape of public health. Nowhere in the literature has this term been used as the basis for designing and/or promoting public health initiatives. "Culturally

comprehensive" does not appear in the research literature as a concept, construct, or useful strategy for public health.

Introducing the concept of GxE interaction into intervention planning for rural AA youth is a significant addition to the literature. By integrating genetics, behavioral, and environmental manifestations of a disease, culturally comprehensive approaches can lead to successful interventions, with sustainable outcomes. This study addresses specific concerns for southern rural AA populations in the area of modifiable risk factors for CHD. In pursuing the subject of culturally comprehensive initiatives, this research focuses on the identifiable differences for southern rural AAs, namely the prevalence of hypertension, smoking, the lack of physical exercise and the sustaining unhealthy diets.

Using the information generated by research of AAs and hypertension, this study incorporates the genetic difference of salt sensitivity. Whereas there are a number of genetic differences and theories to be explored, it is a substantial addition to the literature to include at least one genetic component to an intervention. This research seeks to address the benefit of sharing information on salt sensitivity and the relationship to the prevalence of hypertension in southern rural AAs communities.

The core principle of ecological modeling is the change of specific behaviors due to the interaction of multiple influences from multiple levels of the model. The downstream influence of rural AA youth on the upper levels on the ecological model may prove to be of great significance. The importance of behavioral changes, related to the different modifiable risk factors for CHD has now been suggested for youth in high risk categories. Educational interventions at the individual level have experienced success in behavior change when working with young people. It is important to evaluate an intervention designed to influence adults in the

upper levels of the ecological model. A pre- and post-survey can be used to determine if a community of adults experienced any behavior modification due to necessary exposure to young people; equipped with information on diet, physical activity, smoking, and other risk factors for CHD. Designing an intervention employing children to influence others is proposed to be beneficial, because the atherosclerosis process has been shown to start in childhood and gradually progress toward conditions leading to heart disease.

Framework

The framework used for this research is the "Empowerment" of youth within the socio-ecological model, more specifically Critical Social Theory of Youth Empowerment. The success of the proposed intervention may hinge on a framework, which allows researchers the latitude to incorporate the information known regarding genetics, social/behavioral, and environmental variables together. For the purposes of this research, the use of Critical Youth Empowerment (CYE) integrates significant aspects of the Social Cognitive Theory (SCT). The use of these theories in combination helped to design the intervention, guide the research and fulfill the purpose of this study.

Empowerment is defined as the process by which individuals and groups acquire power, influence, and control over their lives and environment to facilitate a condition of well-being (Maton, 2008). Empowerment is a concept used in many disciplines with ties to the field of Psychology. Empowerment in social work has been the foundation of creating healthy families and communities for decades. As the name suggests, to use "empowerment" as a key construct in research would be to obtain power. In health promotion, this translates into educating and strengthening individuals and building capacity in communities. Youth empowerment has been described as a core principle in ecological matters and tracing development outcomes (Christens,

2012). Empowerment in community development is seen as a concept, a process and a pathway, pivotal in changing lives (Zimmerman, 2000; Maton, 2008; Christens, 2012; Prilleltensky, 2012).

Social Cognitive Theory (SCT) advocates that people are not just compelled by internal powers or spontaneously molded and regulated by the environment. However, individuals are underwriters of their own motivation, behavior, and development within a system of interacting influences (Bandura, 1989). The SCT is useful as a guide to describe how individuals understand, acquire, and maintain behavioral change (Bandura, 1997). SCT provides a framework for designing interventions and/ or health promotion programs, implementation and the evaluation of those programs. The importance of SCT in combination with the critical social empowerment theory is in identifying methods to modify or change behavior (Bandura, 1996).

Rural youth are a significant entity in rural society and to negate their potential for health promotion influence within a community is short-sighted. In an intervention where innovative solutions are desired to achieve measurable outcomes, empowered young people may prove to be indispensable. Youth are innovators with the propensity to grasp new ideas and technologies, which may advance and expand change in their communities and beyond. The literature reviewed does not consider the type of influence the most malleable resource in the socio-ecological model can contribute to the reduction of risk factors for a community's health. Research in community health has touted a multifaceted and multilayer approach, using the socio-ecological model as the most effective strategy in behavior change (McLeroy, 1988; Israel, 1994; Stokols, 1996). The brunt of the literature states the upstream factors of policy makers and community are significant in influencing health (Krieger, 2001; Sallis, 2006; Scott, 2011). The "upstream" in the socio-ecologic model has become the focus of researchers and health promotion professionals. These scientists stress that policy and environmental alterations at the

top of the model are needed as a catalyst for behavioral change on the individual level (UNC, 2009).

It is the hypothesis of this research that the most vulnerable population in the socio-ecological model can in fact be the most valuable in terms of a health promotion contribution. To change behavior and realize long-range positive health outcomes, it may be necessary to reprogram a younger generation to influence the other levels of the socio-ecological model. The research questions addressed in "Kids Playing for KEEPS" are as follows:

Research Question 1

> How will a limited, focused approach targeting the most vulnerable in our society, change behaviors known to reduce the prevalence of modifiable risk factors for coronary heart disease found in rural southern AA communities?

Research Question 2

> What ability does youth in an after school program have to exert influence and change behaviors for members of a rural community?

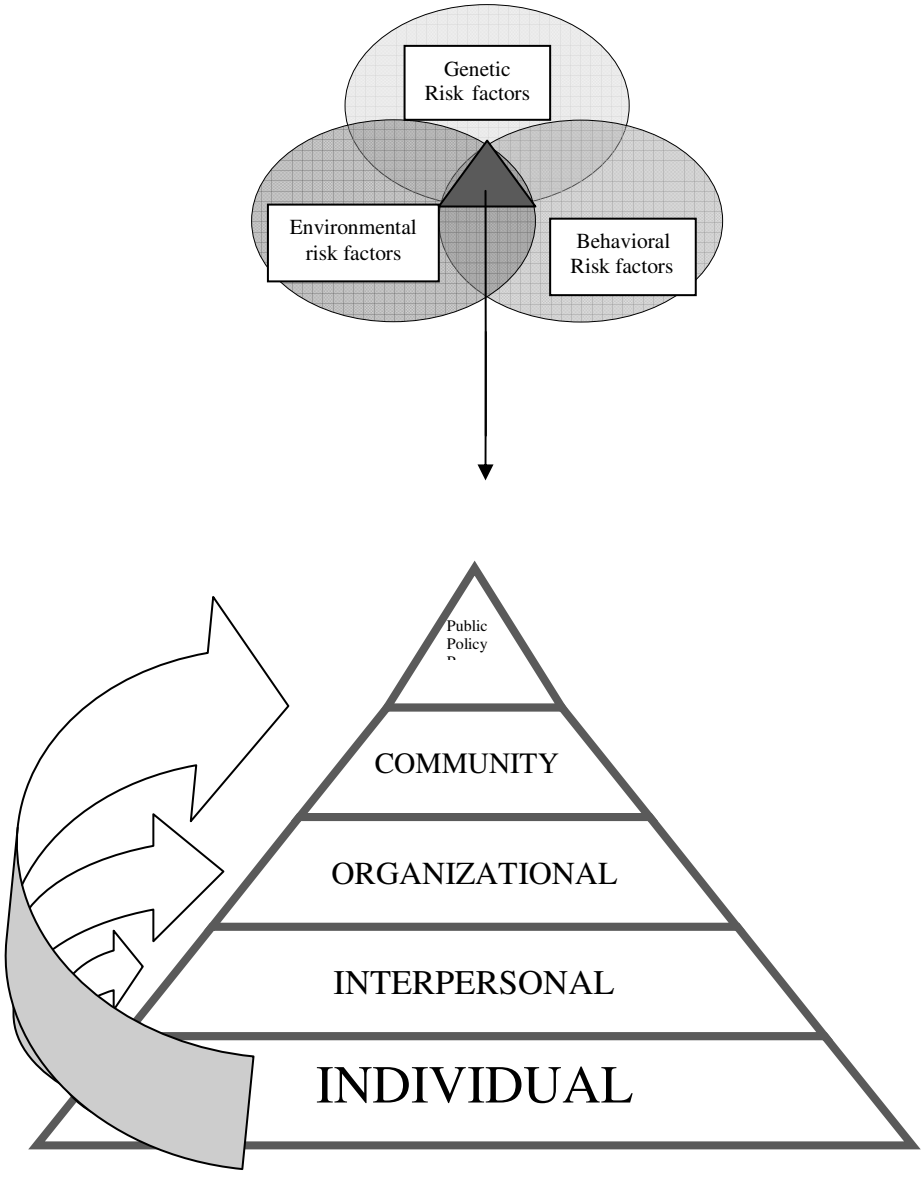
Research Question 3

> What is the causal relationship, if any between empowered youth of a rural AA setting on environmental and policy change within their community?

This research explores the potential for downstream influence within the socio-ecological paradigm. The conceptual model used in this research is set forth to achieve two objectives. One, provide a conceptual model (see figure 2) to underscore the relationship of modifiable risk factors such as hypertension, obesity, smoking, physical inactivity, unhealthy eating habits and CHD. Two, simplify the complex interdependent, top- down relationships illustrated by the

socio-ecological model and generate a persuasive alternate mode of influence originating from the bottom of the model moving upward. There is a critical omission in the research regarding the modifiable risk factors for CHD in southern rural communities and the role of children. In this study, it is the influence of children in predominately AA communities that will provide insight to CHD prevention and community health promotion.

Figure 2. Conceptual Model



Methodology

The purpose of this pilot study was to evaluate the feasibility and procedures used in Kids Playing for KEEPS. The intent of the KEEPS research was to develop and implement an intervention, and assess change in the behavior of a rural community relative to modifiable risk factors for coronary heart disease. A health promotion program for the empowerment of young people was introduced within the structure of an after school program. This study involved a quasi-experimental design consisting of an experimental group and a control group. Each group was composed of three smaller subgroups. Youth study participants were selected based on their residency in a rural community and their participation in an after school program. This study also included the parents of the after school participants. The final subgroup of participants were community members, selected based on their residency in a rural community with access to an after school program. Youth and parent participants for the intervention group were recruited from an existing after school program in Keysville, GA. The control group participants were recruited from existing after school programs in other townships. Announcements (Appendix A) soliciting participation were made during after school orientation and scheduled events in the community. Individuals and families who responded to the solicitations were screened (ages 5-17 for youth participants and over the age of 18 for parent/guardian and community resident participants); eligible individuals were asked to participate. The study was explained to potential participants and informed consents were completed (Appendix B). The youth and their parent(s)/ legal guardian(s) were asked to complete a survey and undergo body assessment (height, weight, waist circumference and blood pressure) measurements. Body assessments were suspended after the first 34 individuals due to inability of the researcher, working alone, to complete body measurements in the allotted time frame.

Recruitment and Eligibility

The recruitment of the intervention group was from a subset of Keysville, Georgia children attending the after school program during the hours of 4:00 pm- 6:15 pm, Monday through Thursday. The recruitment of the control group was made up of a subset of children with a residence in a rural township outside of Keysville, Georgia. This control group participants attended an after school program, outside of the rural area of Keysville, with various hours between 3:00 pm - 6:00 pm Monday through Thursday. Eligible children for this study were between the ages of 5 and 17 years of age, residing in a rural community, and enrolled in some form of after school program. The intervention group and the control group were similar in number and racial composition. To eliminate the possibility of cross contamination in the study, youth participants, parents, and relatives/ community members' home addresses and after school access did not overlap pre-existing town boundaries. A survey (Appendix C) was completed, pre- intervention, with information from all recruited children. A pre-survey was also completed for the recruited parents/ legal guardians (Appendix D) and community members. The survey instrument was used to collect data to assess physical activity and dietary information of the participants. The study protocols were reviewed and approved by the Institutional Review Board (IRB) at Georgia Southern University. Appropriate permissions from outside facilities were documented. All participants in the study completed surveys approved by Georgia Southern University's IRB (Appendix F).

Study Design

The aim of this research was to identify the association between children's participation in an after school program and their influence within their community related to the risk factors for CHD. A quantitative, quasi-experimental, pre and post-test design was used to investigate

the effects of an intervention for several factors of CHD. There is lack of quantitative data available from research conducted in southern rural communities, addressing the most common risk factors for CHD, hypertension, obesity, diet and physical inactivity for African Americans of different age groups. To date, no known study has explored the relationship between children and their residency in southern rural communities as it relates to behavioral change among other members of the community. In the final analysis, a comparison was completed of the study participants' (children and their community) scores on pre-assessments and post-assessment surveys, analyzing the current behaviors relevant to risk factors of heart diseases. The feasibility issues addressed are the recruitment of AAs in a research study, the effectiveness of an intervention for rural minority youth and the retention of participants, community wide.

Questionnaires

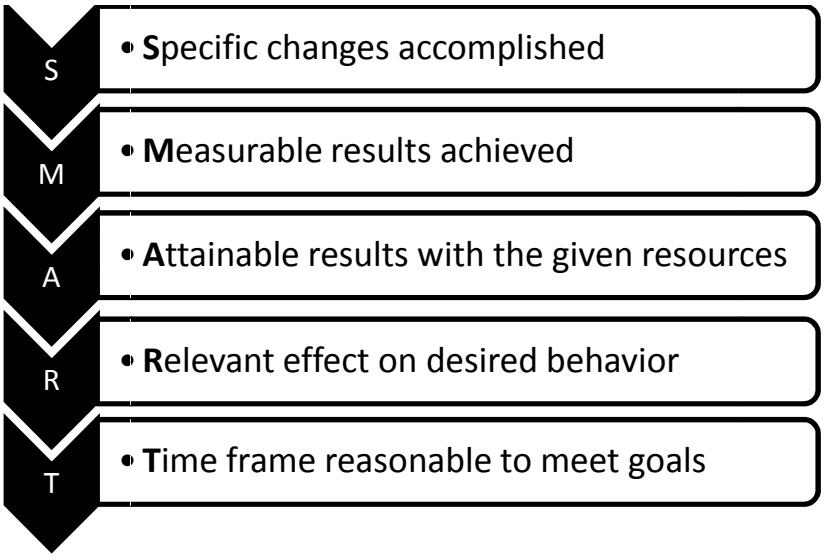
The pre-and post- assessment surveys being used were a modified version of the Behavioral Risk Factor Surveillance System (BRFSS), nationwide survey conducted each year. The BRFSS is a state-based telephone survey coordinated by the Centers for Disease Control and Prevention (CDC) to assess overall health and contributing behaviors of the U.S. population (Pierannunzi, 2011) . Information on chronic conditions and health risk behaviours are collected via surveys during the course of a year. A review of reliability and validity research indicated that past BRFSS data were reliable and valid as measured against other surveys. The CDC instructs users of the BRFFS that question-modules within the questionnaire are optional. The BRFFS questionnaire was too lengthy and cumbersome for the KEEPS purposes. A multiple choice, age-appropriate questionnaire, relevant to risk factors for CHD, was formed from fill- in styled questions found on the BRFSS questionnaire. A 33-43 item questionnaire was used to assess heart health awareness, dietary intake habits, and physical activity. A 33 item

questionnaire was designed for the students. A 42 item questionnaire was designed for the parents, while the community members completed a 41 item survey. The present study used internal validity survey techniques and the review of experts to deliberate on the reliability and content validity of the KEEPS questionnaire.

Intervention Design

An intervention was provided to meet specific aspects of southern rural AA communities with a high prevalence of CHD. The intervention topics being addressed were sodium and calorie reduction in meal preparation and increases in physical activity during the week. The feasibility objectives of KEEPS were to evaluate the efficacy of the implementation of a health promotion process among students and parents associated with an after school program. Using the CDC Division for Heart Disease and Stroke Prevention Evaluation Guide and SMART objectives (see Figure 3), this study was designed to determine:

Figure 3. SMART Objectives for Heart Disease Intervention



(Centers for Disease Control, 2005)

The present study was also designed to evaluate the effectiveness of an after school curriculum to influence the surrounding community. Data collected in AA communities on the effectiveness of interventions has the potential to assist in the reduction of risk factors for CHD. Program effectiveness was determined by

1) an increase in the frequency of desired behaviors in the after school participants and community members.
2) a decrease in frequency of risky behaviors for CHD in after school participants and community members.

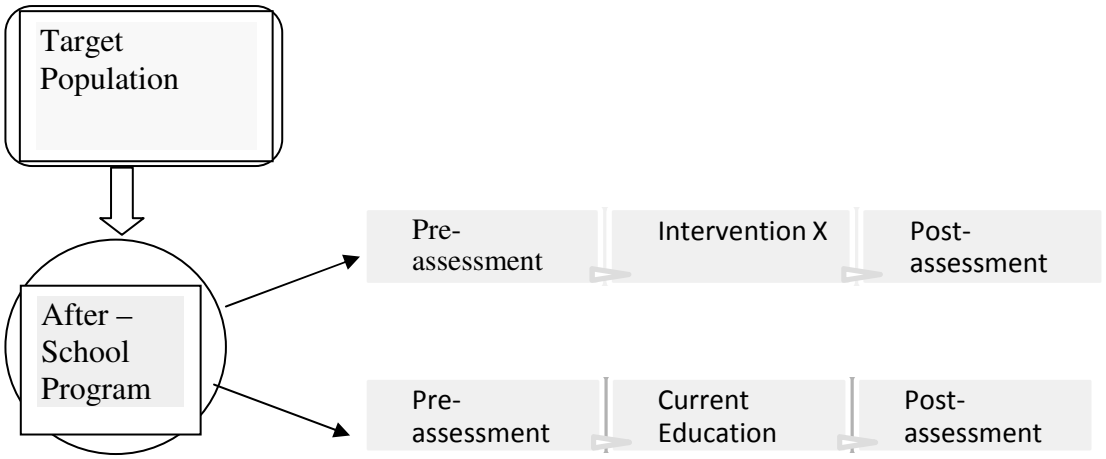
Intervention Description

The designed intervention was introduced to children in an after school program in the rural community of Keysville, Georgia. The population of Keysville is approximately 330 people, with 59% being African American. The predominately AA community of Keysville, Georgia is parcel of Burke County, the largest county in Georgia. Burke county is designated a rural county with a population of 23,125 and an AA population of 11,323 (49%).

The program, named the Kids Educational Exercise Program Study (KEEPS), served to increase healthy diet awareness and to increase play time during the after school period. The educational modules were self-contained, structured learning capsules with a consistent and clear series of objectives and assessments. A key consideration for the health modules was to identify and incorporate appropriate public health initiatives in the area of coronary heart disease. More importantly, it was imperative to implement interventions with educational modules that would provide a contextual framework. This involved installing the key subject elements into learning activities, thereby enhancing synthesis, relevance of content, and comparability of interventions

(RTI International–University of North Carolina at Chapel Hill, 2012). The modules for this intervention were structured using national guidelines for diet and exercise in the reduction of risk factors for heart disease. The educational modules helped to maintain a focus on the quality of learning for each student due to the time constraint of the intervention period. Each week during a six week intervention, a topic related to diet and physical activity was introduced and reinforced through learning activities, in and outside of the after school classroom. The educational modules were designed to provide nutrition and physical activity guidance for school-aged children. The individual -level intervention served to motivate rural youth in making decisions about their health (see Figure 4).

Figure 4. Study Design



Note. Experimental Group: Health promotion/Empowerment intervention
Control Group: Existing health education at baseline

Each week, youth in the intervention group were given the opportunity to consume healthy snacks and increase their level of physical activity (play) during the after school session.

For a period of six weeks, the intervention group was offered low calorie snacks consisting of vegetables, protein, and whole grains. Beverages of milk and water were available. Twice a week, instructors introduced learning materials on healthy eating and the benefits of a healthy diet to youth participants. Each day of the intervention, young people were given the opportunity to prepare a wholesome snack with healthy ingredients of their choosing. During the exercise portion of the intervention, young participants were given the opportunity to engage in different ranges of physical activity, at least two days a week, for approximately 60 minutes. New activities were selected by the participants each week as part of the empowerment process.

The control group was not introduced to the educational modules, but continued their normal course of study during the afterschool program. The control group was composed of participants residing in townships outside the rural area of Keysville, Georgia. During the six week intervention, the control group was introduced to topics related to diet and physical activity. The control group continued with the regular course of homework completion. Each week, youth in the control group experienced no change in their daily nutrition provided or the level of physical activity allotted in the after school program. For a period of six weeks, the control group experienced no changes to their daily routine.

Summary

Kids Playing for KEEPS is a quantitative, quasi-experimental pilot study. Pre-and post-survey design of the study allow me to investigate the effects of an intervention targeting risk factors for CHD within an after school program. The final analysis will compare participants' (children and their community) answers on pre-assessment and post-assessment surveys, analyzing the behaviors relevant to risk factors of heart disease. The quantitative analysis will tabulate the frequency of current physical activities, dining habits, and measured physical

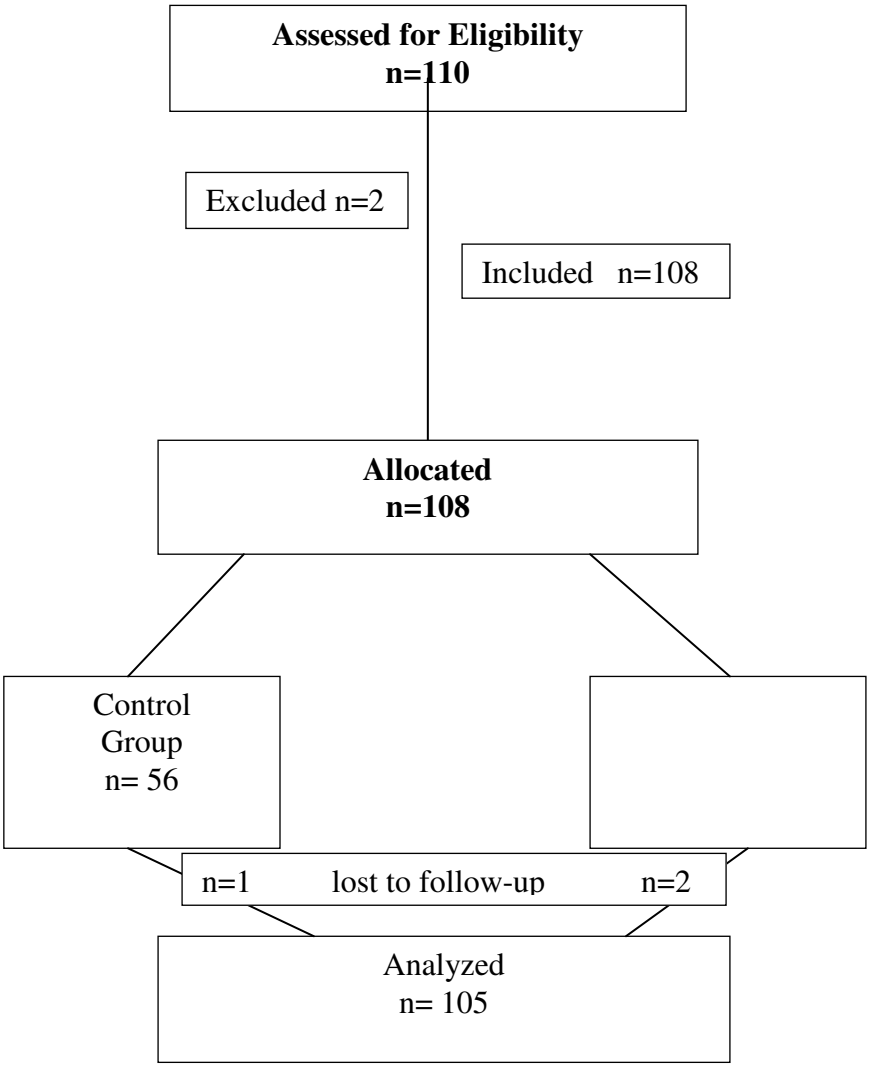
characteristics, such as blood pressure, height, weight, Body Mass Index (BMI) and waist circumference of the survey groups. Final study information will be shared with parents, program administrators, community officials and potential academic venues. All data presented or reported will be summary statistics and devoid of personally identifying information.

Chapter 4: Results

The KEEPS research was a quantitative, quasi-experimental design with matched comparison communities. The purpose of the intervention was to determine if a change in behavior, among members of a rural AA community was attainable. The independent variable was a diet and physical activity intervention in an experimental group. The dependent variable was an increase in heart healthy behaviors. The feasibility in recruiting school-age participants, their parents and community members and the importance of initial testing, prior to implementation of an intervention, dictated the use of a quantitative, quasi- experimental design. This chapter consists of an analysis of the KEEPS procedures, descriptive data, and results from the pre-and post-intervention surveys.

Participants for KEEPS were recruited from announcements made during events held in the two rural townships. Interested persons completed a short interview to determine eligibility and potential participants read and signed an informed consent form approved by the Institutional Review Board of Georgia Southern University. Inclusion criteria for youth participants were rural residency and enrollment in an after school program. Inclusion criteria for parents were rural residency and children who participated in an after school program. The inclusion criterion for community members was rural residency in a township serviced by an after school program. A total of 110 participants completed the enrollment paperwork, but one participant from the control group and one from the intervention group were loss due to death.

Figure 5. Flowchart of Study Population



Feasibility of Recruitment and Study Design

The recruitment strategy, utilizing flyers and public announcements to reach potential participants was effective in enrolling the desired study population. All participants agreed to complete a pre- and post-survey. All children and parent enrolling in the study, agreed to submit to physical assessments of height, weight, waist circumference (BMI), and blood pressure measurements, pre- and post-intervention. The BMI and blood pressure measurements of

participants were suspended due to a lack of time and human resources to enroll participants, administer the questionnaire, and perform the body assessments. Enrollment in future studies should be modified to include more than one researcher for body assessments. The recruitment of 110 participants was successful, aided by a strategy of approaching potential study subjects during an event in their weekly routine.

Intervention

Each day, the after school program participants have snacks available to them. In the interventions group, the daily snack, which consisted of cookies or chips and a sweetened beverage was discontinued for the intervention. In the control group, the daily snack continued as part of an unaltered routine. Twice a week, the intervention group increased the level of physical activity to at least 60 minutes during the study period. The diet and exercise intervention has to be constructed with an emphasis on simplicity, ease for compliance, and uncomplicated administration and implementation among school aged children.

Data Analysis

A 33- item questionnaire was administered to youth participants and a 42 and 41 item questionnaire was administered to parent and community participants, respectively. The pre-intervention questionnaire was given to establish a baseline for information about the participant's health status, personal knowledge, dietary habits and physical activity levels.

The effectiveness of the KEEPS research was established by the analysis of pre- and post-surveys administered to individuals of the control and intervention groups. Pre- and post-data was analyzed using paired t-tests. A p-value of less than .05 was considered statistically significant. The control and experimental groups were similar in composition, both groups

ranged in ages from 5 to 17. The pre survey control group (n=30) was comprised of 21 girls and 9 boys, while the experimental group (n=31) acquired 20 girls and 11 boys.

Complete data for the control and experimental group, pre- and post-intervention period was available for 58 children, 21 parents, and 26 community members, a total of 105 participants(N=105) for the study. This is a reduction from the 61 children enrolled at the time of the pre-intervention survey. One child from the control group moved out of the area and was not available for the post survey. Two participants from the intervention group stopped attending the after school program. The parent count was not affected because each child, who did not return, had siblings in the study. The intervention group had a rate of completion of 93% for enrolled participants at the end of the study. The control group finished the study with a 96% rate of completion (see Table 1).

Table 1. *Gender - Youth Participants*

Group	**Males**		**Females**	
	Frequency	**Percent**	**Frequency**	**Percent**
Control youth pre-survey	9	30.0	21	70.0
Experimental youth pre-survey	11	35.5	20	64.5
Control youth post-survey	8	27.6	21	72.4
Experimental youth post-survey	10	34.5	19	65.5

Demographic characteristics of the youth and adults (parents and community members) in the control group and the experimental group are outlined in Table 2.

Table 2. *Race- All Participants- Post Survey Results*

Group	African Americans		Hispanic/Latino	
	Frequency	Percent	Frequency	Percent
Control youth post-survey	29	100.0	0	0.0
Experimental youth pre-survey	25	86.2	4	13.8
Control adults post-survey	26	100.0	0.0	0.0
Experimental adults post-survey	21	100.0	0.0	0.0

Participants self-reported their household income, choosing from six categories with income levels ranging from $15,000 to greater than $75,000. The majority of participants, 38.5 % in the control group (n=10) reported an income of $25,000 to $35,000, while the majority of the experimental group, 33.3% (n=7) were categorized in the $20,000 to $25,000 range for household income. The majority of adult participants in the control, 57.7% (n=15) and 33.3% in the experimental (n=7) groups were married. Demographic characteristics of parents and community members are described in Table 3.

Table 3. *Demographic Characteristics- Parents and Community Members*

Income Level	**Control Group**		**Experimental Group**	
	Frequency	**Percent (n=26)**	**Frequency**	**Percent (n=21)**
$15,000 - $20,000	1	3.8	6	28.6
$20,000 -$25,000	3	11.5	7	33.3
$25,000 - $35,000	10	38.5	5	23.8
$35,000 - $50,000	6	23.1	2	9.5
$50,000 - $75,000	3	11.5	1	4.8
> $75,000	2	7.7	0	0
Missing data	1	3.8	0	0
Marital status				
Married	15	57.7	7	33.3
Divorced	3	11.5	5	23.8
Widowed	1	3.8	1	4.8
Separated	0	0.0	2	9.5
Never Married	5	19.2	5	23.8
Unmarried Couple	2	7.7	1	4.8
Missing Data	0	0	0	0

Measures

The KEEPS self-administered questionnaire asked participants to recall dietary habits and types of physical activities. Answer choices ranged from a score of 0 - 5. A zero (0) was the

corresponding score if a respondent did not know or was not sure of the answer. A score of 1 was equivalent to a "no" response in categories of dietary intake and/or exercise. A score ranging from 2-5 was a graduated response to the amount of intake and/or amount of physical activity. A question specific to AAs in this rural area referenced preparing vegetables with meat or fat for seasoning. Questions were asked to assess the influence of children less than 18 years of age exerted on meal preparation. The questionnaire also assessed respondents' participation in any type of physical activity and how often did informants engaged in the activity with individuals under the18 years of age. The survey had a possible total score ranging from 17 to 113. Scores were used as a marker to determine if any improvement was seen when comparing the pre- and post-survey scores. Approximately 98% of individuals, who met the study criteria and consented to participate in the study, completed the requirements.

Responses to questions of concern in AA populations were isolated for analysis using SPSS-v22 software. Hypertension has been proven to be a major contributor in the development of CHD. In the KEEPS survey, results for hypertension were similar between the control and the experimental groups (see Table 4). In youth control group, 10 % of the students responded yes to having been previously informed they were hypertensive or at risk for hypertension. In the experimental group, 10% of those students were also hypertensive or pre-hypertensive. Among parents and community members of the control group, 69% had been diagnosed with hypertension. Of the parents and community members in the experimental group, 66% had been diagnosed with hypertension. The recorded responses for this question, among all the participants remained unchanged over pre- and post-surveys.

Table 4. *Hypertension Awareness*

Have you ever been told that you have high blood pressure?	**Control Youth Group**		**Experimental Youth Group**	
	Frequency	Percent	Frequency	Percent
Don't know/Not sure	2	6.9	1	3.4
No	24	82.8	25	86.2
Yes	3	10.3	3	10.3
	Control Community Group		**Experimental Community Group**	
	Frequency	Percent	Frequency	Percent
No	8	30.8	7	33.3
Pre-hypertensive	0	0.0	4	19.0
Yes	18	69.2	10	47.6

As a part of a culturally comprehensive approach to identify behaviors specific to AA populations, the addition of salt in meals was explored. A question related to adding meat to vegetables during preparation was included to address the issue of hidden salt in rural AA diets. Pre-intervention responses of "Always" and "Most of the time" reflected 65.4% of the control group. The same responses can be attributed to 61.9% of respondents in the experimental group (see Table 5).

Table 5. *Addition of salted meat to vegetables*

How often do you add meat or fat to your vegetables?	**Control Community Group**		**Experimental Community Group**	
	Frequency	Percent	Frequency	Percent
Always	9	34.6	5	23.8
Most of the time	8	30.8	8	38.1
About half the time	5	19.2	7	33.3

Sometimes	2	7.7	0	0.0
Never	2	7.7	1	4.8

Health research has established that rural areas lack built environments that may facilitate an active lifestyle for community members. The KEEPS pre-intervention survey results show that 90% of youth, in the control group answered affirmative to using places in their community for physical activity. In the experimental group, 100% of youth also responded affirmative to the same question of using a place for exercise in their rural community (see Table 6). The recorded responses for this question, among all youth participants remained unchanged over pre- and post-surveys.

Table 6. *Environment for Physical Activity*

Are there places in your community you have used for physical activity or exercise?	**Control Youth Group**		**Experimental Youth Group**	
	Frequency	Percent	Frequency	Percent
Don't know/Not sure	1	3.3	0	0.0
No	2	6.7	0	0
Yes	27	90.0	29	100.0

Data were analyzed to compare responses given in the categories of dietary habits, physical activity and youth influence. A paired- sample t-test was conducted to compare pre- and post-survey mean scores for youth and adult (parent with community member) participants

in the control group, followed by a paired-sample t-test for youth and adult participants in the experimental group.

The difference in the pre- and post-survey mean scores for the control youth group was shown not to be significant ($p > .05$). Therefore, there was not a significant difference found in the behaviors and habits recorded pre-intervention when compared to those for the same youth post- intervention (see Figure 6 and Table 7).

Figure 6. Control Youth: Pre and Post Survey Mean

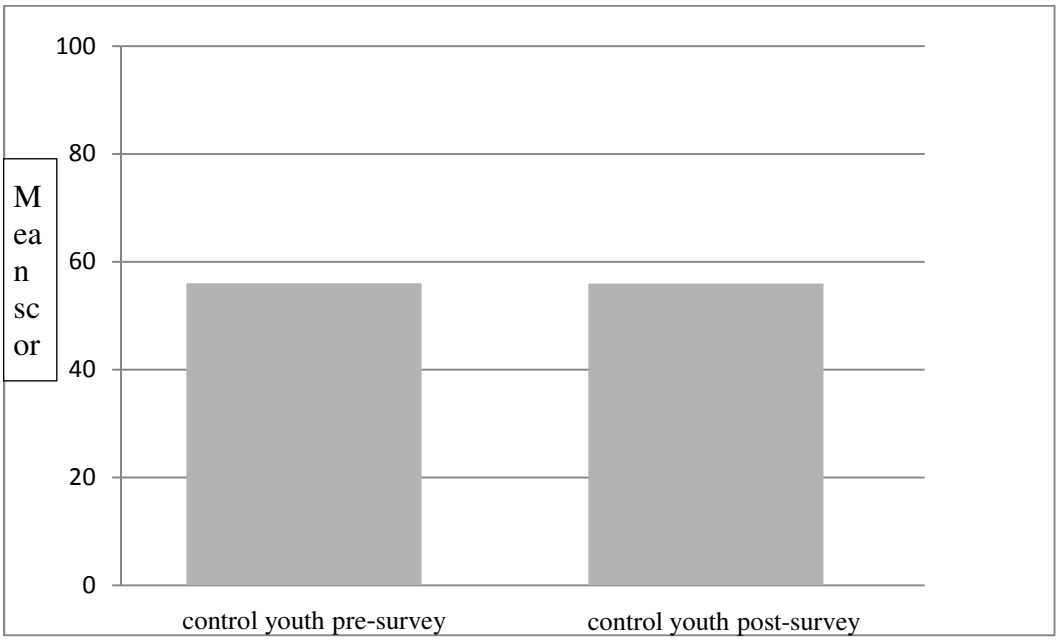


Table 7. *Paired Samples Statistics Control Youth*

Control Youth

Survey	Mean	N	Std. Deviation	Std. Error Mean	Significance
pre	56.00	29	14.940	3.050	
post	55.92	29	14.714	3.004	.627

The difference in the pre- and post-survey scores for the control parents and community groups were shown not to be significant ($p > .05$). Similar to the control youth results, there was not a significant difference found in the behaviors and habits reported by the community pre-intervention in comparison to the post- intervention responses. The differences in the control parent and community group mean scores are illustrated in Figure 7 and Table 8.

Figure 7. Control Parents and Community: Pre and Post Survey Mean

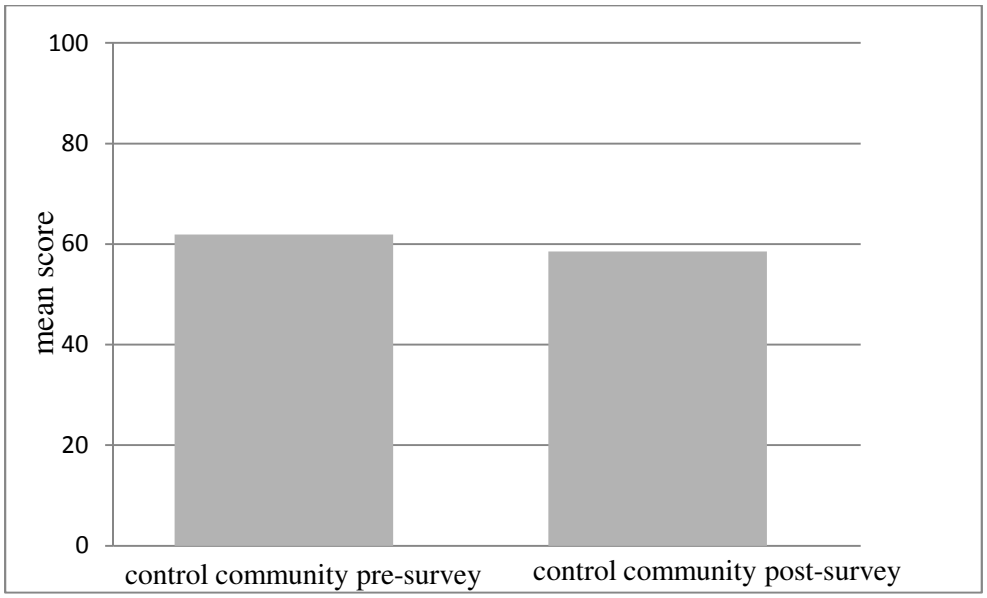


Table 8. *Paired Samples Statistics Control Community*

Control Parents and Community

Survey	Mean	N	Std. Deviation	Std. Error Mean	Significance
pre	61.92	26	8.07922	1.584	
post	58.50	26	7.13442	1.399	1.83

The difference in the pre- and post-survey scores for the experimental youth group was shown to be significant ($p < .05$). The change in behaviors and habits recorded post-intervention for the experimental youth group was statistically significant, represented in Figure 8 and Table 9.

Figure 8. Experimental Youth: Pre and Post Survey Mean

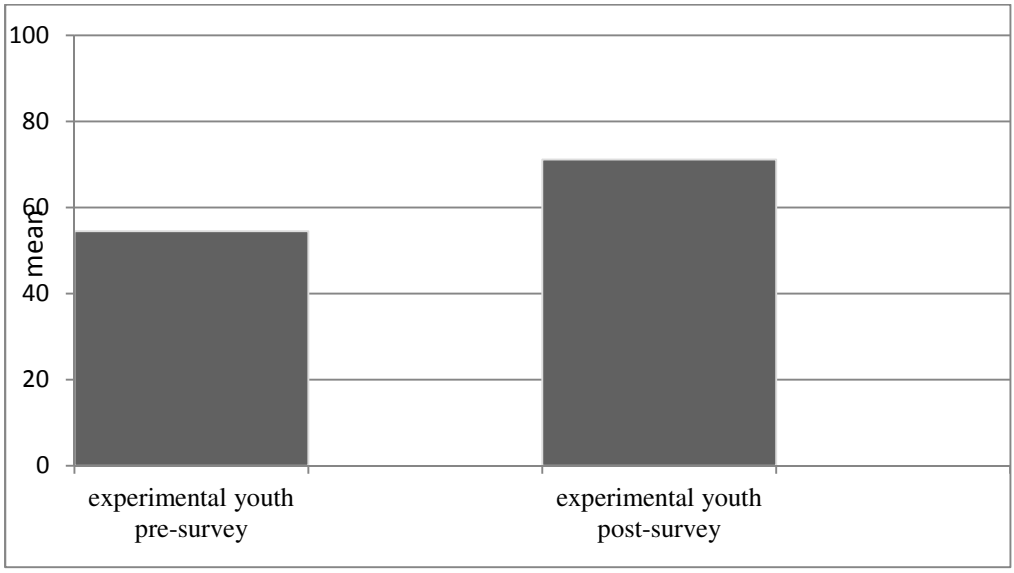


Table 9. *Paired Samples Statistics Experimental Youth*

Experimental Youth

Survey	Mean	N	Std. Deviation	Std. Error Mean	Significance
pre	54.45	29	18.770	3.486	
post	71.14	29	25.258	4.690	.000

The difference in the pre- and post-survey mean scores for the experimental parents and community group was shown to be significant ($p < .05$). The comparison of the experimental parent and community group mean scores are shown in Figure 9 and Table 10.

Figure 9. Experimental Parents and Community: Pre and Post Survey Mean

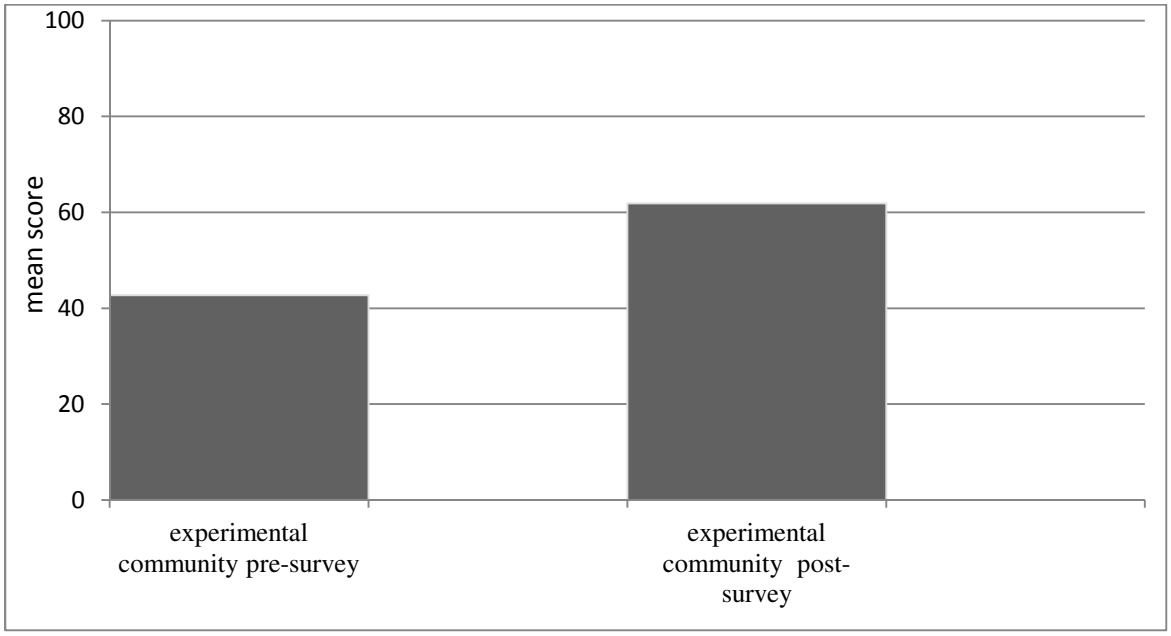


Table 10. *Paired Samples Statistics Experimental Community*

Experimental Parents and Community

Survey	Mean	N	Std. Deviation	Std. Error Mean	Significance
pre	42.71	21	15.87	3.462	
post	61.86	21	7.164	1.563	0.00

An independent sample t- test was performed, which determine the difference between the control group post mean score and the experimental group post mean score were statistical significant (see Table 11).

Table 11. *Control and Experimental Comparison*

Independent sample t-test

Survey	Mean	N	Std. Deviation	Std. Error Mean	Significance
Control	42.71	21	15.87	3.462	0.00
Experimental	61.86	21	7.164	1.563	

Chapter 5: Discussion

The quantitative, quasi-experimental pilot study examined the efficacy of a culturally comprehensive strategy targeting AAs. The procedures used in "Kids Playing for KEEPS," after school intervention were successfully initiated within a southern rural AA community. This KEEPS feasibility research was conducted in an after school program environment for a period of 6 weeks. Participation data from the present study suggest that an increase in physical activity in an after school program can be sustained, when added to the weekly curriculum. The Critical Youth Empowerment and the Social Cognitive Theory framework provided a practical and attainable approach to implement a diet and exercise curriculum in an after school program for the express purpose of community health promotion. One adult, without funding for equipment, instituted the necessary additions to the coursework in an existing after school program. An implementation of the exercise portion of this program may require only minimal modifications to accommodate unique neighborhood or community settings. The increase in exercise can supplement after school programs, whether public or private care programs, whether faith-based or municipal sponsored tutoring.

The results from the present study showed that the KEEPS individual-level intervention, targeting youth is feasible. Participation and retention rates were exceptionally high, with 96% of families recruited completing pre- and post-surveys. The high participation rate is attributed to having access to parents/guardians during daily dismissal. Parents were reminded each day after the conclusion of the study to return completed surveys to the researcher.

Objectives

The CDC Division for Heart Disease and Stroke Prevention Evaluation Guide and SMART objectives were used in this study to create appropriate goals to determine the efficacy of a diet and exercise intervention. The aim of this study was to assess the feasibility and effectiveness of an after school diet and exercise intervention:

1) among participants in an after school program
2) to effect behavior change among members of their community.

The objectives of an effective KEEPS intervention were to:

1) increase physical activity and fruit and vegetable consumption among after school participants and
2) a decrease in the frequency of modifiable risk behaviors for CHD among community members.

The feasibility of this study was determined by an examination of the processes involved in the recruitment and retention of study participants, the assessment of intervention suitability, and the determination of study outcomes. The study addressed the following feasibility questions:

1) What percentage of eligible youth participants will consent and complete a 6-week intervention period?
2) What percentage of eligible youth participants will complete pre- and post-surveys?
3) What percentage of eligible parent and community participants will consent and complete pre and post surveys?
4) What is the effect of cost on the intervention process?
5) What type of usable data will the study generate?

SMART Objectives were used to assess implementation of each intervention component in Table 13.

Table 12. *Calendar of Events*

	1) **Specific changes**	2) **Measurable results achieved**	3) **Attainable results**	4) **Relevant effect**	5) **Time-frame**	
Week 1	1-1)intro Increased Physical activity	2)increase time of activity	3)increased active time	4)incorporate in daily routine	5)1 week	**Successful**
Week 2	2-1)No Sugary Drinks/ Increase Water & fruits/ vegetables	2)Decreased # of sugary drinks/replace snack with fruits and veggies	3)Created water bottle/fruit and veggies as snacks	4)The benefits asked for water/ ask for fruits & veggies	5)1 week	**Successful**
Week 3	3-1)Intro to whole grains(WG)	2)Increase WG consumption	3)Make snack with WG	4)Looked for WG on labels	5)1 week	**Successful**
Week 4	4-1)Intro to reducing salt	2)Find salt substitutes	3)Make salt substitutes	4)find ways to use	5)1 week	**Successful**
Week 5	5-1) Counting calories	2) distinguish	3)read difference	4) Read labels and menus for calories	5)1 week	**Successful**
Week 6	6-1) Intro to gardening	2) plant seeds	3)Prepare fruit for snacks	4)Increased physical activity and exposure to gardening	6)1 week	**Successful**

Effectiveness

The intervention met the SMART objectives outlined in the planning of the study. The first objective of the KEEPS intervention was achieved with the increase in the levels of physical activity and the amount of fruit and vegetable consumption by the intervention group. The second objective of the intervention was successful in decreasing the frequency of modifiable risk factors for CHD among experimental group. The data from the experimental group's youth, parents and community members suggest a decrease in the amount of inactivity, high fructose drink intake and a decrease in the practice of adding salted meat to flavor vegetables.

The primary aim of the KEEP Study, created to meet specific differences in the AA community, could lead to the reduction of CHD risk factors within a southern rural community. Although, this study is not the first to test an after school linked intervention, it is distinctive in the approach to community health promotion. To my knowledge, no other study has examined the effects of an after school diet and exercise intervention, on the surrounding community of AAs. Consequently, the challenge for future KEEPS intervention is to draw a parallel between the intervention and the improvement in AA heart health.

Research Question 1

How will a limited, focused approach, targeting the most vulnerable in our society, change behaviors known to reduce the prevalence of modifiable risk factors for coronary heart disease found in southern rural AA communities?

> The increase physical activity and fruit and vegetable consumption among after school participants was reinforced in the youth participants' daily activities. Young participants continued increased levels of play during unscheduled physical activity days of the after school program and invited family

members to participate. Therefore, the KEEPS intervention met an established goal of healthy habits being adopted by the youth and the parents of after school program.

Research Question 2

What ability does the youth in an after school program have to exert influence and change behaviors for members of a rural community?

The current research revealed adults exhibited greater knowledge of healthy dietary habits and improved reported physical activity after their children received diet and exercise education during an after school intervention.

Research Question 3

What is the causal relationship, if any between empowered youth of a rural AA setting on environmental and policy change within their community?

It was beyond the reach of this pilot/ feasibility study to infer any causal relationship between the intervention in an after school program and the resulting change in the community. The causal relationship may be determined by a larger study involving a framework of youth empowerment. This pilot study provides support for further investigation of youth influence in the planning and delivery of effective public health promotion programs.

Strengths

This study's feasibility in southern rural AA communities is evident by the high participant retention rates. Approximately 96% of individuals who met the study criteria and consented to participate completed the study. Strategies for study participant recruitment in

rural areas should target highly publicized community events and established organizations with routinely scheduled meeting times. Subsequently, this recruitments strategy provides a necessary foundation for participant retention and finalization of study requirements. The researcher from the KEEP Study found the structured meeting schedules of organization within rural communities was an invaluable resource and key in providing access and familiarity to the research process. The completion of the necessary phases in the KEEPS research relied heavily on the rigid routine of the community. The high return rate of completed surveys was aided by the flexibility of the data collection procedures. Participants in this study had the option of completing a paper copy of the KEEPS Questionnaires, or a digital copy. Questionnaires could be completed as a phone survey for those individuals requesting an alternative method of compliance.

This study highlights the cultural behavior of adding salted meat or fat in the preparation of vegetables. There is limited literature on the combined effect of added salt to the AA diet and salt sensitive. This research seeks to feature the importance of salt sensitivity knowledge and hypertension awareness in the AA community.

Limitations

There are a number of limitations when addressing the feasibility of the KEEPS research. These limitations illustrate the need to conduct the study on a larger scale. An intervention period of greater than 6 weeks would aid the project. Research conducted in rural areas is limited by the number of study participants available over a relatively large geographical area. Rural research requires additional time considerations for recruitment, enrollment, and follow-up periods. A study involving rural participants will demand more than one investigator to navigate the different phases of the research. The collection of data in rural areas may be

complicated by the additional effort necessary to locate an ample pool of study participants for sufficient enrollee retention. The scarcity of time and vast geographical areas are issues working in tandem as barriers in rural research projects.

This study was limited by certain aspects of the KEEPS questionnaire used in the present research. A self-reporting tool requiring recall information greater than a week in duration is more suitable for preteen through adults, compared to very young children. Dietary habits and physical activities were reported based on a weekly or monthly recall. Therefore, the survey data from very young participants may not be characteristic of daily intake or activity but an average representation. Additionally, the scores assigned to the survey questions were not tested on a large scale, nor were weighted estimators used to minimize bias. Scores were assigned to BRFSS questions to determine if a change in behaviors had occurred between the pre-intervention survey and the post-intervention survey.

Delimitations

There are some delimitation to this dissertation. The narrow selection of AAs from a southern rural township may decrease the ability to generalize feasibility finding to interventions in non-rural geographical areas of the U.S. The educational and exercise modules may not transition to larger academic environments, such as large classrooms or schools.

Implications

The KEEPS research employed the Critical Youth Empowerment (CYE) model as a guide for the intervention design. CYE stresses the concept of planning individual level interventions in a safe and welcoming environment. Providing opportunities for meaningful participation and engagement in this cooperative and supportive setting encourages tangible achievements of youth within their community. This outcome was realized in the KEEPS

research among the experimental group participants. During the extended physical activity period, students developed and planned three initiatives to influence community involvement. The first was distance markers being added to a designated walking track. The second activity was the creation of a team sport, inviting members of the community to participate. Lastly, students created a day of physical activities, which involved the pairing of adults with students in a basketball competition. During the dietary module of the intervention, the students petitioned the city council for a garden on city property, adjacent to the after school program building. The implications of a service project or civic engagement may have greater impact on policy development within a community. Interventions that can influence the individual and policy can produce advantageous decisions resulting in the narrowing of the disparities gap in southern rural AA communities.

The empowerment and SCT framework, as in the KEEPS research, proves conducive to community policy development. The implementation of a health promotion program, within an established organization in a rural setting, provides a forum for collaboration and public health policy development. The KEEPS research results support policy creation. The interaction of young people in a structured program with a formative curriculum can contribute to the enrichment of other community practices. The successful implementation and outcome of this research may be a conduit to inform policy makers and initiate the elimination of food insecurities in rural communities. Public policy can encourage a sustained commitment to the development of positive, healthy outcomes by setting minimum requirements in after school programs for diet and physical activity. All of the aforementioned actions are relevant to public health. It is necessary to begin with public health promotion programs that are deemed feasible and effective. The KEEPS research concentrated on an individual level intervention to influence

the upper levels of the socio-ecological model. Once the hierarchy of community is influenced, policy can provide guidance and produce amplified results, potentially impacting community health.

Future Research

Previous studies on the subject of CHD interventions have suggested future research include more AAs and/ or recruit participants with known risk factors for the disease. This present study accomplished that objective. The challenge for a future KEEPS intervention is to draw a parallel between the intervention and the improvement in AA heart health.

The KEEPS research provided an informative glimpse into using vital organizations in rural African American communities as a resource. It is feasible and necessary to use established institutions within a targeted community. Building upon or expanding any type of municipal, faith-based, or private program with health promotion education is not only attainable, but may prove to be sustainable.

The groundwork of developing and implementing a simple addition to a community for the express purpose of health promotion can have desirable outcomes. A larger research study would be needed to determine if an after school intervention is responsible for any causal relationship between the youth of a southern rural community and the community members. After identifying the unique challenges of an intervention in a rural setting, this study determined the feasibility of implementing a larger research project. Delivery of the KEEPS intervention is possible, with consistency in protocol, with or without any imposed time constraints. A cost-benefit analysis in future studies may provide further insight to the effectiveness of the KEEPS intervention. This pilot study was able to purchase necessary items, while managing the cost of the intervention. The researcher maintained budget of $40.00 per week for food and educational

materials during the intervention. Although no previous guidelines to evaluate the cost-effectiveness of the current study were established, the weekly expenditures seemed reasonable for the number of study participants. In a systematic review of economic evaluations of public health interventions, the authors state the cost-effectiveness of a program should answer if the intervention produced outcomes worthy of the investment (Edwards, 2013).

Beyond the recognized morbidity and mortality inequalities, there are racial differences in disease frequency and health behavior in the AA community. It is pertinent to address the disparities with targeted community interventions incorporating specific differences of AAs relating to CHD. An example is the introduction of salt sensitivity information into an intervention, which adds a specific genetic component for the benefit of AA communities. In addition, the KEEPS pilot considered disparities in minority participation and retention in research. Moreover, this study addressed issues of rural AAs, time constraints, distance from organized events, the lack of health information, the need of social support, and limited access to built environments.

Conclusion

The KEEPS research explored the feasibility and the efficacy of a diet and exercise intervention for the expressed purpose of health promotion within a southern rural AA community. Despite the simplistic intervention design, the individual-level, health promotion program resulted in an increase in physical activity and a decrease in behaviors associated with CHD modifiable risk factors. The significance of this research was it provided information regarding reasonable and effective means to improve AA participation in research; focused on unique characteristics of the targeted population and the effects of a realistic intervention in a rural community. This culturally comprehensive approach was instrumental in designing and

implementing a successful pilot study, which suggest a larger study is feasible with modifications. This research highlights lessons-learned, in addition to the appraisal of employing research methods favorable to ethical and logistical issues, time considerations, and limited resources.

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Appendix A

Greetings Everyone,

Volunteers Needed for Research Study

The study

The research project is named "Kids Playing for KEEPS: Keys to Heart Disease in a Rural Community".

Description of Project: Residents of a rural community who are being invited to participate in research on the preventable risk factors for heart disease. Participation in this research will include completing a survey about diet and physical activity before and after the study.

To participate: You must be currently live in a rural area, enrolled in or have access to an After School Program in Richmond, Columbia or Burke counties.

To learn more, contact the principle investigator of the study, Carla Noah, at 706-738-3145 or Carla.a.noah@georgiasouthern.edu

This research is conducted under the direction of the School of Public Health, Georgia Southern University

Appendix B

COLLEGE OF PUBLIC HEALTH

INFORMED CONSENT
FOR
PARENT/LEGAL GUARDIAN OF STUDY PARTICIPANTS

Name of Principal Investigator: Carla Noah
Name of Organization: Georgia Southern University
Name of Sponsor: Jiann-Ping Hsu College of Public Health
Name of Proposal and Version: "Kids Playing for KEEPS: Keys to Heart Disease in a Rural Community".

This Informed Consent Form is for the parents/legal guardians of children and adolescence who are being invited to participate in research on the preventable risk factors for heart disease. The research project is named "Kids Playing for KEEPS: Keys to Heart Disease in a Rural Community. I am going to give you information and invite you and your child to be a part of this Research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

Please ask me to stop as we go through the information if you have any questions and I will take time to explain. If you have questions later, you can contact me.

I, Carla Noah, am conducting a study on the reduction of preventable risk factors for heart disease. In the United States, heart disease is the leading cause of death. The purpose of this research is to identify which risk factors, if any, can be reduced through working with children and adolescence in an afterschool program.

I am asking you for permission for your child to participate in learning about health foods and physical activity. You and Your child will participate by completing a survey and submit to having blood pressure, height, weight, Body Mass Index (BMI) and waist measurements taken before and after the study. The results of participation will help to identify healthy habits, which are teachable and sustainable within a population at risk for heart disease.

Discomforts and Risks

Minor discomfort may arise when discussing sensitive personal issues. There may be the risk of embarrassment from the body measurements being taken.

Right to Ask Questions

You have the right to ask questions and have those questions answered. If you have questions about this study, please contact the researcher named below or the researcher's faculty advisor, whose contact information is located at the end of the informed consent. For questions concerning your rights as a research participant, contact Georgia Southern University Office of Research Services and Sponsored Programs at 912-681-0843.

Voluntary Participation

Participation in the study is voluntary. You may end their participation at any time by telling the person in charge or by not returning the survey. There is no penalty for deciding not to participate in the study. You must be 18 years of age or older to consent to participate in this portion of the study research study and to give consent for your child or children's participation. You will be given a copy of this consent form to keep for your records. This project has been reviewed and approved by the GSU Institutional Review Board under tracking number **H13021.**

Confidentiality Clause

With the information collected through surveys, no attempt will be made to connect your child's name with their responses. All study records including this signed informed consent form will remain in a locked cabinet as not to divulge the names of any participants, keeping all transactions confidential. Any computer use will have password protection to prevent access by unauthorized users. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations.

Contact Information

If you have any questions about the research as a study subject, you may contact any one of the following people listed Carla Noah at 706-738- 3145 or Dr. Greg Evans, Faculty Advisor Georgia Southern University at 912-478-2674.

I, the undersigned, verify that the above informed consent procedure has been followed.

_____ _____

_____ _____

Participant Signature Date

I, the undersigned, verify that the above informed consent procedure has been followed.

_____ _____

Investigator Signature Date

COLLEGE OF PUBLIC HEALTH

MINOR'S ASSENT

Hello,

I am Carla Noah, a graduate student at Georgia Southern University and I am conducting a study on Kids Exercise Enrichment Programs and heart disease.

You are being asked to be a part of a project that will be used to learn about kids and exercise in an after school program. If you agree to be part of the project, you may receive information on how to fix healthy snacks and play games for exercise. In this study, I will find out your Body Mass Index (BMI). Your height and weight will be measured along with your waist. I will measure your blood pressure. I will also ask you questions about what you like to eat and what games you play and how often. After the study is completed in November 2012, we will celebrate with a big party as a thank you for participating. Everyone is invited to the study party whether you participated in the study or not. But if you choose not to attend the party there will be an activity in the media center for your enjoyment.

You do not have to do this project. You can stop whenever you want. If you do not want to play some or any of the games, it is ok, and you can go back to your classroom, and nothing bad will happen.

None of the teachers or other people at the after school program will see the answers to the questions that I ask you. All of the answers that you give me will be kept in a locked cabinet in my office at Analyze America Labs, Inc. and only I and my teacher will see your answers. We are not going to put your name on the answers that you give us, so no one will be able to know which answers were yours.

If you or your parent/guardian has any questions about this form or the project, please call me at 706-738-3145 or my teacher, Dr. Evans at 912-478-2476. Thank you!

If you understand the information above and want to do the project, please sign your name on the line below:

Yes, I will participate in this project: _____

Child's Name: _____

Investigator's Signature: _____

Date: _____

COLLEGE OF PUBLIC HEALTH

INFORMED CONSENT
FOR
COMMUNITY PARTICIPANTS

I, Carla Noah, am a graduate student at Georgia Southern University. I am conducting a study on the reduction of preventable risk factors for heart disease. In the United States, heart disease is the leading cause of death. The purpose of this research is to identify which risk factors, if any, can be reduced through working with children and adolescence in an afterschool program.
I am going to give you information and invite you to be a part of this Research. You do not have to decide
today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.
Procedures to be followed: Participation in this research will include completing a survey before and after the study.
Discomforts and Risks: Minor discomfort may arise when discussing sensitive personal issues.

Statement of Confidentiality
All study records including this signed informed consent form will remain in a locked cabinet as not to divulge the names of any participants, keeping all transactions confidential. Any computer use will have password protection to prevent access by unauthorized users. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations. All study information will be maintained in a secure location for a minimum of three years following completion of the research.

Right to Ask Questions
You have the right to ask questions and have those questions answered. If you have questions about this study, please contact the researcher named below or the researcher's faculty advisor, whose contact information is located at the end of the informed consent. For questions concerning your rights as a research participant, contact Georgia Southern University Office of Research Services and Sponsored Programs at 912-681-0843.

Voluntary Participation

Participation in the study is voluntary. You may end their participation at any time by telling the person in charge or by not returning the survey. There is no penalty for deciding not to participate in the study. You must be 18 years of age or older to consent to participate in this portion of the study research study.

There is no penalty for deciding not to participate in the study. Anyone at any time may decide not to participate in the study without penalty.

You must be 18 years of age or older to consent to participate in this research study. If you consent to participate in this research study and to the terms above, please sign your name and indicate the date below.

You will be given a copy of this consent form to keep for your records. This project has been reviewed and approved by the GSU Institutional Review Board under tracking number H13021.

Title of Project: Kids Playing for KEEPS: Keys to heart disease in a rural community.

Principal Investigator: Carla Noah, 1840 Wrightsboro Rd. Augusta, GA 30904
706-738-3145 email: cn00502@georgiasouthern.edu

Faculty Advisor: Dr. Greg Evans, Georgia Southern University, P.O. Box 8015, Statesboro, GA 30460
912-478-2674 email: rgevans@georgiasouthern.edu

_____ _____

Participant Signature Date

I, the undersigned, verify that the above informed consent procedure has been followed.

_____ _____

Investigator's Signature Date

Appendix C

SURVEY (parent participants)

You are being asked voluntarily participate in a research study. By Completing and returning this survey it implies that you agree to participate and your data may be used in this research. At the end of the survey if you want a copy of the survey, ask the person giving the survey when you are finished. A copy will be given to you. It will take no longer than 20 minutes to answer questions. A researcher will answer any questions you have and you may stop the survey at any time.

My initials mean I have read and understand._____

1. What is your date of birth? _____

2. Which one of these groups would you say best represents your race?

   □ White
   □ Black or African American
   □ Asian
   □ Hispanic/ Latino
   □ Native Hawaiian or Other Pacific Islander
   □American Indian or Alaska Native
   □ Other [specify] _____
   □ Don‘t know / Not sure

3. What is your marital status?
   □ Married
   □ Divorced
   □ Widowed
   □ Separated
   □ Never married
   □ A member of an unmarried couple
   □ Don‘t know / Not sure

4. How many children less than 18 years of age live in your household?
   _____

5. Have you EVER been told by a doctor, nurse, or other health professional that you have high blood pressure?

   □ Yes
   □Yes, but female told only during pregnancy
   □ No

□ Told borderline high or pre-hypertensive
□ Don‘t know / Not sure

6. Are you currently taking medicine for your high blood pressure?
□ Yes
□ No
□ Don‘t know / Not sure

7. Have any of your children been told by a doctor or other health professional that they have
high blood pressure?
□ Yes
□ No
□ Told borderline high or pre-hypertensive
□ Don‘t know / Not sure

8. Have you ever been told by a doctor or other health professional that you have pre-diabetes or borderline diabetes?
□ Yes
□Yes, but only during pregnancy
□ No
□ Don‘t know / Not sure

9. How old were you when you were told you have diabetes?
_____

10. Have any of your children been told by a doctor or other health professional that they have pre-diabetes or borderline diabetes?
□ Yes
□ No
□ Don‘t know / Not sure

11. Do you now smoke cigarettes every day, some days, or not at all?

□ Every day
□ Some days
□ Not at all
□Don‘t know / Not sure

12. During the past 2 months, have you stopped smoking for one day or longer because you were trying to quit smoking?

□ Yes
□ No
□ Don‘t know / Not sure

13. Do you currently use chewing tobacco or snuff, every day, some days, or not at all?

□ Every day
□ Some days
□ Not at all
□ Don‘t know / Not sure

14. During the past month, how many times per day did you drink 100% PURE fruit juices? Only include 100% juice.

□ I don’t drink juice every day
□ 1 glass (8 ounces)
□ 2 glasses (16 ounces)
□ 3 or more glasses (24 ounces)
□ 4 or more glasses (32+ ounces)

15. How much water do you drink in a day?
□ I don’t drink water every day
□ 1 glass (8 ounces)
□ 2 glasses (16 ounces)
□ 3 or more glasses (24 ounces)
□ 4 or more glasses (32+ ounces)

16. About how often do you drink regular soda or pop that contains sugar?

□ I don’t drink soda every day
□ 1 soda (8 ounces)
□ 2 sodas (16 ounces)
□ 3 or more sodas (24 ounces)
□4 or more sodas (32+ ounces)

17. About how often do you drink sweetened fruit drinks, such as Kool-Aid, cranberry, and lemonade?
Include fruit drinks you made at home and added sugar to.

□ I don’t drink fruit drink every day

□ 1 glass (8 ounces)
□ 2 glasses (16 ounces)
□ 3 or more glasses (24 ounces)
□ 4 or more glasses (32+ ounces)

18. During the past month, not counting juice, how many times per week did you eat fruit? Count fresh, frozen, or canned fruit

□ I don't eat fruit every week
□ I eat fruit every day
□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

19. During the past month, how many times per week did you eat cooked or canned beans, such as refried, baked, black, garbanzo beans, beans in soup, soybeans, tofu or lentils? Do NOT include long green beans.

□ I don't eat them every week
□ I eat them every day
□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

20. During the past month, how many times per week did you eat dark green vegetables for example broccoli or dark leafy greens including romaine, chard, collard greens, or spinach?

□ I don't eat them every week
□ I eat them every day
□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

21. During the past month, how many times per week did you eat orange-colored vegetables such as sweet potatoes, pumpkin, winter squash, or carrots?

□ I don't eat them every week
□ I eat them every day
□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

22. How many times per week did you eat OTHER vegetables? Examples of other vegetables include tomatoes, tomato juice or V-8 juice, corn, eggplant, peas, lettuce, cabbage, and white potatoes that are not fried such as baked or mashed potatoes.

□ I don't eat them every week
□ I eat them every day
□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

23. How often do you add meat or fat to your vegetables for flavoring?
□ Always
□ Most of the time
□ About half the time
□ Sometimes
□ Never

24. How many times per week did your diet include low-fat dairy?
□ I don't include them every week
□ I include them every day
□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

25. How many times per week did you eat whole grains?
Example is whole wheat bread.

□ I don't eat them every week
□ I eat them every day
□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

26. Has anyone under the age of 18 prepared lunch or dinner for you in the past 2 months?
□ Always
□ Most of the time
□ About half the time
□ Sometimes
□ Never

27. Does anyone under the age of 18 suggest vegetables to be prepared at home?
□ Always

□ Most of the time
□ About half the time
□ Sometimes
□ Never

28. Does anyone under the age of 18 prepare fruits and/or vegetables as snacks in your household?
□ Always
□ Most of the time
□ About half the time
□ Sometimes
□ Never

29. If the above answer is yes, in the past month how often did anyone under 18 prepare fruits and/or vegetables for snacks in your household?
□ Less than once a week
□ Once a week
□ 2 times a week
□ 3-5 times a week
□ More than 5 times a week

30. The next question is about eating out at fast food and chain restaurants. Do you notice the calorie information at restaurants?

□ Yes
□ No
□ Don‘t know / Not sure

31. The next question is about eating out at fast food and chain restaurants. When calorie information is available in the restaurant, how often does this information help you decide what to order?
□ Always
□ Most of the time
□ About half the time
□ Sometimes
□ Never
□ Don‘t know / Not sure

32. During the past month, other than your regular job, did you participate in any physical activities or exercises such as running, sports, gardening, or walking for exercise in your community?
□ Yes
□ No

□ Don‘t know / Not sure

33. How many times per week did you take part in this activity during the past month?

□ I didn’t take part in physical activity
□ I took part in physical activity everyday
□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

34. And when you took part in this activity, did any member of your family under age 18 participate with you?
□ Always
□ Most of the time
□ About half the time
□ Sometimes
□ Never

35. During the past month, did you participate in any gardening or growing food?
□ Yes
□ No
□ Don‘t know / Not sure

36. During the past month, did you participate in sports?
□ No, I didn’t play sports
□ I played sports everyday
□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

37. How many times per week did you play sports with someone under the age of 18?

□ I didn’t take part
□ I took part everyday
□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

38. Are there places in your community you have used for physical activity or exercise?
□ Yes
□ No
□ Don‘t know / Not sure

39. In the past month, have you participated in physical activity or exercised with your family in your community?
    □ I didn't take part
    □ I took part everyday
    □ 1-2 times a week
    □ 3-4 times a week
    □ 5-6 times a week

40. In the past month, has anyone under the age of 18 influenced your participation in any physical activity in the community?
    □ Yes
    □ No
    □ Don't know / Not sure

41. Which best describes your household income level:
    □ $75,000 or more
    □ $50,000 - $75,000
    □ $35,000 - $50,000
    □ $25,000 - $35,000
    □ $20,000 - $25,000
    □ $15,000 - $20,000
    □ Don't Know/ Not sure

42. What is your age?_____

_____
height

_____
weight

_____ waist
circumference

_____ _____
BP

_____

SURVEY
(youth participants)

You are being asked voluntarily participate in a research study. By Completing and returning this survey it implies that you agree to participate and your data may be used in this research. At the end of the survey if you want a copy of the survey, ask the person giving the survey when you are finished. A copy will be given to you. It will take no longer than 20 minutes to answer questions. A researcher will answer any questions you have and you may stop the survey at any time.

My initials mean I have read and understand._____

1. What is your date of birth? _____

2. Which one of these groups would you say best represents your race?

□ White
□ Black or African American
□ Asian
□ Hispanic/ Latino
□ Native Hawaiian or Other Pacific Islander
□American Indian or Alaska Native
□ Other [specify] _____
□ Don‘t know / Not sure

3. How many children less than 18 years of age live in your house?

_____

4. Have you EVER been told by a doctor or a nurse that you have high blood pressure?

□ Yes
□ No
□ Don‘t know / Not sure

5. Are you currently taking medicine for high blood pressure?

□ Yes
□ No
□ Don‘t know / Not sure

6. Have you ever been told by a doctor or nurse that you have diabetes?

□ Yes
□ No
□ Don‘t know / Not sure

7. Do you smoke cigarettes?

□ Yes
□ No
□ Don‘t know / Not sure

8. Does someone in your house smoke?

□ Yes
□ No
□ Don‘t know / Not sure

9. Do you currently use chewing tobacco or snuff ?

□ Yes
□ No
□ Don‘t know / Not sure

10. During the past month, how many times per day did you drink 100% PURE fruit juices? Only include 100% juice.

□ I don’t drink juice every day
□ 1 glass (8 ounces)
□ 2 glasses (16 ounces)
□ 3 glasses (24 ounces)
□ 4 or more glasses (32+ ounces)

11. How much water do you drink in a day?
□ I don’t drink water every day
□ 1 glass (8 ounces)
□ 2 glasses (16 ounces)
□ 3 glasses (24 ounces)
□ 4 or more glasses (32+ ounces)

12. About how often do you drink regular soda or pop that contains sugar?
    □ I don't drink soda every day
    □ 1 soda (8 ounces)
    □ 2 sodas (16 ounces)
    □ 3 sodas (24 ounces)
    □4 or more sodas (32+ ounces)

13. About how often do you drink sweetened fruit drinks, such as Kool-Aid, cranberry, and lemonade?
    □ I don't drink fruit drink every day
    □ 1 glass (8 ounces)
    □ 2 glasses (16 ounces)
    □ 3 glasses (24 ounces)
    □ 4 or more glasses (32+ ounces)

14. During the past month, not counting juice, how many times per week did you eat fruit? Count fresh, frozen, or canned fruit.

    □ I don't eat fruit every week
    □ I eat fruit every day
    □ 1-2 times a week
    □ 3-4 times a week
    □ 5-6 times a week

15. During the past month, how many times per week did you eat dark green vegetables for example broccoli or dark leafy greens including romaine, chard, collard greens or spinach?

    □ I don't eat them every week
    □ I eat them every day
    □ 1-2 times a week
    □ 3-4 times a week
    □ 5-6 times a week

16. During the past month, how many times per week did you eat orange-colored vegetables such as sweet potatoes, pumpkin, winter squash, or carrots?

□ I don't eat them every week
□ I eat them every day
□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

17. How many times per week did you eat OTHER vegetables? Examples of other vegetables include tomatoes, tomato juice or V-8 juice, corn, eggplant, peas, lettuce, cabbage, and white potatoes that are not fried such as baked or mashed potatoes.

□ I don't eat them every week
□ I eat them every day
□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

18. How many times per week did your diet include low-fat dairy?

□ I don't include them every week
□ I include them every day
□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

19. How many times per week did you eat whole grains?
Example is whole wheat bread.

□ I don't eat them every week
□ I eat them every day
□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

20. Have you cooked lunch or dinner for your family in the past 2 months?

□ Always
□ Most of the time
□ About half the time
□ Sometimes
□ Never

21. In the past 2 months have you asked for a certain vegetable for a meal at home?

□ Always

□ Most of the time
□ About half the time
□ Sometimes
□ Never

22. Do you prepare fruits or vegetables for snacks in your house?
□ Always
□ Most of the time
□ About half the time
□ Sometimes
□ Never

23. In the past month how many times have you eaten fast food (Burger King, McDonalds, Bo jangles, or Pizza Hut) or eat away from home?
□ Less than once a week
□ Once a week
□ 2 times a week
□ 3-5 times a week
□ More than 5 times a week

24. When calorie information is available in the restaurant, how often does this information help you decide what to order?
□ Always
□ Most of the time
□ About half the time
□ Sometimes
□ Never

25. During the past month, did you participate in any physical activities or exercises such as running, sports, gardening, or walking for exercise in your community?

□ Yes
□ No
□ Don‘t know / Not sure

26. During the past month how many times per week did you take part in this activity for 45 minutes or more?

□ I didn’t take part in physical activity
□ I took part in physical activity everyday

□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

27. And when you took part in this activity, did any member of your family over age 18 participate with you?

□ Always
□ Most of the time
□ About half the time
□ Sometimes
□ Never

28. During the past month did you participate in any gardening or growing food?
□ Yes
□ No
□ Don‘t know / Not sure

29. During the past month did you participate in sports?
□ No, I didn’t play sports
□ I played sports everyday
□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

30. How many times per week did you play sports with someone over the age of 18?

□ I didn’t take part
□ I took part everyday
□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

31. Are there places in your community you have used for physical activity or exercise?
□ Yes
□ No
□ Don‘t know / Not sure

32. In the past month have you participated in physical activity or exercised with your family in your community?
□ I didn’t take part

□ I took part everyday
□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

33. What is your age? _____

_____ height

_____ weight

_____ waist circumference

_____ _____ BP

_____

SURVEY

(Community members)

You are being asked voluntarily participate in a research study. By Completing and returning this survey it implies that you agree to participate and your data may be used in this research. At the end of the survey if you want a copy of the survey, ask the person giving the survey when you are finished. A copy will be given to you. It will take no longer than 20 minutes to answer questions. A researcher will answer any questions you have and you may stop the survey at any time.

My initials mean I have read and understand._____

1. What is your date of birth? _____

2. Which one of these groups would you say best represents your race?

   □ White
   □ Black or African American
   □ Asian
   □ Hispanic/ Latino
   □ Native Hawaiian or Other Pacific Islander
   □American Indian or Alaska Native
   □ other [specify] _____
   □ Don‘t know / Not sure

3. What is your marital status?
   □ Married
   □ Divorced
   □ Widowed
   □ Separated
   □ Never married
   □ A member of an unmarried couple
   □ Don‘t know / Not sure

4. How many children less than 18 years of age live in your household?
   _____

5. Have you EVER been told by a doctor, nurse, or other health professional that you have high blood pressure?

   □ Yes
   □Yes, but female told only during pregnancy
   □ No
   □ Told borderline high or pre-hypertensive
   □ Don‘t know / Not sure

6. Are you currently taking medicine for your high blood pressure?

□ Yes
□ No
□ Don‘t know / Not sure

7. Have any children in your family been told by a doctor or other health professional that they have
high blood pressure?
□ Yes
□ No
□ Told borderline high or pre-hypertensive
□ Don‘t know / Not sure

8. Have you ever been told by a doctor or other health professional that you have pre-diabetes or borderline diabetes?

□ Yes
□Yes, but only during pregnancy
□ No
□ Don‘t know / Not sure

9. How old were you when you were told you have diabetes?
_____

10. Have any children in your family been told by a doctor or other health professional that they have pre-diabetes or borderline diabetes?
□ Yes
□ No
□ Don‘t know / Not sure

11. Do you now smoke cigarettes every day, some days, or not at all?

□ Every day
□ Some days
□ Not at all
□Don‘t know / Not sure

12. During the past 2 months, have you stopped smoking for one day or longer because you were trying to quit smoking?

□ Yes
□ No
□ Don‘t know / Not sure

13. Do you currently use chewing tobacco, snuff, or snus every day, some days, or not at all?

□ Every day
□ Some days
□ Not at all
□ Don‘t know / Not sure

14. During the past month, how many times per day did you drink 100% PURE fruit juices? Only include 100% juice.

□ I don’t drink juice every day
□ 1 glass (8 ounces)
□ 2 glasses (16 ounces)
□ 3 glasses (24 ounces)
□ 4 or more glasses (32+ ounces)

15. How much water do you drink in a day?
□ I don’t drink water every day
□ 1 glass (8 ounces)
□ 2 glasses (16 ounces)
□ 3 glasses (24 ounces)
□ 4 or more glasses (32+ ounces)

16. About how often do you drink regular soda or pop that contains sugar?
□ I don’t drink soda every day
□ 1 soda (8 ounces)
□ 2 sodas (16 ounces)
□ 3 sodas (24 ounces)
□ 4 or more sodas (32+ ounces)

17. About how often do you drink sweetened fruit drinks, such as Kool-Aid, cranberry, and lemonade? Include fruit drinks you made at home and added sugar to.
□ I don’t drink fruit drink every day
□ 1 glass (8 ounces)
□ 2 glasses (16 ounces)
□ 3 glasses (24 ounces)

□ 4 or more glasses (32+ ounces)

18. During the past month, not counting juice, how many times per week did you eat fruit? Count fresh, frozen, or canned fruit.

□ I don't eat fruit every week
□ I eat fruit every day
□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

19. During the past month, how many times per week did you eat cooked or canned beans, such as refried, baked, black, garbanzo beans, beans in soup, soybeans, tofu or lentils. Do NOT include long green beans.

□ I don't eat them every week
□ I eat them every day
□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

20. During the past month, how many times per week did you eat dark green vegetables for example broccoli or dark leafy greens including romaine, chard, collard greens, or spinach?

□ I don't eat them every week
□ I eat them every day
□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

21. During the past month, how many times per week did you eat orange-colored vegetables such as sweet potatoes, pumpkin, winter squash, or carrots?

□ I don't eat them every week
□ I eat them every day
□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

22. How many times per week did you eat OTHER vegetables? Examples of other vegetables include tomatoes, tomato juice or V-8 juice, corn, eggplant, peas, lettuce, cabbage, and white potatoes that are not fried such as baked or mashed potatoes.

□ I don't eat them every week

□ I eat them every day
□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

23. How often do you add meat or fat to your vegetables for flavoring?
□ Always
□ Most of the time
□ About half the time
□ Sometimes
□ Never

24. How many times per week did your diet include low-fat dairy?
□ I don't include them every week
□ I include them every day
□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

25. How many times per week did you eat whole grains?
Example is whole wheat bread.
□ I don't eat them every week
□ I eat them every day
□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

26. Has anyone under the age of 18 prepared lunch or dinner for you in the past 2 months?
□ Always
□ Most of the time
□ About half the time
□ Sometimes
□ Never

27. Has anyone under the age of 18 suggested vegetables to be prepared at your house?
□ Always
□ Most of the time
□ About half the time
□ Sometimes
□ Never

28. Has anyone under the age of 18 prepared fruits and/ or vegetables as a snack for you?
□ Always
□ Most of the time
□ About half the time
□ Sometimes

□ Never

29. The next question is about eating out at fast food and chain restaurants. Do you notice the calorie information at restaurants.
□ Yes
□ No
□ Don‘t know / Not sure

30. The next question is about eating out at fast food and chain restaurants. When calorie information is available in the restaurant, how often does this information help you decide what to order?
□ Always
□ Most of the time
□ About half the time
□ Sometimes
□ Never
□ Don‘t know / Not sure

31. During the past month, other than your regular job, did you participate in any physical activities or exercises such as running, sports, gardening, or walking for exercise?

□ Yes
□ No
□ Don‘t know / Not sure

32. How many times per week did you take part in this activity during the past month?

□ I didn’t take part in physical activity
□ I took part in physical activity everyday
□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

33. And when you took part in this activity, did any member of your family under age 18 participate with you?
□ Always
□ Most of the time
□ About half the time
□ Sometimes
□ Never

34. During the past month did you participate in any gardening or growing food?
□ Yes
□ No

□ Don‘t know / Not sure

35. During the past month did you participate in any sports?
□ No, I didn’t play sports
□ I played sports everyday
□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

36. How many times per week did you play sports with someone under the age of 18?

□ I didn’t take part
□ I took part everyday
□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

37. Are there places in your community you have used for physical activity or exercise?
□ Yes
□ No
□ Don‘t know / Not sure

38. In the past month have you participated in physical activity or exercised with your family in your community?
□ I didn’t take part
□ I took part everyday
□ 1-2 times a week
□ 3-4 times a week
□ 5-6 times a week

39. In the past month has anyone under the age of 18 influenced your participation in any physical activity in the community?
□ Yes
□ No
□ Don‘t know / Not sure

40. Which best describes your household income level:
□ $75,000 or more
□ $50,000 - $75,000
□ $35,000 - $50,000
□ $25,000 - $35,000
□ $20,000 - $25,000
□ $15,000 - $20,000
□ Don’t Know/ Not sure

41. What is your age?_____

_____
height

_____
weight

_____ waist
circumference

_____ _____
BP

Appendix D

Georgia Southern University
Office of Research Services & Sponsored Programs

Institutional Review Board (IRB)

Phone: 912-478-0843
Fax: 912-478-0719
IRB@GeorgiaSouthern.edu
Veazey Hall 2021
P.O. Box 8005
Statesboro, GA 30460

To:	Carla Noah Dr. Greg Evans
CC:	Charles E. Patterson Vice President for Research and Dean of the Graduate College
From:	Office of Research Services and Sponsored Programs Administrative Support Office for Research Oversight Committees (IACUC/IBC/IRB)
Initial Approval Date:	09/19/12
Expiration Date:	12/31/12
Subject:	Status of Application for Approval to Utilize Human Subjects in Research

After a review of your proposed research project numbered **H13021** and titled **"Kids Playing for KEEPS: Keys to Heart Disease in a Rural Community,"** it appears that (1) the research subjects are at minimal risk, (2) appropriate safeguards are planned, and (3) the research activities involve only procedures which are allowable. You are authorized to enroll up to a maximum of **150** subjects.

Therefore, as authorized in the Federal Policy for the Protection of Human Subjects, I am pleased to notify you that the Institutional Review Board has approved your proposed research.

If at the end of this approval period there have been no changes to the research protocol; you may request an extension of the approval period. Total project approval on this application may not exceed 36 months. If additional time is required, a new application may be submitted for continuing work. In the interim, please provide the IRB with any information concerning any significant adverse event, **whether or not it is believed to be related to the study**, within five working days of the event. In addition, if a change or modification of the approved methodology becomes necessary, you must notify the IRB Coordinator **prior** to initiating any such changes or modifications. At that time, an amended application for IRB approval may be submitted. Upon completion of your data collection, you are required to complete a *Research Study Termination* form to notify the IRB Coordinator, so your file may be closed.

Sincerely,

Eleanor Haynes
Compliance Officer