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Physical Activity and African American Women at High Risk for Coronary Heart Disease: A Worksite Wellness Program Perspective

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by

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A dissertation submitted to the faculty of the Medical University of South Carolina in partial fulfillment of the requirements for the degree of Doctor of Philosophy in the College of Nursing.

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Abstract

Physical activity (PA) is a major indicator of health and a strong predictor of risk for coronary heart disease (CHD). The high mortality and morbidity from CHD is associated with high prevalence of risk factors including sedentary lifestyle. As one of the most sedentary among ethnic groups, African American (AA) women are at high risk for CHD and interventions to improve health outcomes need to be identified. A crucial gap exists in understanding the impact of PA as it pertains to the experience of AA women in identifying the most effective interventions to address specific needs of this high-risk population. This dissertation focuses on PA as it pertains to AA women in the context of CHD. The dissertation encompasses the role of worksite wellness programs (WWP) in facilitating PA health promotion for this "hard to reach" group. Specifically, the following research questions are addressed in this dissertation: 1) what do AA employees at high risk for CHD perceive as barriers and motivators to PA, 2) in the context of CHD, what valid instruments are available to measure PA among AA women, and 3) is it feasible to examine telephone support approaches, delivered by a nurse versus a trained peer coach, to improve PA and evaluate health outcomes of two groups of AA female employees at high risk for CHD? The conclusions from this dissertation are that: 1) interventions to alleviate physical limitations as the number one reported barrier to PA and discussion about importance of family relationships as a motivating factor should be incorporated in health promotion programs to improve PA behaviors, 2) the integrative review found 14 self-report instruments with modest but inconsistent psychometric validity, none of the instruments were exclusively used to measure PA in AA women, thus, future research should focus on identification of valid and culturally competent instruments specifically for AA women, and lastly, 3) examination of two telephone support approaches - delivered by a nurse versus a trained peer coach - is feasible among AA

female employees at high risk for CHD enrolled in a WWP, and differences in secondary health outcomes offer preliminary estimates of outcome measures to inform future large scale randomized controlled trials. This body of work provides deeper understanding about the PA experience of AA women at high-risk for CHD and highlights the need to identify valid and culturally competent instruments to measure PA to guide interventions specifically for AA women. Lastly, examination of telephone support delivered by a nurse versus a peer coach demonstrates limited feasibility. However, preliminary data shows significant differences in PA represented by pedometer step count and MET-time between groups and across time points irrespective of delivery personnel. Establishing feasibility and acquiring estimates of outcome variability provide preliminary evidence for large scale randomized controlled trials to examine the most effective intervention to promote PA to support health outcomes of AA women in the context of CHD. This dissertation is useful for administrators, researchers, and clinicians because it provides guidance in designing PA programs for high-risk minority populations, specifically, AA women and opportunities to highlight the value of PA in health promotion programs especially in worksite settings.

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Chapter 1: Introduction

Coronary Heart Disease Burden

Coronary heart disease (CHD) is the leading cause of death in the United States. Approximately 610,000 Americans die of CHD every year, accounting for 1 out of 4 deaths [1]. The financial burden associated with CHD is estimated at $108.9 billion each year [2]. Many health conditions can increase the risk for development of CHD, including, hypertension, diabetes, obesity, poor dietary choices, and physical inactivity.

The Disparity of Coronary Heart Disease in African American Women

CHD is the leading cause of death in women. Death in women from CHD has exceeded that of men and has continued to rise [3]. It is reported that each year, 39% of all deaths in women are from CHD [4]. African American (AA) women account for a disproportionately high incidence of CHD and are 1.4 times more likely to die from CHD than their White counterparts [1]. AA women have the highest prevalence of risk factors for CHD such as obesity, hypertension, sedentary lifestyle, and high cholesterol levels compared to other ethnic groups [5, 6]. The high prevalence of these risk factors may explain the high mortality for CHD among AA women. Most of the risk factors for CHD are related to unhealthy lifestyle behaviors among AA women. To address the increasing prevalence of risk factors, public health programs specifically targeting AA women such as *Heart and Soul, Sisters in Motion, Heart Truth, WISEWOMAN Campaign, etc*. have been implemented focusing on promoting healthy lifestyle related to diet, exercise, and weight management [6]. Despite concerted efforts to address lifestyle behaviors, the risk for CHD persists to be higher in AA women compared to other ethnic groups.

Socioecological risk factors for CHD among AA women

In order to understand the increased risk for CHD in AA women, an examination of contributing socioecological factors is important. Socioecological factors interact with one another and encompass intrapersonal, interpersonal, environmental, and organizational correlates. These factors may have direct or indirect influence on the development of CHD among AA women.

Intrapersonal or individual factors include socioeconomic status, educational level, age, and personal value of spirituality. Studies have shown that low socioeconomic status is associated with increased risk for CHD [4, 7, 8]. AA women with low income and education below college level tend to be obese, sedentary, and have poor dietary habits [7]. This is consistent with a study that found individuals with low SES tend to have low knowledge of risk for CHD [8]. In a national survey involving 2,500 AA women, those with low education and income had the least knowledge of CHD risk factors [8]. Moreover, the study reported that AA women with low SES did not perceive themselves to be at risk for CHD and view CHD as not a serious disease [9]. Thus, education is a strong predictor of risk of cardiovascular risk.

Interpersonal factors include social support, family, and friends. In a study to examine factors influencing physical activity (PA) in AA women, the findings suggested that AA women were motivated to change their behaviors, but were precluded by socio-cultural values and familial roles to incorporate PA in their lives [10]. The women in the study felt a tremendous responsibility for their families because most have been raised to put family first, leaving them with very little time for their personal health needs [6]. This is consistent with the cultural concept of a "Strong Black Woman" and many AA women struggle with the responsibilities associated with this image (Banks-Wallace, 2000). For some AA women, being strong means

taking care of others before themselves. Their desire to participate in PA to improve their health takes into consideration their cultural and familial obligations.

Environmental resources play a role in exposing AA women to risks for CHD. In the WISEWOMAN study examining health disparities in cardiovascular disease risk factors, AA participants were found to mostly live in communities with high proportions of poverty and crime, which pose as a major risk factor for poor health [11]. Additionally, the lack of access to preventive care, stressful lifestyle, inadequate housing, and low paying jobs in AA communities are strong predictors of poor health outcomes [11]. Finkelstein et al. (2004) reported, after adjusting for individual level factors, that AA women living in deprived neighborhoods have increased levels of CHD. Therefore, community-level income inequality was associated with increased prevalence of CHD.

The underlying causes of health disparities in CHD at the organizational level are complex and include broad societal issues, such as institutional racism, discrimination, poor access to healthcare, and lack of community resources [12]. Organizational factors related to the risk for CHD are often represented by racial inequities and health disparities. Health disparities have become a prominent issue in national debates and are particularly well documented in CHD. Yet studies to improve health behaviors mostly focused on White middle class populations and few have focused specifically on AA women.

Understanding the socioecological factors that influence the risk for CHD in AA women is necessary to design and develop interventions to improve health outcomes in this high-risk population. These factors may pose as impediments for engaging in healthy lifestyle and consequently contribute to the increased risk for CHD among AA women. Thus, the purpose of Manuscript 1 of this dissertation was to explore the barriers to PA among individuals with

highest risk for CHD. With a high proportion of AA women in the sample, Manuscript 1 also investigated socioecological motivators that can bolster efforts to improve engagement of AA women with PA. Examination of socioecological factors that can have positive or negative effects on PA participation is important to identify multi-level interventions to reduce risk factors for CHD specifically among AA women.

Physical activity and Coronary Heart Disease

The number of deaths from CHD has significantly declined over the last 50 years. The decline in deaths was partly attributed to interventions to reduce risk factors for CHD. Many public heath promotion programs emphasized lifestyle behaviors focusing on smoking cessation; blood pressure control, healthy dietary choices; weight management; and PA. In particular, PA has increasingly become a central focus for health promotion programs in the last few years.

Increasing evidence about the benefits of PA in improving overall health outcomes have been documented recently in several studies. Evidence about the inverse association of PA patterns and CHD and all-cause mortality are well documented in the literature [13, 14]. Most recently, a large cohort study found that even small increases in PA could reduce all-cause mortality among sedentary individuals [15]. Conversely, insufficient PA is an independent risk factor for mortality and CHD [16]. According to the World Health Organization, lack of PA is 1 of the 10 leading risk factors for death worldwide.

PA is defined as "any bodily movement produced by the skeletal muscles that requires energy expenditure," and should not be confused with exercise that is a planned, structured, and repetitive sub-category of PA [16]. The 2008 Physical Activity Guidelines for Americans recommends that adults should do at least 150 minutes a week of moderate-intensity or 75 minutes a week of vigorous-intensity aerobic physical activity, or an equivalent combination of

moderate to vigorous intensity aerobic activity. PA has significant health benefits that include improved muscular-cardiorespiratory fitness, improved bone function, and reduces the risk for hypertension, stroke, diabetes, and CHD [16]. Understanding of the impact of PA on health outcomes warrants the use of valid and reliable instruments to measure PA. However, there is a paucity of evidence on psychometric validation of instruments used to measure PA in AA women. Therefore, the purpose of Manuscript 2 of this dissertation was to conduct an integrative review evaluating the validity and reliability of self-report instruments to measure PA in AA women. Practical and accurate measurement of PA will help designate interventions that will meet the specific needs of this high-risk population.

PA has been shown to be an effective strategy in the prevention and treatments for CHD [17]. Results from a recent study showed PA is the only lifestyle factor that is protective against the metabolic risk for cardiovascular mortality and morbidity among overweight and obese women [18]. Additionally, the population risk of CHD attributable to lack of PA in women outweighs that of other risk factors, including high BMI, high blood and smoking [19]. Consistent evidence about the positive impact of PA has led to recommendations to increase PA and maximize opportunities to reach those with the highest risk for CHD.

Worksite Wellness Programs

With Americans spending more time at work time, the worksite offers an ideal setting to reach high-risk populations. It is estimated that an average individual spends about one-third of his or her waking time and over 40 years of life at work [20, 21]. The worksite offers a positive environment for promoting health and wellness programs because of existing channels of communication, support, and established corporate standards of behavior [22, 23]. From 1999 to 2009, employer sponsored health insurance more than doubled; in 2010, 74% of all firms offered

at least one wellness program [24]. In addition to rising insurance premiums, the increasing cost of corporate health expenditures presents a strong incentive for many employers to invest in wellness programs [25].

The most common intervention offered in worksite wellness programs is PA [24]. The benefits of regular physical activity in reducing the risk for CHD are well documented. Conversely, lack of PA is one of the major risk factors for CHD, which is the number one cause of death for all Americans [26]. Despite the risks associated with a sedentary lifestyle, most American workers do not engage in regular PA [26]. As previously mentioned, the number of workers considered sedentary is increasing. This is largely the result of economic and industrial innovation from increased automation and reliance on laborsaving machines in industries. This trend towards sedentary workplaces is likely to continue to rise contributing to more sedentary workers [27]. Physical inactivity leads to obesity, and obesity increases risk for CHD, diabetes, and overall mortality [28]. Current estimates indicate that 68% of the adult population and half of full-time workers are either overweight or obese [24]. Moreover, poor employee health related to obesity and physical inactivity has been associated with high rates of absenteeism, disability, and injury leading to decreased productivity [28-30]. This negative health trend presents a strong incentive for employers to establish worksite health promotion programs to address unhealthy behaviors among employees.

Worksite PA programs have been shown to improve personal fitness, health, and well-being [20, 31, 32]. However, engaging employees in PA is a challenging problem for many worksite health programs [21]. Previous studies have shown lack of time, body image, family, and work commitment can have a negative impact on PA levels [33, 34]. Examination of trends over the past five decades among occupation related PA and the association with obesity have demonstrated

that less than 20% of jobs require any moderate PA. This lack of PA is thought to be a contributing factor to the current obesity epidemic that is a comorbid factor for the development of CHD [35].

In a study to assess the most costly health conditions, employers identified chronic conditions related to CHD with the highest burden partly due to lost productivity [21]. Enhancing PA levels of employees has been shown to reduce risk on several health outcomes [36]. Additionally, even moderate increases of physical activity result in significant reductions in morbidity and mortality [37]. Despite concerted public health efforts to mobilize individuals from a sedentary to an active lifestyle, majority of American adults do not meet PA recommendations. These findings persist at worse levels among AA women [1]. This highlights a great need to for healthcare professionals to focus on identifying interventions to increase PA and facilitating opportunities to increase participation among AA women in various settings.

Telephone support and physical activity

Telephone support is any intervention using a telephone (mobile or land line) to provide repeated contacts necessary to promote behavior change [38, 39]. Telephone-based interventions offer the same advantages of face-to-face encounters while increasing cost effectiveness, timeliness, and reach [27]. Telephone support has been effectively used to promote PA in various settings.

A recent systematic review reported strong evidence for telephone-delivered PA interventions and recommended greater dissemination in the real world practice [38]. Most studies found in the literature on PA programs with telephone support effectively utilized professionals to implement the interventions [40-43]. These studies employed professional services provided by psychologists, physicians, diabetes educators, researchers, and nurses. In a study involving

overweight and obese United States veterans, a weekly phone counseling sessions delivered by a professional lifestyle coach resulted in weight reduction and increase in PA over 12 weeks [44]. A study investigating the use of telephone aftercare delivered by a sports therapist among obese rehabilitation patients (n = 487) reported higher levels of PA among patients who received telephone support versus usual care after 12 months [45]. Likewise, a study investigating the effectiveness of a pedometer-based behavioral modification program with telephone support provided by a psychologist showed positive effects on pedometers steps per day, PA, and sedentary behavior among patients with type 2 diabetes [43].

Studies utilizing peer-led telephone support, which utilized volunteers, community members, and patients' family members with no formal training or professional education on cognitive-behavioral modification methods reported improvement in PA levels [46-48]. The underlying rationale for peer support is the notion that peers have the "insider" perspective to provide a realistic description about the experience of changing a behavior and adopting a new lifestyle [47]. This unique position allows them to be more relatable and credible to other members of the group. The benefits of peer support were exemplified in a study of patients with CHD undergoing outpatient rehabilitation. Patients who received peer support maintained their PA level after completing the inpatient cardiac rehabilitation program, while those who did not receive peer support experienced gradual decline in PA over 12 months [47]. A case study investigating the feasibility of telephone counseling in promoting PA in patients with diabetes found peer telephone support to be effective in increasing receptiveness of diabetic adults to physical activity [48]. Moreover, a randomized clinical trial evaluating three different PA interventions in inactive adults demonstrated similar increase in PA between telephone-based PA delivered by volunteer peer mentors and professional staff compared to a control group.

Evidence shows that a wide range of individuals can deliver telephone support effectively [48]. However, studies identifying the most effective approach in providing telephone support for AA women are limited. The purpose of Manuscript 3 of this dissertation was to examine the feasibility of comparing two approaches to telephone support to increase PA in a randomized sample of AA women. Manuscript 3 evaluated specific health outcomes related to PA between two groups of participants receiving telephone support, one led by a nurse coach and the other by a peer coach.

Theoretical Framework

Bandura's social cognitive theory and specifically, the construct of self-efficacy provide the framework for this dissertation, [49, 50]. As a predictor of PA, social cognitive theory emphasizes how personal, behavioral, and environmental factors interact to determine behavioral patterns. Additionally, studies have documented the relationship of PA with self-efficacy and social support [6, 50-52].

Grounded on Bandura's social cognitive theory, self-efficacy is the judgment of one's own capability to accomplish a certain level of performance [53]. Several studies have documented the relationship of self-efficacy to PA [6, 50-52]. A key principle of self-efficacy is the individual's belief that he or she can carry out an activity and continue to engage in that activity, and that belief also is a predictor of treatment outcome [54].

According to Bandura (1977), four sources of information influence self-efficacy: performance outcomes, vicarious experiences, verbal persuasion, and physiological feedback [53]. These four factors establish the individual's capacity to accomplish the task. Performance outcome refers to how positive and negative experiences can influence one's ability to perform a task [51]. Accordingly, if an AA woman participating in a church-based walking program were

able to complete a quarter of a mile walk around the church building, she would feel more confident and willing to walk more than a quarter mile at another time. The PA accommodates varying physical abilities and age levels to be effective.

Modeling provides a vicarious experience by observing other people's behavior [51, 53]. This source of information allows for comparison of one's ability to perform a task with other people. An AA woman, who observes a peer perform a 2-mile walk successfully, may increase her self-efficacy and motivate her to perform the routine. However, if she sees the other woman struggle, this can lower her confidence to successfully perform the task. Thus, social observations can influence the confidence to accomplish a goal and facilitate participants' vicarious experiences to increase self-efficacy.

Verbal persuasion is also a form of positive reinforcement [51, 53]. Giving positive feedback encourages the AA woman to participate and adhere to the exercise regimen even if it is challenging. Social support is an important attribute of self-efficacy [51, 53]. Conversely, lack of verbal persuasion often leads to discouragement and disillusionment, resulting in lower self-efficacy. Utilizing verbal persuasion, studies have documented the effectiveness of telephone support programs in improving PA in various settings [43, 48]. Manuscript number 3 demonstrates the role of verbal persuasion through a telephone support intervention to increase PA. Family support and verbal encouragement from friends also influence self-efficacy to accomplish a task.

People experience certain physiological sensations, and their perception of these emotional arousals influences their self-efficacy [53]. Participants may feel anxious about learning a new task or exercise routine. However, learning to channel the negative effects of anxiety to a positive physiological feedback can enhance self-efficacy [51]. Manuscript 3 emphasizes discussions with participants about setting goals, solving problems, and self-motivation about

engaging in PA to alleviate emotional arousals. For this dissertation, social cognitive theory, and in particular self-efficacy, will frame the examination of issues about the experience of AA women at high-risk for CHD, as it pertains to PA and the worksite setting.

Together, these three manuscripts inform the central purpose of this dissertation which is to provide a deeper understanding of the unique experience of AA women at high risk for CHD with PA. This dissertation will explore key issues specific to AA women to provide guidance in developing interventions and highlight the importance of PA in improving health outcomes in this high-risk, hard to reach population. The first manuscript explores the barriers and motivators to PA in a sample of employees at high risk for CHD that includes a high proportion of AA women. The second manuscript evaluates instruments used to measure PA among AA women in the context of CHD. Finally, the third manuscript investigates feasibility of telephone support interventions and variability of outcome measures between two groups of AA women at high risk for CHD, one group led by a nurse and the other led by a trained peer coach. Informed by social cognitive theory, and specifically by self-efficacy model, this dissertation seeks to answer this broad question: Among AA women at high risk for CHD, are telephone support interventions – delivered by a nurse versus a trained peer coach – feasible approaches to improve PA and health outcomes in the setting of WWP?

Chapter 2: Barriers and Motivators to Physical Activity among Employees at High Risk for Coronary Heart Disease

Background/Objective: Worksite wellness programs present an ideal setting to target high-risk employees and to increase physical activity in order to improve their health status. Despite the risks of physical inactivity, the number of sedentary workers is increasing in the US. This study examined the barriers and motivators for physical activity among employees at high-risk for coronary heart disease who enrolled in a worksite wellness program.

Methods: Grounded theory was used to analyze qualitative data from a purposive sample of 24 high-risk employees enrolled in a wellness program at a tertiary healthcare center in rural South Carolina. Qualitative data were obtained through semi-structured face-to-face interviews.

Results: Three major themes on barriers to physical activity emerged: physical limitations, lack of motivation, and lack of time. The desire to become healthy for the sake of family was reported as the strongest motivator along with social support. Other motivators included potential health benefits and available worksite health promotion programs.

Conclusions: The study highlights the unique experience of high-risk employees and the impact of identified barriers and motivators to physical activity. The findings underscore the need to design and implement effective interventions tailored to high-risk employees to enhance their physical activity in worksite wellness programs. A large-scale quantitative study is needed to replicate and validate the results of the study.

Background

It is estimated that an average individual spends about one-third of his or her waking time and over 40 years of life at work [20, 21]. Examination of trends over the past five decades among occupation related physical activity and the association with obesity have demonstrated that less

than 20% of jobs require any moderate physical activity. This lack of physical activity is thought to be a contributing factor to the current obesity epidemic that is a comorbid factor for the development of Coronary Heart Disease (CHD) [35]. With a large proportion of Americans spending a substantial amount of their time at work, the worksite offers an ideal setting to implement multi-faceted wellness programs to promote health and prevent diseases.

Physical activity promotion is the most common intervention offered in worksite wellness programs [24]. Lack of physical activity is one of the major risk factors for CHD, which is the number one cause of death for all Americans [26]. Despite the risks associated with a sedentary lifestyle, most Americans do not engage in regular physical activity [26]. As previously mentioned, the number of workers considered sedentary is increasing. This is largely the result of economic and industrial innovation due to increase automation and reliance on laborsaving machines in industries; this trend towards sedentary workplaces is likely to continue to rise [27]. Physical inactivity leads to obesity, and obesity increases risk for CHD, diabetes, and overall mortality [28]. Current estimates indicate that 68% of the adult population and half of full-time workers are either overweight or obese [24]. Moreover, poor employee health related to obesity and physical inactivity has been associated with high rates of absenteeism, disability, and injury leading to decreased productivity [28-30].

In a study to assess the most costly health conditions, employers identified chronic conditions related to CHD with the highest burden partly due to lost productivity [21]. The benefits of regular physical activity in reducing the risk for CHD are well documented. Enhancing physical activity levels of employees has been shown to reduce risk on several health outcomes [36]. Additionally, even moderate increases of physical activity result in significant reductions in morbidity and mortality [37].

Worksite wellness programs offer a positive environment for promoting physical activity because of existing channels of communication, support, and established corporate standards of behavior [22, 23]. From 1999 to 2009, employer sponsored health insurance more than doubled; in 2010, 74% of all firms offered at least one wellness program [24]. In addition to rising insurance premiums, the increasing cost of corporate health expenditures presents a strong incentive for many employers to invest in wellness programs [25]. This is particularly significant considering that nearly 60% of after-tax corporate profit is spent on corporate health benefits, but approximately 80% of this cost is currently being spent on only 10% of the employees [29].

Worksite physical activity programs have been shown to improve personal fitness, health, and well-being [20, 31, 32]. However, engaging employees in physical activity is a challenging problem for many worksite health programs [21]. Previous studies have shown lack of time, body image, family, and work commitment can have a negative impact on physical activity levels [33, 34]. Although well documented in other settings and populations, evidence about barriers associated with physical activity among employees at high-risk for CHD is limited. To this investigator's knowledge, no qualitative study has investigated the experiences of high-risk employees enrolled in worksite wellness program. Physical activity promotion is an essential component of worksite wellness programs emphasizing the need to understand factors that impact employee engagement. In this study, analyses of internal data revealed that fewer than 50% of employees enrolled in the worksite wellness program participated in physical activity (WalkingSpree, 2013). Therefore, the purpose of this study was to examine the barriers and motivators that influence physical activity among employees with the highest risk for CHD enrolled in a worksite wellness program.

Table 1. Participant Characteristics

	n	%
Gender		
Male	5	20
Female	19	80
Ethnicity		
White	11	46
African American	13*	54

** Note: 9 out of 13 African American participants are women*

METHODS

Setting

The study was conducted on-site at a rural 400-bed acute care facility in South Carolina. The worksite employs approximately 2,500 workers and is the biggest employer in the area. A worksite wellness program is available to all full-time and part-time employees offered through one of the two Group Health Insurance plans. Primarily designed to promote healthy behaviors and wellness, employees enrolled in the wellness program receive approximately 80% lower insurance premium costs, compared to the standard plan. About three-fourths of the employees participated in the worksite wellness program. Maintaining participation eligibility requires an employee to demonstrate compliance with the worksite wellness program requirements as shown in Table 2.

Table 2. Worksite Wellness Program Participation Requirements

• Perform 30 minutes of physical activity no less than twice per week*
• Accept guidance and follow direction given by a Health Coach
• Have an annual examination with a primary care physician
• Complete annual health risk assessment with the Employee Health
• Be a non-tobacco user

* *Note: specific time and frequency on honor system, but documentation of "active participation" required measured by a worksite-issued pedometer*

Study Design

A grounded-theory qualitative design was selected for this study because the methodology allowed themes to emerge describing the experiences of high-risk employees in a worksite wellness programs [55]. This approach was well suited to gain a deeper, richer, and more personal understanding of participants' perceptions about barriers associated with physical activity programs. The study was designed to address one broad question: What factors do participants perceive as barriers and motivators, respectively, to physical activity in a worksite wellness program? Qualitative methods enable a holistic approach to participants' experiences, as researchers seek to interpret and understand the meanings associated with responses and behaviors [56].

Sampling

The study used a purposive sample of 24 employees at high risk for CHD who were enrolled in the designated worksite wellness program. Participants also were part of a special secondary program specifically designed for high-risk employees that offered additional health interventions such as scheduled check-ups with the worksite nurse practitioner, telephone health coaching, discounted prices for drug prescriptions, dietary counseling, diabetes education, free membership to fitness centers, free healthy meal cards, and assistance with exercise clothing and gear. Employees considered high-risk for CHD had one of the following risk factors: 1) Body Mass Index (BMI) of 30 or greater, 2) fasting glucose of 200 or greater, 3) total cholesterol/HDL risk ratio of 4.5 or greater, and 4) self-report of being sedentary. Data saturation guided the final number of included participants the sample.

Data Collection

After obtaining approval from the worksite's Institutional Review Board (IRB), individuals were invited to take part in the study. Informed consent was obtained from subjects prior to their participating in semi-structured in-depth interviews that consisted of three main questions to explore perceived barriers and motivators to physical activity in the worksite wellness program. A semi-structured interview allows for a more loose and natural conversational flow centering on the topic of discussion [56]. The interview sessions conducted between July and August 2013 began with the Primary Investigator (PI) introducing himself, explaining the purpose of the study, and assuring confidentiality of responses. The interview was held in a private room next to the employee health clinic and lasted approximately 15 to 30 minutes. Probes were used to clarify and explore responses in more depth, when necessary. The interviews were audio-recorded with permission from participants and were professionally transcribed verbatim. Only the PI conducted the interviews. Field notes and reflexive memos were taken by the PI during the interview to add more depth and meaning to the participants' responses. For researchers, reflexivity is important in recognizing one's own background, beliefs, and values that may influence interactions and relationships with respondents [56].

Data Analysis

An inductive grounded theory approach was used to interpret data using qualitative procedures. Interview tapes were listened to while reading the transcription at the same time to ensure accuracy. Codes were established using literal, interpretative, and reflexive approaches to represent the true meanings behind verbal responses expressed by the participants during the interview. Responses were segmented using descriptive and analytical methods. Field notes and reflexive memos were compared with participant responses to ensure that segmented phrases and

concepts were well differentiated without losing their contextual meanings. Data with similar content were coded and grouped to develop respective preliminary categories, which then were examined for interrelationships and organized into major categories in order to identify emerging themes. A peer review process was conducted as part of the analysis. Another researcher, a PhD nursing professor, reviewed the transcripts independent of the PI. The faculty researcher coded and merged related responses, and identified major themes. Thematic interpretation of the faculty researcher was analyzed and compared with that of the PI. Differences in interpretation were discussed until divergent views were reconciled and consensus reached. Consensus between the two researchers was high. The faculty researcher also agreed that the data saturation point was reached during sampling, based on the lack of new emerging themes from the last three transcribed interviews.

RESULTS

The results are presented into two major categories: 1) barriers to physical activity and 2) motivators to physical activity. The main themes that emerged from each major category are discussed based on diminishing prevalence, as analyzed and interpreted by the researchers.

Barriers to Physical Activity

Physical limitations related to pain and weakness

A large proportion of participants cited physical limitations related to pain and weakness as a major barrier to physical activity. Seventy five percent of participants attributed the associated pain and weakness to chronic disease and previous injuries. With all participants considered high-risk, this finding is not surprising given that many suffer from chronic cardiovascular and musculoskeletal conditions. Many suffered from knee, ankle, foot, or back pain from rheumatoid arthritis, osteoarthritis and/or previous injuries. They complained about

weakness from diabetes and depression, shortness of breath from asthma, palpitations from heart disease, and joint pain from fibromyalgia as major obstacles to participation in physical activity. One spoke of the fear of having chest pain during physical activity and the need to slowdown, which often ended up in withdrawing from physical activity. Notably, 8 of the 9 African American women in the study pointed to physical limitations as a major barrier to physical activity.

Box 1. *Salient responses: Physical limitations related to pain and weakness*

"I have some issues…and I'm not saying that I blame it on them, but I really have a bad knee that's like bone-on-bone…it's probably gonna have to be replaced one day. I have back problems, too. I have degenerative discs, arthritis…..I'm sure there's a program out there for me but I just haven't pursued it to see if there's anything I can do."

"I be wantin' to but I have a "bum" ankle that I have to get surgery on.….my ankle hurting so bad feel like something tearin' loose in it. When I get off work it take me 10 minutes sometimes to get in the car. Really people say that you lazy when you do stuff like that……well you're not lazy I just can't get up on to do things when I get off."

"You know the older you get….you get tired quicker and what not. Sometimes that kind of stirs in my head. I start running, I be done give out before I get 25 steps…that kind of scares me because it causes my heart to speed up!"

"I just don't have energy…For one thing, I have migraines and fibromyalgia, and I don't feel good most of the time…..I be so tired from hurting all day. I guess, just when I get home, I'm just glad to be there and just sit down and looking at TV."

"Well, I'm diabetic, and sometimes I just don't feel well. I feel weak and stuff like that. Today wasn't one of my better days…. I woke feeling bad today. It's just all tied up with diabetes and stuff."

Lack of motivation

Participants reported lack of interest, drive, and motivation to engage in physical activity as a common barrier to physical activity. A few acknowledged "laziness" and lack of inner desire to be active despite presence of health risks. Many cited difficulty initiating and getting

started with physical activity. Some expressed sheer dislike towards physical activity. While others cited no specific reason, many participants pointed to lack of encouragement and outward support from others as a reason for the lack of motivation.

Box 2. *Salient responses: Lack of motivation*

"Just being lazy… Can do it, but just being lazy…. 'cuz I could do a lot of exercise …I could walk…I mean, I live right down the street from the civic center, so there's no excuse…. It's just me being lazy."

"I've never had a reason not to be active… I just never did it, that's all."
"My barriers are getting motivated and getting started…I'm not the one to motivate myself. Because leave it up to me and I'll come up with all reasons why. Well, I'm just tired. I'll do it tomorrow…"

"I guess, I mean….I wanna say it's the motivational factor. Sometimes, it's just not there because when you get off work, you're tired…You're tired mentally, you're just not feeling it. "

A big part of it is the incentive to go and do it…I think for me running is not my ideal exercise but I feel like I need to do something for cardiovascular…. I hate doing it…. Just trying to convince myself to go out and run is difficult."

Lack of time

Many reasons for the lack of time are associated with family commitment, busy work schedule, and school activities. Participants identified difficulty with finding time while balancing family time, work responsibilities and with getting the house chores and school activities done. Long working hours and shift work were also perceived as impediments because of physical and mental exhaustion. Participants reported that caring for sick family members often left them with no time and energy to engage in physical activity.

Box 3. *Salient responses: Lack of time*

"When you have a full-time job… then you have to go home…. I have a chronically ill husband, a son that still lives at home, and…animals, and things that have to be done at home. I mean, you're still doing physical activity but its not fun physical activity."

"Working night shift is the main…It's really the hardest thing 'cuz I'm tired all the time from working. Then, I'm a full-time student too, so I'm doing classes in the morning after work…It's just…it's just really hard."

" With work, we don't get out until 7:30 PM, and then I have three children….I am a single parent, so homework, clothes, getting them ready for day care the next day. By the time I'm through with that…it's 10 PM, and it's time to go to bed…then get up at 5:30 AM…. So really no time."

Motivators to Physical Activity

Desire to be healthy for the family and family history of illness

Participants reported being motivated to participate in physical activity to become healthy for the sake of their family and other family members. Many participants pointed to being healthy in order to live longer and enjoy the company of family and friends. They expressed the desire to spend quality time with children and grandchildren by being able to engage in physical activities with them. The fear of illness and hereditary risk factors from a chronic disease also were reported as big motivators. Many participants reported witnessing first hand the pain and suffering their own family members endured due to chronic illness. The experience provided them with a strong motivation to improve their own health. Participants also spoke about a sense of obligation to become healthy for their family and not let other people down.

Box 4. *Salient responses: Desire to be healthy for the family*

"You know, I've been down this road all my life. I guess when I got to my heaviest weight, I decided that if I was gonna live to see my children grow up…. that I was gonna have to do something….so, I'd say my family and children motivate me most."

"I do have a granddaughter who's going to be one, so I run…I'm just lovin' to run after her. She's my one motivation right now 'cause I keep her a lot. Plus, I want to see her grow up. That's what's gonna motivate me to do what I need to do"

"My sister is on dialysis. Watchin' her suffer three days a week….she still gets sick every time she's dialyzed….It's physically horrible and mentally horrible for her…I also have two children in college, and I wanna be around to watch them grow up."

"I see my son running around and I wanna be able to do that with him. Sometimes I feel I'm on the sideline…. I'm just not able to do that… I want to be able to run after him and play with him…I'm not able to right now"

"I really do wanna get my sugar in check, because I see how it's doing my brother…Right now my brother is on dialysis…he was being in the hospital for three and four weeks at a time. I don't wanna get to that point."

Positive health benefits

Perceived positive health benefits from physical activity were reported as a motivating factor. They identified positive health benefits from physical activity such as losing weight, as well as gaining a sense of well-being and control over their health. Many participants expressed wanting to become healthy to feel better, more energetic, and free from pain. These positive health benefits correspond to their desire to become healthy, having experienced first hand the uncomfortable symptoms associated with chronic illness. Female participants, in particular, felt motivated to engage in physical activity due to societal pressures to look attractive and feel comfortable around other people. They cited the desire to lose weight to look good and fit in clothes.

Box 5. *Salient responses: Positive health benefits*

"Feeling better, watching the health numbers get corrected, energy….being able to fit nicely into clothes----just some good things like that."

"They told me I was pre-diabetic, so the doctor wanted to start me on some meds. I don't want it to escalate any more than what it was….In order for me to get better, I gotta lose the weight."

"I just…I know I would feel better if I got a lot of the weight off of me. I know it would help my back. It would help my knee. It would help my all around, just general feeling about myself."

"I wanna feel better. I actually just wanna have energy. Not just function. Actually wake up and feel good…I just wanna have the energy level, being able to keep up and do things without having to sit a whole lot and without being exhausted…trying to push myself…. knowing that I don't have energy to do."

"Seeing results from physical activity…once I start getting involved and doing that kind of thing…I want to see some results from it, whether it be feel better…I'm feeling better, feeling more energetic, which I usually do."
"Seeing myself in a bathing suit….just the size of clothes I'm wearing. I'd like to be smaller which I have been, and I know I can be…. gaining 5 pounds, then 5 becomes 10, before you know it you got 50 pounds in you… it didn't happen overnight. It's not going away overnight."

Presence of Social Support

Participants identified the importance of support from other people to provide encouragement to engage in physical activity and maintain an active lifestyle. Support from family, friends, and co-workers were reported as strong motivators to help enable them to participate in physical activity. Many participants mentioned the need for someone to push them, provide encouragement, and act as a partner in their efforts to become active. Some also pointed to advice from healthcare professionals as a source of motivation to engage in physical activity.

Box 6. *Salient responses: Presence of social support*

"The biggest motivation for me is having somebody to do it with. For a little while my wife was running with me, and that was great motivation. Her health now kind of prevents her from being able to do that."

"Part of my problem is I need motivation…Yeah. Just having somebody there to say, you got to go. You need to be there. You need to do this…. That's my biggest thing."

"Having somebody there with me...If I had a friend or somebody who would go and exercise with me….when I had somebody to meet up with me and we would go exercise. 'cuz then it's like, well….I'm not gonna let them down and not show up."

"I know we did walk as group, so like other peers walking with you and encouraging you to go. I really enjoyed all of us go…. It was like for of us that went, and I got tired…but they was like…you can do it. You can do it."

"My son and then there's some co-workers that I say care about me….I know I need to get some pounds off…I mean I know what to do….but I need an extra push."

"The doctor said…well, you start, you made some progress, you've lost five pounds…. so that made me feel better…some people it means nothing, but to me it means a lot."

Worksite Support through Wellness Program

Participants identified health programs offered through the worksite wellness program as motivators. Participants in the study also participate in a secondary program specifically designed for high-risk employees and currently receive additional health interventions. Many are receiving health-coaching advice and regular health check-ups with onsite health professionals. They also suggested company-sponsored incentives to help facilitate participation in physical activity such as paid-time off, financial rewards, and on-site fitness centers.

Box 7. *Salient responses: Worksite wellness support*

"Well, like when I was talking to the nurse practitioner. She said something about…and actually it's in my head now, about going to the fitness center twice a week and I would have a personal trainer….I'm like ready for that."

"Maybe the different kinds of food to eat….'cuz they had me on Medifast. The hospital was paying for that Medifast at one time. It really worked for me. I lost 68 pounds but I gained a lot back now."

"To where on your day-off or maybe an hour you get off, you get in there (on-site fitness center), or you get in there after work…they could make it mandatory that you do it….not to go way across town to get it….here it's more convenient."

"Like if we had more incentives…or money on your flexible spending accounts if you walk so many miles."

DISCUSSION

To the author's knowledge, this is the first qualitative study using grounded theory to investigate the physical activity experiences of employees at high risk for CHD enrolled in a worksite wellness program. The purpose of the study is to gain a deeper understanding about perceived barriers and motivators to physical activity among high-risk employees in a worksite wellness program. Numerous themes emerged highlighting the main barriers and motivators to physical activity. Major factors that negatively impacted participation in physical activity included physical limitations, lack of motivation, and lack of time. Conversely, the desire to become healthy for the sake of family, perceived positive health benefits from physical activity, presence of social support, and worksite wellness programs were seen as major motivators to physical activity. These findings underscore the significance of understanding and addressing the major barriers while bolstering the motivators to physical activity.

The results of the study highlight the impact of physical limitations due to pain and weakness as the number one barrier to physical activity. This finding is unique especially

because many participants suffer from symptoms of CHD and other chronic health conditions. The finding contradicts results from previous studies that identified lack of time and lack of motivation as primary barriers to physical activity [33, 57]. The majority of the participants complained about the negative effects from chronic debilitating health conditions such as rheumatoid arthritis, degenerative disc disease, palpitations, depression, diabetes, fibromyalgia, migraines, or other illness that hindered their mobility and negatively affected their motivation to engage in physical activity. With this finding, the worksite may consider offering low impact physical activities (e.g. Yoga therapy, tai-chi, and water exercise designed to target joint pain) and interventions focusing primarily to alleviate the physical symptoms associated with chronic diseases (e.g. therapeutic massage, referral to pain management specialist or physical therapist). Increased coordination between worksite health professionals and participants' primary care providers may improve disease management and hasten control of symptoms. Additional barriers to physical activities include lack of motivation and time. These findings are consistent with previous studies citing lack of time along with lack of motivation as impediments to physical activity [27, 33, 57]. Lack of motivation was commonly attributed to being "lazy", difficulty getting started, and sheer dislike towards physical activity. The lack of motivation may have been compounded by the lack of encouragement from family members and demonstrative support from others. Many participants mentioned difficulty of balancing work with family commitments, which left them with no remaining time for physical activity. This result is not surprising given the high number of female participants in the study. Traditionally, women take on the primary responsibility of managing household duties (i.e. cooking, cleaning, shopping, and children school activities) in addition to having a full-time job; these responsibilities may explain the lack of time to engage in physical activity for many participants [44]. Because lack of

time appears to be a significant impediment to physical activity, the worksite may consider offering short on-site physical activity programs available throughout various times of the day. Seeing co-workers participate in on-site physical activity programs can be a source of motivation for others.

Participants in the study reported a desire to become healthy for the sake of the family as a major motivator to engage in physical activity. They view their family as the main reason for living. With many in the study already suffering from symptoms of chronic disease, participants fear that the pain and weakness associated with illness will further limit their ability to enjoy time with their loved ones. As caregivers, they also have witnessed family members suffering from chronic illness. This experience may have increased their awareness about the importance of being healthy and avoiding the negative consequences of illnesses that family members have endured. Worksite interventions should take into account the importance of family and family history of illness when providing counseling and health education. Participants also mentioned the potential positive health benefits gained from physical activity as a motivator. They expressed the positive health benefits of losing weight, feeling energetic, and gaining a sense of well-being. Participants also reported the role of social support from others as a motivator for physical activity. The worksite may need to consider enhancing and expanding interventions geared towards social support such as a telephone coaching, peer-to-peer support programs, and on-site group exercise programs to promote social support. Telephone support has been shown to improve physical activity in various settings [46, 47]. Lastly, participants pointed to programs offered through the worksite wellness programs as an important motivator to physical activity such as worksite-issued pedometers, group walking activities, and free memberships to the worksite fitness center. Group exercise programs available at various times throughout the day

and held at on-site location can facilitate physical activity by improving accessibility. Although it may not be feasible to offer to all employees, financial rewards or paid time to exercise may need to be considered for high-risk employees. Incentives can be an effective motivator because it rewards high-risk employees for something they would not generally do on their own given the various barriers to physical activity they already have [57]. It has been suggested that financial incentives can result in cost savings. With these findings, the worksite needs to design and implement interventions taking into account all the factors that emerged as major themes to enhance engagement in physical activity among high-risk employees.

Limitations

The study provides an in-depth qualitative evaluation highlighting previously unexplored experiences of high-risk employees with physical activity. Despite the strength of the current analysis, the findings are subject to limitations. The study was conducted in a single location, and participants were all recruited from one site. Although participants have risk factors for CHD, the sample was not necessarily representative of all employees considered at high-risk for CHD. No stratification based on gender, ethnicity, age, or comorbidities was performed. Also, the PI and the participants are employed in the same worksite. Although the PI doesn't directly work with the participants, response bias may have occurred. It is possible that participants' responses in the interview may have been influenced by their familiarity with the PI and desire to present a positive view of their experience. Lastly, the subjective nature of this qualitative study limits the generalizability of the findings to other settings and population.

A large-scale quantitative study is needed to replicate and validate the qualitative findings. The study can examine correlates of physical activity among employees at high risk for CHD in relation to ethnicity, gender, age, marital status, income, and available worksite health

promotion programs. A study of this type can include a large sample that can be stratified by gender or ethnicity to evaluate differences between different groups. This type of research can evaluate extensively the impact of perceived barriers and motivators to physical activity among a large sample of employees at high risk for CHD.

CONCLUSIONS

Worksite health promotion programs can prevent disease, reduce complications from chronic illness, reduce absenteeism, and increase productivity. Results of the current study will inform the science on worksite wellness programs by providing a deeper understanding of various factors perceived as barriers and motivators to physical activity. This study is distinctive because it focuses on the experience of employees who are considered high-risk for CHD. Given the paucity of published data, the study underscores the unique experience of high-risk employees participating in a worksite wellness program and the impact of the different factors perceived as barriers and motivators to physical activity. Additionally, the large proportion of AA women in the study provides a secondary viewpoint about the physical activity experience of this sub-group of high-risk employees. Despite having the highest prevalence of risk factors for CHD, AA women are the one of most sedentary among ethnic groups. Future studies should examine the unique experience of high-risk AA women to identify culturally competent interventions to improve physical activity in this population.

The findings of the study are useful for researchers, program managers, and policy makers as they design programs to improve physical activity engagement specifically for high-risk employees. A number of potential health programs were discussed to address the barriers and reinforce motivators to physical activity identified in the study. However, these interventions need to be examined first to make sure that they take into account the individual

needs of employees. To promote physical activity effectively, targeted multi-modal and multi-level interventions are needed to address factors that emerged as barriers and motivators to physical activity, specifically for high-risk employees. With physical inactivity as an independent risk factor for CHD, enhancing physical activity through worksite wellness programs can lead to improvements in various health outcomes, which can potentially lead to increased productivity and significant financial savings to the organization.

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Chapter 3: Integrative Review of Self-Report Instruments for Measuring Physical Activity among African American Women: A Coronary Heart Disease Perspective

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Lack of physical activity is associated with increased risk for coronary heart disease, the main cause of death in African American women. This integrative review aims to evaluate self-report instruments to assess physical activity in African American women, within the context of coronary heart disease. A systematic literature search was conducted using PubMed, CINAHL, PsycINFO, and PubMed Central databases. Only peer-reviewed studies (a) that included African American women and (b) that assessed the psychometric properties of physical activity instruments in the context of heart disease were included in the search. Initial search located 691 articles but only 7 studies were included in the final review. Of the 7 studies, 6 utilized a combination of self-report and objective measures. While most self-report instruments yielded modest validity and reliability, results were inconsistent and modest at best for African American women. Further studies are needed to identify psychometrically and culturally competent instruments for African American women.

The impact of physical activity (PA) as a major indicator of health and wellness has been well-established. Lack of PA is associated with increased risk for obesity, hypertension, hyperlipidemia, diabetes, and coronary heart disease (CHD) [58, 59]. African American (AA) women have one of the highest death rates from CHD among all ethnic groups [2]. The high prevalence of risk factors contributes to high mortality and morbidity from CHD in AA women [2, 60]. Despite the known risks of inactive lifestyle, a large proportion of AA women do not engage in regular PA [6, 61, 62]. Studies show that adopting an active lifestyle reduces the risk

for CHD and improves overall health outcomes [63].

Increasingly, health initiatives such as Heart and Soul, Racial and Ethnic Approaches to Community Health (REACH), and Project Joy have focused on strategies to address PA in AA women due to their high risk for CHD [64, 65]. Studies conducted to examine PA in AA women have primarily focused on the influence of socioecological factors in reducing risk factors for CHD [49, 66]. The benefit of PA in reducing risk for CHD is well-established but how the different aspects of PA are associated with certain health outcomes remains unclear [67]. A greater understanding about the relationship between PA and health outcomes among AA women warrants the need to evaluate the reliability and validity of instruments to ensure accurate assessment of the impact of PA on CHD.

There are two main methods used for measuring PA: (a) objective measures and (b) subjective measures or self-report [68]. Objective measures include direct calorimetry, indirect calorimetry, doubly labeled water (DLW), accelerometers, and pedometers. DLW provides measurement of PA by assessing the rate of metabolism of isotopes over a period of time. The difference in elimination rates of the isotopes provides a measure of energy expenditure represented by carbon dioxide production that directly relates to PA [69]. Indirect calorimetry accurately measures energy expenditure from oxygen consumption and carbon dioxide production in a ventilated hood [69]. Direct calorimetry is more accurate in assessing metabolic rate than indirect calorimetry and DLW but is primarily utilized for laboratory-based studies [70]. Although considered to be the gold standard for validating PA measures, these three methods are too complicated and too expensive to administer in large-scale studies [69, 70]. Accelerometers and pedometers are wearable motion sensors that can objectively measure acceleration, duration, and intensity of PA. Previous studies have demonstrated the utility of pedometers and

accelerometers as valid measures of PA [71, 72]. Relatively inexpensive and easy to use compared with DLW and indirect calorimetry, they require technical expertise to manage and analyze data [73]. While newer models have greatly improved their accuracy, the utility of wearable motion sensors on assessing improvement in health outcomes remains inconclusive [74]. Self-reports are the most widely used measure for PA. They include PA questionnaires, surveys, logs, and diaries. Self-reports are inexpensive, easy to administer, and the instrument of choice in large population studies [67]. The validity of the instrument is based on the subjective assessment, recall, and interpretation of different aspects of PA over a period of time [69]. Studies examining validity and reliability of self-report against objective measures of PA have concluded that self-report methods provide a valid measure of PA [75-77]. However, validation studies on AA women are lacking. Therefore, the purpose of this integrative review is to evaluate the different self-report instruments used to measure PA in AA women in the context of their risk for CHD. Assessment of validity and reliability of self-report instruments used in AA women will provide additional insight to help designate which PA interventions offer the most significant health benefits for AA women.

Theoretical Definition and Operational Definition

The World Health Organization (WHO) defines PA "as any bodily movement produced by skeletal muscles that requires energy expenditure" [16]. Although the term "physical activity" is sometimes used interchangeably with "exercise," the WHO defines exercise as a subclass of PA in which physical fitness is the objective [16]. PA encompasses exercise as well as other activities involving bodily movement including play, work, active transportation, house chores, and other recreational activities. The Department of Health and Human Services (DHHS) PA Guidelines defines "physical activity" as "any body movement that works your muscles and requires more

energy than resting" [78]. In their early work investigating interventions to promote physical activity in AA women, Banks-Wallace and Conn (2002) expanded the definition to include bodily movements that produce progressive healthy benefits. Given the variability in how PA is defined, the following conceptual definition was used for this integrative review: *Any bodily movement produced by skeletal muscles that results in energy expenditure*. Operationalization is the process of outlining how a concept can be measured; this process is used to take an abstract idea and make it into an observable and measurable concept [44, 79]. The variability among the different instruments used to measure PA makes operationalization of the concept problematic. Previous studies have highlighted this challenge by advocating for greater precision and more clarity for the term PA in order to operationalize the concept in research [80]. The DHHS PA Guidelines provide an operational definition of PA as "at least 150 minutes (2 hours and 30 minutes) a week of moderate-intensity, or 75 minutes (1 hour and 15 minutes) a week of vigorous-intensity aerobic physical activity, or an equivalent combination of moderate - and vigorous-intensity aerobic activity" [78]. However, in this review for PA among AA women within a CHD perspective, PA will be operationally defined as bodily activities performed for at least 10 minutes a day resulting in energy expenditure quantified using the following measures and standards: DHHS 2008 PA Guidelines, Centers for Disease Control and American College of Sports Medicine (CDC ACSM) PA Guidelines, DLW, indirect calorimetry, treadmill testing, actigraph, accelerometer, and pedometer; it is expressed as minutes of exercise per day or week, steps per day or week, metabolic equivalent (MET), maximum oxygen consumption (VO_{2max}), kilocalories per day or week, and resting energy expenditure (REE). The self-report methods and objective measures used in AA women will be evaluated in the context of CHD.

Method

Search Strategy

The authors conducted a systematic search of the literature to review publications evaluating instruments used to measure PA in AA women. PubMed, CINAHL, PsycINFO, and PubMed Central databases were used to search for literature reporting on the reliability and validity of the instruments using various combinations of the following key terms: PA, motor activity, exercise, AAs, Blacks, African Continental Ancestry Group, female, women, data collection, surveys, questionnaires, measurement, reproducibility of results, and test validity. All located studies that described some form of PA among AA women and reported some form of measurement data were initially included. Located articles were excluded if there was no detailed description of reliability or validity measures, no full text English version, no association with CHD or chronic diseases, sample younger than 18 years of age, or fewer than 18% of AA women in the total sample. All the articles were collected in 2013. A summary of the systematic search of literature is presented in Figure 1.

Level of Evidence

The level of evidence for each study was appraised using the Center for Evidence Based Medicine Levels of Evidence (2009). Studies were evaluated and rated based on their strength of evidence.

Results

Initial search used a combination of key terminologies including Medical Subject Headings (MeSH®) terms and subject headings. Out of the initial 691 articles, 7 studies were included in the final review as summarized in Figure 1.

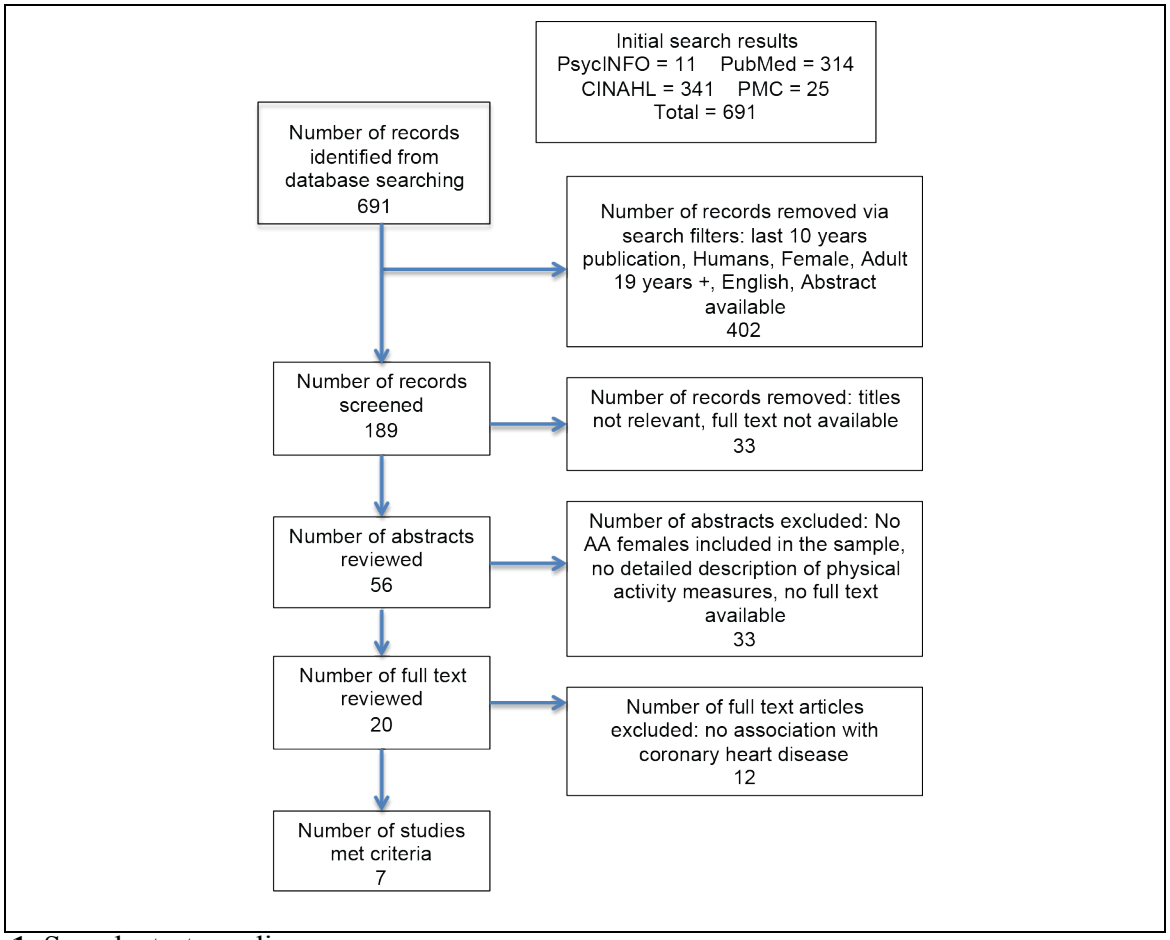

Figure 1. Search strategy diagram.

All seven studies included in this integrative review used self-report as the main measurement method. Six studies utilized a combination of self-reports and objective measures to assess validity and reliability of the primary instrument in the study [18, 58, 81-85]. Only one study, "Reliability and Validity of the Self Efficacy for Exercise and Outcome Expectations for Exercise Scales with Minority Older Adults," explicated a theoretical framework [82]. Overall, 14 self-report questionnaires and surveys were used: Self-Efficacy for Exercise Scale (SEE), Outcome Expectations for Exercise Scale (OEE), Yale Physical Activity Survey (YPAS), Community Healthy Activities Model Program for Seniors (CHAMPS), Arizona Activity Frequency Questionnaire (AAFQ), 7-Day Physical Activity Recall (7-D PAR), Women's Health Initiative Personal Habit Questionnaire (PHQ), Two-Part Survey Item to Assess Adherence to Moderate Physical Activity Recommendation (MPA), Physical Activity Records (PAR), Checklist Questionnaire, Global Questionnaire, 7-Day Diary Physical Activity Estimation Questionnaire, International Physical Activity Questionnaire–Short (IPAQ-S), and Physical Activity Questionnaire (IPAQ) [18, 58, 81-85]. The self-report instruments were used to assess PA in sample of AAs along with other ethnic groups. None of the instruments were utilized exclusively on AA women.

Criterion validity was examined in the instruments used in this review. Five objective measures of PA were used to validate self-reports: DLW [18, 58], indirect calorimetry [18, 58], treadmill protocol [83], accelerometer [58, 84, 85], and pedometer [84]. Criterion validity correlations tended to be modest and inconsistent among AA women, the energy expenditure (TEE) and the Checklist and Global Questionnaires (.54-.62) and between diary and the questionnaires (.32-.67) [58]. Yet, higher correlations were found among males between maximum oxygen consumption (VO_{2max}) and CHAMPS indices than among females; only the sports index

significantly correlated among females (r = .19) [83]. Likewise, the IPAQ-S performed worse among AA women than among AA men when validated against accelerometer [85]. However, a study validating a two-part survey against accelerometer and pedometer revealed that the survey can reliably differentiate between higher and lower PA levels among AAs [84]. Participants who reported meeting the PA recommendation in the survey had significantly higher steps per day and kilocalories per day (all p < .0001) compared with those who reported not meeting the recommendation [84]. Construct validity was established using factor analysis in one study [82]. Overall, construct validity demonstrated acceptable validity for body mass index (BMI), blood pressure, cholesterol, ethnicity, age, gender, educational attainment, and income [58, 81, 84, 85].

BMI and age were inversely correlated with steps per day, kilocalories per day, and self-reported PA among AA women [18, 58, 81-85]. The study using the Modified CHAMPS Questionnaire reported high correlations with oxygen consumption for participants with income below US$30,000 and no college degree [83]. Internal consistency and reliability were reported in studies using the YPAS, SEE, and OEE, and in a study establishing reliability between the primary study with the reliability study group [18, 82, 83]. Resnicow et al. (2003) reported 2-week test-retest correlations of total activity index of r = .5 and r = .65 for the YPAS. Although AA women and Hispanics under-reported PA in AAFQ and PAR, reproducibility of biomarker measures was reported examining energy expenditures using the self-report questionnaires, namely, AAFQ, PAR, and PHQ (R^2 = 25.2, 21.5, and 21.8, respectively) [18]. Furthermore, internal consistency was established for SEE and OEE with alpha coefficients of .89 and .90, and .72, and .88, respectively [82].

Discussion, Gaps in the Literature, and Implications

The aim of this review was to evaluate self-report instruments that have been used to measure PA in AA women in the context of the risk for CHD. In general, the reviewed studies reported correlations between self-report and objective measures that were within previously observed ranges for determining PA levels. However, some of the self-report instruments used in the reviewed studies exhibited slight inconsistencies in validity among AA women. This was evident in both the self-report methods and objective measures. The use of objective measures was valuable for detecting systematic errors and bias. One study using indirect calorimeter and DLW as validation standards revealed differential bias by the instrument that resulted in over-reporting and under-reporting of some measures in the study [18]. Use of indirect calorimetry and DLW involve highly specified protocols using sophisticated laboratory equipment to analyze PA; if error is present among these methods, it is more likely to be systematic resulting from imprecise instrumentation across all participants.

Although all the studies examined the validity of the self-reports, only three studies evaluated reliability. A self-report instrument cannot be useful for what it intends to measure unless the instrument is able to assign scores consistently. Resnicow et al. (2003) reported 2-week test-retest correlations of total activity index of $r = .5$ and $r = .65$ for the YPAS. However, the authors did not perform test-retest reliability study on CHAMPS, the main self-report instrument used in the study. Reliability is an essential prerequisite of validity [79]. The variability and inconsistency in PA behavior adds additional challenges to establish reliability when administering self-report instruments.

Studies that utilized objective measures such as DLW and indirect calorimetry as criterion standards provide robust evidence of the test validity of self-report instruments in assessing PA in

AA women. Moreover, DLW and indirect calorimetry are gold standards in measuring PA providing physiological evidence for precise validation [69]. Logistical and financial constraints reduce feasibility and preclude widespread use of objective measures in many field-based studies [67]. In contrast, self-report methods are inexpensive, practical, and easy to administer in large-scale studies [69]. Self-report instruments allow PA recommendations to be easily communicated and understood by the public. Issues such as under-reporting, over-reporting, or misreporting of actual PAs can restrict the reliability and validity of self-report methods [73]. As a result, establishing the validity of self-report instruments based on subjective assessment is extremely important.

Overall, findings in this review indicate that most self-report instruments evaluated in this review yielded modest validity and reliability consistent with previous studies. However, the limited number of AA women included in the studies used in this review may limit understanding about the direct effects of PA behaviors on specific health outcomes.

Conclusion and Limitations

The integrative review included a small spectrum of self-report instruments used to evaluate PA in AA women. The number of studies identified in this review may be limited by the search strategy method and publication date. Although a number of validation studies of self-report measures were included, none were conducted solely on AA women. However, the results are promising with the focus toward identifying the most accurate and practical instrument to measure PA in this population.

In conclusion, the findings highlight the need to identify and evaluate self-report instruments that can accurately assess PA behaviors among AA women and specifically support positive health outcomes. In addition, it is possible that AA women may have divergent views

about PA and can influence their behavior toward PA measurement. Future studies should focus on developing culturally competent PA instruments and adapting self-report measures specifically for use on AA women. Identifying the most valid and reliable self-report instrument for AA women will help designate the most effective intervention to achieve their PA goals and ultimately reduce the risk for CHD.

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Table 1. Self-Report and Objective Measures of Physical Activity in African American Women.

Instrument/references	Research subjects	Description	Method of measure	Validity	Reliability	Findings	Level of evidence
7-Day PAR, AAFQ, and Women's Health Initiative PHQ (Neuhouser et al., 2013)	Enrolled participants from 9 of 40 WHI clinical centers between 2007 and 2009 *N* = 450 AA = 84 Subsample of 88 women repeated entire protocol 6 months later to provide repeatability measures	PAR questions included time spent in sleep and performing moderate, hard, and very hard intensity activities for each segment of each day over the 7 days before the interview. AAFQ is a self-administered questionnaire previously validated using DLW and includes specific activities grouped by domain with categorical responses for frequency and duration of activities. WHI PHQ is a short, self-administered questionnaire that inquires about usual frequency, intensity, and duration of different types of activity.	Self-report Biomarker objective measures: DLW and indirect calori-meter	Regressing log biomarker AREE revealed that self-report explained minimal biomarker variance (R^2 = 7.6, 4.8, and 3.4 for AAFQ, PAR, and PHQ, respectively).	Unadjusted Pearson correlation coefficients estimating reliability between primary (self-report) and reliability measures for TEE from DLW, REE from indirect calorimetry, AREE (TEE – REE), and calculated AREE are .59, .75, .42, and .42, respectively. Intraclass correlation coefficients for primary and reliability measures of TEE, REE, AREE, and calculated AREE were .58, .77, .42, and .42, respectively.	Use of biomarker-calibrated estimates of self-report provides objective assessment of physical activity as revealed in the study and should be used to reduce measurement error.	Level 3b
CHAMPS Physical Activity Questionnaire, YPAS–Modified Version (Resnicow et al., 2003)	AA adults in Atlanta, GA. *N* = 138, females = 109	Adapted from the original 41-item measure, CHAMPS PAR is self-administered instrument developed for underactive populations and tested primarily on older adults. YPAS comprises five individual frequency	Self-report Treadmill test (Balke protocol)	CHAMPS indices and estimated VO_{2max} significant correlation in vigorous and sports-related activities (*r* = .19 and *r* = .32, respectively). For females, sports index (*r* = .19) significantly	YPAS test-retest correlations of total activity index of *r* = .55 and *r* = .65.	CHAMPS Physical Activity Questionnaire is a valid measure of physical activity with higher validity for more intensive physical activity measures and may be useful for assessing physical activity among AAs. May not be feasible for AA women without medical clearance from health care provider. Treadmill is	Level 3b

Instrument/references	Research subjects	Description	Method of measure	Validity	Reliability	Findings	Level of evidence
		items, namely, vigorous activity, leisurely walking, moving around on your feet, standing and sitting duration are assessed. The treadmill measure used Balke protocol.		correlated with estimated $VO_{2max.}$ For females, YPAS (r = .24) significantly correlated with estimated VO_{2max} in diastolic BP.		expensive and requires technical skills for data analysis.	
Checklist Questionnaire and Global Questionnaire (Masse et al., 2012)	N = 260 130 AA women and 130 Hispanic women	The Checklist Questionnaire is a 64-item, self-administered questionnaire that assessed the frequency and duration of physical activities performed in previous 7 days. The Global Questionnaire is a brief 8-item, interviewer-administered survey that was developed to assess moderate-to-vigorous intensity activities for six domains of physical activity (occupation, household, yard, family, church/volunteer work, and transportation). Two self-report questionnaires validated with DLW, Accelerometer, and Diary.	Self-report DLW Accelerometer 7-Day Diary Physical Activity Estimation Questionnaire	Checklist correlated modestly with Diary for all domains (.32-.67). Overall correlation for moderate-intensity activities was .62. Global Questionnaire correlations (.36-.73). Overall correlation between Global and Diary was .42. Overall, correlations with DLW TEE and questionnaires (.54-.62). Correlations among DLW PAEE with questionnaires (.23-.26). Associations between Checklist and total accelerometer counts were .30 (p < .05) and .23 for accelerometer min ≥ METs (p < .05). Associations with Global Questionnaire were .23 for accelerometer counts		The Checklist and Global Questionnaires have measurement properties consistent with other validated questionnaires but the Checklist had slightly better psychometric properties than the Global Questionnaire across validation standards. Findings show that both questionnaires provide valid ranking of participants in their level of physical activity but less ideal for estimating amount of physical activity performed. Instruments may not be feasible to use due to length, time constraint, cost, and participant burden.	Level 3b

Instrument/references	Research subjects	Description	Method of measure	Validity	Reliability	Findings	Level of evidence
				($p < .05$) and .22 for accelerometer min ≥ 3 METs ($p < .05$).			
IPAQ-S (Wolin, Heil, Askew, Matthews, & Bennett, 2008)	AA residents living in two public housing developments in Boston, MA. *N* = 157, females = 91	IPAQ-S assesses activities performed for at least 10 minutes during the last 7 days. Participants report time spent in physical activity performed at each of three intensities: walking, moderate, and vigorous. IPAQ-S used with accelerometer.	Self-report Accelerometer	1-minute bout length, moderate agreement IPAQ-S and accelerometer-determined activity counts ($r = .36$, $p < .001$). 10-minute bout definition, fair correlation between IPAQ-S and accelerometer-measured activity counts ($r = .48$, $p = .003$).		Findings suggest that IPAQ-S may be appropriate for use in measuring physical activity with a continuous scale variable among low-income Black men. IPAQ-S performed less well among AA women. IPAQ-S is a short version of IPAQ-Long which reduces burden to respondents and is more feasible to use than the original version	Level 3b
PAQ (Buchowski et al., 2010)	Women enrolled in Southern Community Cohort Study between 2002 and 2006 who self-report race as either Black or White. *N* = 31,502 AA = 22,948	Measure wide range of active and sedentary behaviors done at home, work, and leisure time	Self-report	Spearman correlation coefficient of sitting items at baseline and 1 year later (.24-.53). No meaningful differences between Blacks and Whites based on questionnaire responses.		Women spent majority of time on sedentary behaviors, higher among obese women, associated with White than Black women. Use of questionnaire is feasible as previously validated.	Level 3b
SEE, OEE, and YPAS (Resnick, Luisi, Vogel, & Junaleepa, 2004)	Older minority adults participating in self-efficacy-based exercise intervention program, SESEP. *N* = 166, 134 females, 73% AA	SEE is a 9-item scale measuring self-efficacy expectations related to the ability to exercise in the face of barriers to exercising. OEE is a 9-item scale developed from a previously validated scale on outcome expectations and	Self-report	Factor analyses show that all items were significantly related to the appropriate construct, either self-efficacy or outcome expectations, with the exception of Items 1 (.44) and 2 (.46) on the OEE at follow-up.	Internal consistency for SEE and OEE with alpha coefficients of .89 and .90, and .72 and .88, respectively.	Study supported use of SEE and OEE when used in minority adults. Scales are easy and simple to use. List of questions in scales is easy to understand.	Level 3b

Instrument/references	Research subjects	Description	Method of measure	Validity	Reliability	Findings	Level of evidence
		benefits associated with exercise in adults. YPAS is an interviewer-administered questionnaire focusing on five major categories of physical activity performed during a typical week: yard work, caretaking, work-related physical activity, exercise, and recreational activities.					
Two-Part Survey Item to Assess Adherence to MPA Recommendation (Whitt, Levin, Ainsworth, & Dubose, 2003)	*N* = 377 168 AA, 157 Native American and 52 Caucasian women	Survey assessed the usual frequency and duration of MPA. Survey is worded to directly reflect CDC ACSM recommendation for ≥30 minutes of MPA on ≥5 days per week. Survey was evaluated using three dependent measures: PAR, Caltrac accelerometer, and pedometer.	Self-report Caltrac accelerometer Pedometer	Least squares method Participation rate differences between those who reported meeting and not meeting MPA (χ^2, p = .02) Mean minutes of MPA between those who reported meeting and not meeting CDC ACSM recommendation (t test, $p < .0001$)		Findings reveal that the two-part survey item can reliably differentiate between higher and lower levels of physical activity. The survey's simplicity and relative ease make it feasible for widespread use in larger populations.	Level 3b

Note. PAR = Physical Activity Recall; AAFQ = Arizona Activity Frequency Questionnaire; PHQ = Personal Habit Questionnaire; WHI = Women's Health Initiative; DLW = doubly labeled water; AREE = activity-related energy expenditure; TEE = total energy expenditure; REE = resting energy expenditure; YPAS = Yale Physical Activity Survey; PAEE = Physical activity-related energy expenditure; IPAQ-S = International Physical Activity Questionnaire–Short; PAQ = Physical Activity Questionnaire; SEE = Self-Efficacy for Exercise Scale; OEE = Outcome Expectations for Exercise Scale; SESEP = Senior Exercise Self-Efficacy Pilot; MPA = Moderate Physical Activity; MET = metabolic equivalent; CDC ACSM = Centers for Disease Control and American College of Sports Medicine.

Chapter 4: Physical Activity Telephone Support in African American Women at High-Risk for Coronary Heart Disease: A Worksite Feasibility Study

Objective: Lack of physical activity (PA) is associated with increased risk for mortality from coronary heart disease (CHD). Despite the risks, African American (AA) women are one of the most sedentary ethnic groups. This study examined the feasibility of telephone support to increase PA and variability of health outcome measures in a sample of AA women at high-risk for CHD.

Method: Twenty AA female employees enrolled in a worksite wellness programs (WWP) were recruited and randomized to one of the two telephone-support groups, one led by a peer and the other by a worksite nurse. Descriptive statistics and repeated measures ANOVA were used evaluate feasibility (i.e., recruitment and retention rates) and compare differences in secondary outcomes (step count, MET-time, BMI, HgA1c, TC/HDL risk ratio, social support and self-efficacy) between groups at baseline, 6 weeks, and 12 weeks. Bandura's social cognitive theory was used as the framework for the study.

Results: The study demonstrated excellent recruitment and retention for both groups (100%). Although adherence was modest, the intervention was acceptable for both groups of participants. There was a significant increase in mean change in step count in the nurse-led group compared to the peer-led group at 6 weeks ($p < 0.05$). MET-time for both groups significantly increased from baseline to 12 weeks ($p < 0.01$). Except for Self-efficacy ($p < 0.05$), there were no significant differences with the other outcomes.

Conclusion: The study demonstrated feasibility of examining two approaches to deliver telephone support to improve PA among AA female employees. Variability of outcome provided preliminary estimates to inform future large randomized controlled trials comparing

effectiveness of peer-led versus nurse-led telephone support to improve PA and health outcomes in this high-risk population.

Introduction

Physical activity (PA) is a major indicator of health and a strong predictor of the risk for coronary heart disease (CHD) [86, 87]. Results from a recently published study on women and heart disease revealed the population risk of heart disease attributable to physical inactivity outweighs that of other risk factors, including body metabolic index (BMI), smoking, and hypertension [46]. Despite the known risks of an inactive lifestyle, a large percentage of African American (AA) women do not participate in regular PA[4, 6, 7, 65]. Accordingly, AA women are one of the most physically inactive ethnic groups [2]. Lack of PA is associated with increased risk for obesity, hypertension, and cardiovascular disease [59]. The high prevalence of these health problems contributes to the high morbidity and mortality in AA women [6, 86, 87]. These disparities call for urgent efforts to effectively reduce CHD risks among AA women. Adopting an active lifestyle is one of the most effective interventions to reduce CHD risk [6, 86, 87]. Additionally, the benefits of PA extend even to women who are overweight or obese. A recent study found that PA is the only lifestyle factor that protects against development of metabolic risks for cardiovascular disease among overweight and obese women [88]. Due to the known health benefits, the opportunity to incorporate PA in everyday life should be considered.

Background

Employer-based worksite wellness programs (WWP) are ideal settings to establish PA interventions and provide the opportunity to target large groups of people with educational and behavioral strategies to modify their health status [89]. With a large proportion of Americans spending a substantial amount of their time at work, investing in PA programs presents a strong

incentive for employers to improve health, reduce risk for chronic diseases, and decrease healthcare cost [36]. In 2010, CHD accounted for half of all cardiovascular events among working aged adults and was estimated to cost 177 billion [90]. Reducing healthcare cost holds particular importance to employers considering that a significant amount of corporate expense is spent on employee health benefits [29]. Moreover, poor employee health related to obesity and chronic disease has been associated with high rates of absenteeism, disability, and injury leading to decreased productivity [28-30]. With more AA women than White women considered obese in the workplace, availability of multi-faceted worksite interventions promoting an active lifestyle in this high-risk population can favorably reduce CHD risk [87]. Even moderate increases in PA can result in significant reductions in morbidity and mortality across patient populations [37].

One of the most popular interventions used to promote PA in WWP is the use of pedometers [91, 92]. The success with pedometers derives from their ability to provide instant feedback in PA programs, e.g., prompt reminders regarding step counts and motivational messages to continue with the PA regimen [93]. Although studies about the effectiveness of pedometer-based PA remain inconclusive, there is solid evidence supporting the use of pedometers with telephone-based interventions in improving PA in various settings [38, 94]. Telephone support presents a low cost, feasible, and effective intervention to improve adherence with PA routines and weight loss programs [38, 95-97]. In a study of university employees, both face-to-face support and telephone support proved to be effective in increasing PA level [98]. Telephone-based coaching programs that include the use of professionals and peer volunteers to provide social support have been demonstrated to be effective in improving PA behaviors [46]. While it has advantages, most PA telephone support programs entail the use of professionals to implement the interventions that may limit the benefits of PA in some populations [40, 99-101]. The

reliance on professionals may hinder widespread dissemination and implementation of telephone support interventions due to limited availability of personnel and the cost to employ professional staff [46]. Notably, use of trained peer volunteers to deliver telephone support has been shown to be an effective and economical approach to enhance PA, education, social support, and health outcomes [46-48, 102, 103]. Evidence shows that a wide range of individuals can deliver telephone support effectively; however, studies using these interventions targeting high-risk AA women are limited. Moreover, few studies have examined the use of telephone support combined with pedometers in WWP [39]. To the investigator's knowledge, no studies have compared PA interventions with telephone support led by a peer coach versus a professional in a worksite program. In view of these gaps in knowledge, empirical research is needed to determine the feasibility of comparing peer-led versus nurse-led telephone support in a WWP. The primary aim of this study was to evaluate the feasibility of PA telephone support intervention delivered by a professional worksite nurse versus a peer coach regarding recruitment, adherence, and retention over a 12-week period. The secondary aim of the study was to examine the variability of outcomes comparing two groups of employees who receive telephone support from a nurse versus a peer coach at baseline, 6 weeks, and 12 weeks. Outcomes include PA as measured by pedometer steps per day and metabolic equivalents (METs), weight loss as measured by basal metabolic index (BMI), blood glucose measured by glycated hemoglobin (HgA1c), hyperlipidemia measured total cholesterol/HDL risk ratio, social support as measured by the social support scale, and self-efficacy as measured by the self-efficacy for exercise scales.

Methods

Setting

The study was conducted in a 400-bed tertiary health center in a rural county in South Carolina with a well-established WWP. The worksite wellness program primarily utilizes pedometers as a PA intervention for its employees. Designed to promote healthy behaviors, employees enrolled in the WWP offered through one of the two Group Health Insurance Plans receive significantly lower insurance premium costs compared to the standard plan. To maintain eligibility for the WWP, employees must demonstrate compliance with the following: 1) perform 30 minutes of physical activity/exercise no less than twice per week (specific time and frequency on honor system, but documentation of "active engagement" required), 2) accept guidance and follow direction given by a health coach, 3) have an annual examination with a primary care physician, 4) complete an annual health risk assessment with the Employee Health Department, and 5) be a non-tobacco user. Yet based on internal analyses of the study site, fewer than 50% of employees enrolled in the WWP participate regularly in physical activity.

Participants and Recruitment

Following approval from the Institutional Review Board, participants were recruited through their membership in the WWP over a two-week period. Potential participants were pre-screened based on the following inclusion criteria: 1) any full-time or part- time employee who 2) self-identified as an AA woman, 3) had at least one risk factor for CHD (i.e. BMI $\geq$ 30 kg/m^2, HgA1c > 6.5, or total cholesterol/HDL risk ratio > 4.5), 4) had access to a phone, and 5) had an average of fewer than 10,000 pedometer steps per day in the three months preceding the recruitment period. Participants were excluded if they reported 1) pregnancy or 2) a plan to relocate in the next 12 weeks following the start of the study.

Using direct recruitment, invitation letters were sent by the WWP study assistant to 50 employees who were pre-screened based on the inclusion and exclusion criteria. The letter detailed instructions to call the WWP study assistant or the primary investigator (PI) to signify their interest to participate in the study. A total of 21 participants responded to the recruitment letter during the three-week recruitment period. Upon responding, participants were scheduled a time to meet with the PI face-to-face. The PI met with each participant individually at different times during the recruitment period to confirm eligibility and obtain informed consent. The first 20 participants who met eligibility criteria during the limited recruitment time frame of three weeks were consented. One participant was found ineligible to participate due to health reasons. Because this was a feasibility study, a priori power calculation was not conducted. Following written informed consent, baseline assessments were obtained. Consented participants were randomized into one of the two treatment groups using a randomization table. Ten participants were assigned to the peer-led group, and 10 participants to the nurse-led group. Additionally, each eligible participant received $10 gift card at the time of enrollment as compensation for his or her time and travel.

Study Design and Procedures

This randomized, repeated measures study (0, 6 weeks, and 12 weeks) examined the feasibility of PA telephone support delivered by a worksite nurse versus a peer coach on retention, adherence, retention, and acceptability of intervention. Outcomes between the two groups were compared to assess variability of outcomes and to detect preliminary evidence of clinical and statistical significance. Twenty participants consented to participate in the study. At the time of consent, participants were given an overview of the study including telephone calls from a telephone support coach once every two weeks during the 12-week study period.

Participants were asked to come to the employee heath department for baseline anthropometric (BMI), PA (Physical Activity Scale), and psychosocial measures (social support, and self-efficacy). Previous test results taken by the WWP from the most recent health exam were used as baseline measures for HgA1c and Total cholesterol/HDL cholesterol risk ratio to reduce participant burden of multiple needle sticks. Since participants were already using pedometers as part of their participation in the WWP, instructions focused on increasing and regular uploading of step count. Participants were instructed to upload their pedometer step counts each week to a WWP-designated website, *Walkingspree*, a secure interactive social networking site that allowed participants to record and track their physical activity [104]. By logging in to the website, participants were able to upload their steps either at work or at their homes. In addition to their steps, the participants also were instructed to maintain a weekly log of their physical activities. The participants were told to turn in their PA logs at each assessment period (6 and 12 weeks). New pedometers were provided to each participant in case they became broken or were lost. During the first two weeks of the study period, the coaches individually met with each assigned participants to get acquainted with each other and establish rapport. The nurse and peer coach discussed the importance of setting goals for PA, employing strategies for changing behaviors, and scheduling ideal times for telephone sessions at least once every 2 weeks for 12 weeks. The telephone support intervention was patterned from the well-validated Active Choices, a free publicly available online telephone support program [46, 95].

Theoretical Framework

Bandura's social cognitive theory provided the framework to guide PA interventions in this study. Social Cognitive Theory emphasizes how personal, behavioral, and environmental factors interact to determine motivation. As a predictor for improvement in PA, studies have

documented the relationship of social cognitive theory with self-efficacy and social support that can be useful in designing interventions to improve PA adoption [6, 50-52]. To account for the effect on PA regardless of which type of intervention is used, self-efficacy and social support were measured at baseline, 6 weeks, and 12 weeks.

Telephone Support Intervention

Grounded in Bandura's social cognitive theory, the Active Choices program was used as the basis for the study's telephone support intervention [73]. The Active Choices telephone support program encouraged behavioral change by providing social support and encouraging the use of self-management skills in adopting and maintaining PA [46, 56]. Both the peer coach and the nurse completed an eight-hour web-based training on the Active Choices telephone support program. The Active Choices program coordinator provided the free online training via SKYPE that consisted of 4 hours of didactic lectures, and 4 hours of simulation practice and return demonstration on telephone support techniques. Telephone support training included practicing face-to-face meetings between the coach and participants, followed by regular one-on-one telephone support counseling that focused on setting up realistic goals, identifying and problem-solving barriers to PA, self-monitoring of progress using pedometers, completing PA logs, and utilizing available social support [73]. As part of the training, the Active Choices coordinator directly observed and provided constructive feedback to ensure that the intervention was delivered correctly. The peer coach and the nurse were each provided with Active Choices resource manuals to be used as a guide and reference to correctly implement the intervention. At the end of the 8-hour training session, the Active Choices coordinator evaluated telephone support coaches to validate their competency based on active listening, asking open-ended questions, and problem-solving skills.

Telephone Support Coaches

A worksite registered nurse and a peer volunteer were recruited to deliver the telephone support intervention. The nurse coach was a White female with a bachelor's degree in nursing and works full-time in a case management role. The peer coach was an African American female and works full-time as an administrative assistant. The peer coach was recruited based on her positive health experience with the WWP PA program and her willingness to help African American women like herself improve their health through PA.

Measures and Instrumentation

Recruitment

Recruitment feasibility was assessed by comparing the proportion of participants screened and confirmed eligible for the study to the number of participants randomized to the treatment groups. The PI collaborated with the WWP to recruit participants to the study. The WWP sent out recruitment letters to 50 employees pre-screened based on an inclusion and exclusion criteria. The first 20 participants who responded to the letter and were confirmed eligible by the PI were invited to participate in the study and were consented. All 20 participants who consented were enrolled and randomly assigned to one of the two telephone support groups.

Adherence

Adherence to the intervention was measured based on weekly upload of pedometer step count via the Walkingspree website, daily step count > 10,000 uploaded per week, self-reported PA MET-time > 50, and telephone session attendance > 50% at 6 weeks and 12 weeks. During baseline assessment, participants were instructed to increase their steps up to 10,000 steps per day and upload their step count via the Walkingspree website every week. Participants were asked to coordinate with the telephone support coach to schedule the best time to attend

telephone sessions delivered at least once every two weeks. Participants completed a PA self-report instrument to assess metabolic equivalent (MET-time) > 50 at 6 weeks and 12 weeks.

Retention

Retention was measured based on the return of at least one completed weekly PA log, completion of the Physical Activity Scale (PAS), and attendance in the post intervention assessment (weigh-in) period scheduled at 6 weeks and 12 weeks. Participants were given and instructed to fill out a weekly PA log to increase their awareness about staying physically active by entering their step count or activities every night. Additionally, each participant was asked to complete the self-report physical activity scale (PAS) at 6 weeks and 12 weeks.

Acceptability

Acceptability of the intervention was measured using the Treatment Acceptability and Preferences (TAP) scale given to all participants at the end of the study. The TAP scale has been shown to be a valid measure of intervention acceptability and preference (Cronbach's alpha > 0.80) [105]. The scores range from 0 to 4. Higher scores indicate higher acceptability and the perception that an intervention is appropriate, suitable, and effective, and participants are willing to adhere to the treatment.

Physical Activity

The Omron Bi pedometers provided objective measurement of PA in the study. As a condition for WWP participation, every participating employee was provided a pedometer as part of the PA intervention. Omron BI pedometers were the first model of pedometers used by the WWP and have documented validity and reliability [94, 106]. Omron Bi pedometers have demonstrated reliability with intraclass coefficients (ICC) of 0.984 when worn in various parts of the body except inside pant pockets. Participants also were provided Omron HJ 324U

pedometers if the current pedometer was defective or lost. The Omron HJ 324U pedometer uses a piezoelectric internal mechanism that has been shown in previous studies to be more accurate than spring lever arm pedometers [1, 107]. In a study examining the accuracy of 5 new piezoelectric pedometers when worn at different locations and at varying speeds, the Omron HJ 324U was the most accurate, even when worn in the pant pocket (with +/- 5% of criterion measure) [1, 107].

The self-report Physical Activity Scale (PAS) provided an alternative method for measuring PA using MET-time. The PAS is a reliable easy to administer scale that includes work, leisure time, and sports activity in one measurement ($r = 0.74$, $P< 0.00$) [67]. A high MET score indicates high metabolic expenditure related to high physical activity at different levels.

Biochemical measures

To calculate BMI, height and weight were measured using the Health-o-Meter professional scale located in the employee health department. HgA1c and Total cholesterol/HDL risk ratio were measured by the worksite lab using Vista 1500 blood analyzer by Siemens.

Psychosocial measures

Social support is an important determinant of behavior change. The well-validated Social Support for Physical Activity Scale was used to measure interpersonal social support by family and friends to modify PA habits (range, $r = 0.55$-0.86, alpha = 0.61-0.91) [108]. High total scores indicate higher perceived social support from others. Given the paucity of validated instruments to measure social support in the context of telephone support interventions, this instrument was used in the study to assess the impact of telephone counseling in relation to family and friends.

A potential mediator of PA, self-efficacy was assessed to evaluate participants' confidence to meet PA goals. Self-efficacy was measured using the validated Self-Efficacy for Exercise Scale (SES) (alpha = 0.92, R^2 = 0.38 to 0.76) [109]. High scores indicate high confidence to engage in PA, while low scores indicate low confidence in engaging in routine PA. SES showed significant moderate correlations with exercise intention (r = 0.33) and physical exercise behavior (r = 0.39) [110]. Moreover, SES was validated in AA women and demonstrated adequate internal consistency reliability (Cronbach's alpha = 0.75) [110].

Intervention Fidelity

Intervention fidelity was measured based on the evaluation of the *Active Choices* coordinator of the intervention content delivery by the telephone coaches during pre-intervention training and during the study period. Fidelity of the intervention also was gauged based on the number of telephone support calls delivered and time spent with each participant. Both the nurse and the peer coach attended required telephone support training prior to the start of the study. After completion of the training, the *Active Choices* coordinator evaluated both coaches to quantify the quality of intervention content delivery. The PI for verification sent all completed transcriptions of the audio recording to the *Active Choices* coordinator at the end of the study. The coaches were instructed at the start of the study to record at least one telephone support session per patient. Evaluation of the quality of the intervention delivery was based on key content areas of the *Active Choices* telephone support program: 1) goal-setting, 2) self-monitoring, 3) problem solving, 4) accessing social support and internal motivation, and 5) relapse prevention [56].

Data Analysis

The Statistical Package for Social Science (SPSS v22.0) was used to analyze the data. Descriptive statistics and frequency distributions were used to calculate differences in demographic and clinical variables for participant recruitment, adherence, retention, and acceptability of intervention. This study was not designed to test a hypothesis or draw inferences about the effectiveness and superiority of one telephone support intervention over another. Rather, its purpose was to assess the feasibility of comparing PA telephone support delivered by a nurse versus a peer coach to improve health outcomes in a sample of high-risk AA female employees. Although the primary aim was to examine feasibility, the study also assessed the variability of outcome to provide preliminary signs of statistical significance and estimates for potential sample size in future adequately powered studies. Differences in intervention scores at different time points, within-groups and between-groups, were calculated using repeated-measures ANOVA with a 95% confidence interval (CI). Because of the small sample of 10 participants per group, the Mann Whitney U test was used when variables displayed non-normal distributions.

Results

A total of 20 participants were consented and were randomized to one of the two telephone support groups: 10 to the nurse-led group and 10 to the peer-led group. Study participant characteristics are described in Table 1.

There was an average difference of 5 years between groups, which was not statistically significant for these data. Both groups had equal number of comorbidities, with 70% of the participants having 2 or more. Commonly reported comorbidities included hypertension, hyperlipidemia, and diabetes. This was not surprising, because participants in this study were

considered high-risk CHD. Although slightly higher in the nurse-led group, step count and MET-time were comparable between the two groups. BMI was similarly high for both groups, suggesting that obesity was prevalent in the overall sample. HgA1c and total cholesterol/HDL risk ratio tended to be lower in the peer-led group versus the nurse-led group. While social support from family and friends was consistently low for participants in both groups, the nurse-led group reported significantly higher self-efficacy than the peer-led group at baseline.

Table 1. Baseline Patient Characteristics

Characteristics	Nurse-led Group	Peer-led Group
Sample size (n)	10	10
Age	49.4 ±10.9	43.6 ±8.7
Number of Comorbidities	2 ±0.8	2 ±0.8
At least 1 (%)	10 (100%)	10 (100%)
At least 2 (%)	7 (70%)	7 (70%)
At least 3 (%)	3 (30%)	3 (30%)
Step count	7311 ±1258	7440 ±1291
MET-time	40.9 ±6.7	42.5 ±14.1
BMI	33.3 ±4.6	36.9 ±4.9
HgA1c	6.2 ± 0.5	5.9± 0.3
TC/HDL risk ratio	4.2 ± 1.5	3.4 ± 1.4
Self-efficacy*	7.8± 2.2	4.9 ± 2.0
Social support – Family	17.1± 9.2	15.8± 4.9
Social support – Friends	14.1 ± 9.5	15.5 ± 8.9

Notes: Mean (Standard Deviation) or count (percentage); * indicates statistical significance ($p < 0.05$); independent t-tests were used to compare differences in baseline characteristics between the two groups; none were significant except for self-efficacy.
Abbreviations: MET-time, metabolic rate; BMI, body metabolic index; HgA1c, glycated hemoglobin; TC/HDL, total cholesterol/high density lipoprotein.

Feasibility: Recruitment, Adherence, Retention, and Acceptability

Recruitment

Of the 21 participants who responded to the recruitment letter during the three-week recruitment period, only one was found ineligible to participate due to illness. All 20 participants who were confirmed eligible to participate in the study were consented. All 20

consented participants were randomized to one of the two telephone support intervention groups, one led by a worksite nurse and the other led by a peer volunteer. The telephone support coaches and participants coordinated with each other the best time for telephone sessions.

Adherence

The nurse-led group (100% attendance at 6 and 12 weeks) demonstrated better adherence with telephone support than the peer-group (30% attendance at 6 weeks, 60% attendance at 12 weeks). Adherence to a weekly upload of pedometer steps was modest for both groups (30% uploaded step count weekly at 6 and 12 weeks for nurse-group, 40% uploaded step count at 6 weeks, 50% at 12 weeks for peer-group). PA adherence measured by average pedometer steps greater than 10,000 per day and MET-time scores greater than 50 ranged from low for average pedometer steps per day (nurse-group > 10,000 steps: 20% at 6 weeks, 30% at 12 weeks versus peer-group: 10% at 6 weeks, 20% at 12 weeks) to modest for MET-time scores (nurse-group > 50 MET-time: 30% at 6 weeks, 80% at 12 weeks, versus peer-group > 50 MET-time: 40% at 6 weeks, 40% at 12 weeks).

Retention

All 20 participants submitted at least 1 weekly PA log (100% at 6 and 12 weeks). Except for one, all participants attended each of the two post-intervention assessment and weigh-in periods (100% at 6 and 12 weeks for the nurse-led group, 100% at 6 weeks and 90% at 12 weeks for the peer-led group). The participant who missed the final assessment period was a member of the Army Reserve and called unexpectedly for duty to the Middle East. The participant asked to remain in the study and continued to submit study data remotely. In view of the circumstance and mobile nature of the study intervention, the participant was not dropped from the study.

Acceptability

All participants responded positively to the intervention based on the TAP scale. A score greater than 2 indicate modest to high acceptability [105]. Mean scores for both groups (nurse-group at 2.91, peer-group at 3.02) represented high acceptability for the intervention among participants. The difference in acceptability scores between groups was not statistically significant ($U = 41.5$, $z = -0.09$, $p = 0.93$).

Health Outcomes

Descriptive statistics and ANOVA results for the health outcomes are presented in Table 2. There were significant differences between the two interventions in PA step count, MET-time, and self-efficacy but none in the other outcomes for these data.

Table 2. Mean (SD) for physical activity, biochemical, and psychosocial measures

	Group	Mean (SD)			RM ANOVA F Value	
		Baseline	Week 6	Week 12	Time	Interaction
Step counts	Nurse	7311 (1259)	8713(1892)	8447(1858)	2.43	5.78*
	Peer	7440 (1291)	6882 (1684)	7598(1669)		
MET-time	Nurse	40.9 (6.67)	48.1 (10.8)	58.1 (10.3)	6.86**	2.45
	Peer	43.6 (14.0)	52.6 (14.3)	49.7 (9.2)		
BMI	Nurse	33.2 (4.6)	32.8 (4.3)	32.5 (4.1)	3.53	1.38
	Peer	36.9 (4.8)	36.7 (4.9)	36.7 (5.1)		
HgA1c	Nurse	6.20 (0.50)	-	6.15 (0.40)	0.62	0.34
	Peer	5.93 (0.28)	-	5.92 (0.29)		
TC/HDL risk	Nurse	4.21 (1.54)	-	4.10 (1.51)	3.04	2.29
	Peer	3.44 (1.40)	-	3.03 (0.91)		
Self-efficacy	Nurse	7.81 (2.23)	6.72 (2.27)	6.44 (2.36)	1.57	3.75*
	Peer	4.94 (2.02)	4.87 (1.16)	5.63 (1.46)		
Social support	Nurse	17.10 (9.19)	23.1 (12.6)	21.7(12.7)	0.38	0.93
Family	Peer	15.80 (4.87)	20.0 (6.46)	20.9 (8.53)		
Social support	Nurse	14.10 (9.47)	19.5 (11.5)	16.4 (9.1)	0.49	2.59
Friends	Peer	15.50 (8.90)	15.9 (11.9)	24.1 (14.8)		

* indicates significance at $p < 0.05$
** indicates significance at $p < 0.01$

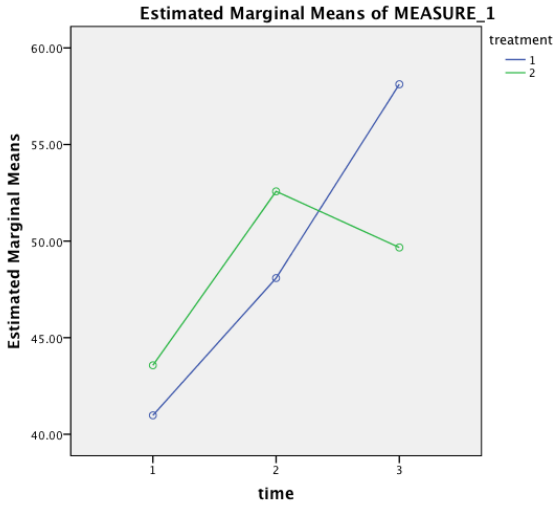
Step Counts

A significant interaction effect occurred for step counts ($p < 0.05$). Follow-up tests for within-subjects effects at each time point found a significant difference in mean change for step counts between nurse and peer at 6 weeks ($F(1,9) = 8.428$, $p < 0.02$, partial $\eta^2 = 0.48$) but none at baseline and at 12 weeks.

MET-time

Although not statistically significant, the data suggest an interaction between groups from 6 to 12 weeks. As shown in Figure 1, the nurse led group tended to show continued increases in MET-time across all time points, while the peer-led group increased initially but decreased at 6 to 12 weeks. A significant main effect of time ($F = 6.86$, $p < 0.01$) was found for MET-time. The post-hoc test showed significant differences in MET-time from baseline to 12 weeks.

Figure 1. Mean MET-time at 6 weeks to 12 weeks (1- nurse, 2-peer)



BMI, HgA1c, and TC/HDL risk ratio

No significant interaction and main effects occurred for BMI, HgA1c, Total cholesterol/HDL risk ratio, and Social Support for these data. Mean scores for BMI, HgA1c, and

Total cholesterol/HDL risk ratio showed a very slight increase from baseline to 12 weeks. The changes between time points, from baseline to 12 weeks, were not significant.

Self-Efficacy and Social Support

There was a significant interaction effect found for self-efficacy ($p < 0.05$). A follow-up test of within-subjects effects found significant differences between groups in mean change at baseline ($F(1/9) = 7.92$, $p < 0.05$, partial $\eta^2 = 0.46$) and 6 weeks $F(1, 9) = 5.388$, $p = .046$, partial $\eta^2 = .372$. No significant difference in mean change occurred between groups at 12 weeks. There were no significant main or interaction effects for social support from family and friends between the two groups.

Fidelity of Intervention

The nurse and peer coach completed the training time (100%) and post-training evaluation of intervention content delivery (98% for both). *The Active Choices* coordinator evaluated the quality of intervention content delivery. The nurse delivered telephone support intervention to all its participants (100% at 6 and 12 weeks) while the peer coach did not (40% of participants at 6 weeks and 60% at 12 weeks). The average length of time spent on telephone calls was equivalent for both groups, averaging between 5 to 10 minutes per call. The peer completed 1 audio recording while 7 were created in the nurse led group. Based on the evaluation of 1 transcription, the peer coach met intervention content delivery. Of the 7 audio-recorded telephone sessions with the nurse coach, 5 met intervention content delivery for intervention fidelity. Comparison of the coaches cannot be made due to the unequal number of telephone session recording.

Discussion

The primary aim of the study was to evaluate the feasibility of examining telephone support interventions led by a nurse versus a peer coach on participant recruitment, retention, adherence, and acceptability of intervention. Results of the study showed that examining telephone support intervention to increase PA among high-risk AA women may not be feasible in a pedometer-based WWP because of the low adherence particularly in the peer-led group. Recruitment rate for both groups is high and may be attributed to the existing relationship and good rapport between the WWP and the participants. Consistent with previous studies on AA women, the good rapport built from previous working relationships may have motivated participants to spread the word about the study with other AA women [44, 111]. Additionally, the short time from participant decisions to join the study to their informed consent helped sustain interest and established continuity from recruitment screening to randomization, thus preventing attrition due to long delays that can allow barriers and gaps to occur in the enrollment process. Regardless of the group assignment, all participants remained until the end the study. The retention rate of 100% is notably higher compared to a similar study examining PA interventions in worksite settings [112].

Adherence to the intervention ranged from modest to low. Attendance to telephone sessions was higher in the nurse-led group than in the peer-led group. This finding contradicts results from a previous study showing participants randomized to a peer-led group received an equivalent amount of PA telephone advice as participants led by professional mentors [46]. The low attendance in the peer-led telephone support group may be attributed to the low intervention fidelity on the part of the peer coach in calling the participants and delivering telephone support intervention. It is also possible that participants may not have had a favorable perception about

learning from a peer as a coach, which may have contributed to less enthusiasm to coordinate telephone sessions with the peer coach. This is a potential area for future research as there are limited studies on participant perception about competence of peer coaches and its effects on social interactions. A recent systematic review on peer delivered PA interventions found limited studies assessing the quality of peer mentor-mentee relationship and its impact on eliciting behavioral change [108]. To increase telephone session attendance, participants may be encouraged to the call the peer coach to facilitate telephone session attendance in case of scheduling conflicts and increase chances of success with telephone interaction between the peer coach and participant.

In a study to assess the effectiveness of an online pedometer program, participants uploaded steps weekly and resulted in significant increase in average weekly steps over a 12-week period [113]. This was not the case in the current study. Participants from both groups had low adherence to weekly uploading of step count. Thus, no significant increase in step count was reported at the end of the study. Online instructions how to upload steps and a 24/7 telephone helpline to help with technical issues may need to be offered to facilitate weekly uploading of pedometer steps.

Both groups demonstrated low adherence with PA as demonstrated by average step count greater than 10,000 steps. Only 20% of participants from both groups averaged 10,000 steps or more at 6 and 12 weeks. This finding is consistent with previous studies that suggest 10,000 steps count per week may not be attainable in certain populations, especially among sedentary AA women at high-risk for CHD [67, 114]. Higher in the nurse-led group than in the peer-led group, participants recorded modest adherence to light/moderate MET-time of 50. Unlike pedometers, MET-time represents the intensity of PA [67]. Since it allows for estimation of

energy expenditure for specific type of activities and not just walking over a 24-hour period, MET-time may have provided a better representation for PA in this population. A study validating the use of a new PA scale suggested that MET-time is a valid alternative to measure PA in sedentary to moderately active adults [67].

Based on the TAP scale, participants from both groups found the intervention highly acceptable. Although the peer-led group had lower attendance to telephone support sessions than the nurse-led group, both groups expressed preference for having a telephone coach to assist them in accomplishing their PA goals. The high fidelity in intervention content delivery during training and study period in both the nurse and peer coach may account for the preference and acceptability of the intervention. Previous studies on the acceptability of pedometer-based telephone support from peer volunteers and professionals in sedentary women support this finding [41, 43, 46, 48].

The secondary aim was to examine variability of outcome between the two groups of participants to detect preliminary signs of clinical and statistical significance. While still lower than what is typically recommended for healthy adults (>10,000 steps per day), the nurse-led group had significantly higher step counts at 6 weeks compared to the peer-led group [114]. The higher telephone session attendance in the nurse-led group may have created greater motivation for participants in the nurse-led group than in the peer-led group to walk more and increase their PA. Although small, the step count among participants in the peer-led group increased from baseline to 12 weeks. The increase in PA is consistent with results from previous studies that showed peer coaching improved PA and functional outcomes in sedentary adults [46, 48]. Interestingly, the significant interaction between the two groups at 6 weeks may appear misleading because this study was not primarily designed or powered to detect group differences.

The low fidelity in the number of telephone support delivered by the peer to participants may have contributed to the statistically significant interaction.

The MET-time for both groups increased significantly from baseline to 12 weeks. MET-time was measured using a self-report instrument at 6 weeks and 12 weeks. It is possible that over-reporting of PA may have occurred due to respondent's bias or the so called "social desirability response bias." This is consistent with previous studies showing that energy expenditure tended to be overestimated when measured by self-report surveys versus objective measures [46, 67]. Nevertheless, taking into account the increasing trend in step count and the significant increase in MET-time from baseline to the end of the study for both groups suggest preliminary signs of the clinical effectiveness of telephone support in improving overall PA, independent of the telephone support interventionist.

No significant changes occurred in BMI, HgA1c, and TC/HDL risk ratio for these data. A possible explanation for the lack of positive change in BMI is the relatively small increase in step count and MET-time among participants in both groups. To lose weight, a sedentary person has to perform 60 to 90 minutes of moderate intensity PA or approximately 6,000 to 9,000 steps per day above baseline [88]. Neither group had step counts that came close to this recommendation during the course of the study. The lack of significant weight loss may have also resulted in lack of significant reductions in HgA1c and total cholesterol/HDL risk ratio. This finding is supported by a recent study that showed weight loss demonstrated a corresponding decrease in cholesterol and insulin levels among obese individuals [115]. Weight loss is an important component of any lifestyle change to achieve health outcomes. Furthermore, no other interventions except PA telephone support were used in this study. It is possible that to improve health outcomes, a multi-modal approach may need to be considered. Studies have

reported that to achieve weight loss and health improvement, obese individuals need nutritional, psychological, and behavioral modifications in addition to PA [90, 110].

A significant mediator of PA in overweight and obese AA women, self-efficacy demonstrated a significant difference between the two groups, but social support did not [50, 52]. The peer-led group reported significantly lower SE compared to the nurse-led group at baseline and at six weeks. Although overall BMI was higher in the nurse-led group, it is possible that participants in the peer-led group felt less confident about their ability to achieve their PA goals. This is consistent with a study that showed a higher baseline BMI was significantly associated with lower self-efficacy among minority women [116]. This finding suggests that women with higher BMI may need interventions other than PA. One intervention shown to be a significant predictor of SE is education. In a study involving obese middle-aged women, education was found to be a significant predictor of performance of health promotion behaviors [107]. Therefore, education should be incorporated in telephone support to improve performance of PA behaviors.

There are several limitations in the study. The small sample size, the short duration, and the timing of the study may have prevented detection of significant differences in outcomes between the two groups. Additionally, this short study was conducted during one of the most challenging seasons of the year for PA and weight loss, December to March. Thus, the results are not intended to be conclusive but rather suggestive. Pedometers are a valid and reliable source of step count measure. However, any missing data from non-compliant users may easily offset pedometer accuracy. The alternative self-report instrument (PAS) was useful in measuring MET-time for PA but has not been validated in AA women. This suggests that the PAS may not be responsive to PA among AA women. Given the lack of PA instruments solely validated for AA women, future trials should evaluate the validity of PAS to measure PA (MET-time) in this

population. Additionally, use of previous test results as baseline data for the study may have led to under detected changes in biochemical markers at the end of the study. Lastly, the social support instrument used in the study has not been validated to take into account the impact of telephone support from a coach on family and friends. This may explain the lack of demonstrated response to measuring change in social support across different time points.

Conclusions

The study demonstrated limited feasibility primarily due to low adherence in the peer-led group. However, a major strength of the study was the clear and rigorous definition of the feasibility measures in the study: recruitment, retention, adherence, and acceptability of intervention. Another substantive achievement of this study was the effective recruitment and retention of difficult to reach AA women at high risk for CHD. The study collaboration with the WWP provided a convenient arrangement to identify high-risk AA female employees for the study, and the existing organizational structure of the WWP facilitated measurement of outcome measures. Although preliminary findings show a more positive trend in PA and health outcomes in the nurse-led group compared to the peer-led group, those observations require thorough investigation through a randomized controlled trial. This feasibility study has the potential to inform large-scale comparative effectiveness and randomized controlled trials to illuminate factors that can help design interventions to improve PA and overall health outcomes of this high-risk, underserved, and understudied minority population.

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Chapter 5: Summary and Conclusions

Synthesis

Together, the three manuscripts of this dissertation address the importance of PA as it pertains to CHD among high-risk populations, specifically AA women. The benefits of PA as a predictor of health are well documented in the literature. Recent studies have highlighted the role of PA in improving mortality and overall health outcomes independent of BMI and other CHD risk factors. The role of worksite wellness programs as an ideal setting to offer PA health promotion programs has also become increasingly important to increase opportunities for participation to hard to reach, high-risk populations. Yet despite the known benefits of PA, many Americans are sedentary and few meet the guidelines for PA based on broad public health policy.

Over the last 25 years, there has been a sudden rise in the number of organizations offering some type of wellness and health promotion programs for their employees. The increasing amount of time spent at work and cost associated with poor employee health has added a strong incentive for many organizations to establish WWP. Moreover, recent studies have suggested that physically inactive employees are particularly at risk for CHD. Understanding factors that impact PA among sedentary employees at high risk for CHD is important to be able to identify interventions to promote PA. In this study (Chapter 2), AA women comprise a large proportion of the sample. Understanding perceived barriers to participation and factors that motivate involvement in PA, as described in the first manuscript of this dissertation, may help identify effective interventions specifically designed to address the unique needs of this high risk population.

The benefits of PA in promoting health and wellness are well documented in the literature. Specific PA recommendations aimed at improving health outcomes have been outlined in public health policy in the last three decades and has continued to evolve based on new evidence. To maximize health benefits, accurate measurement of PA is essential to determine the most effective PA intervention. A valid and practical instrument to measure PA is particularly important among AA women taking into account the high prevalence of risk factors for CHD. The second manuscript (Chapter 3) presents an integrative review of self-report instruments that were used to measure PA in AA women in the context of CHD. Chapter 3 identified 14 instruments that were psychometrically evaluated in 7 studies that included AA women in the sample. With no instrument exclusively utilized AA women, the review yielded modest validity and reliability of PA self-report instruments among AA women. Taking into account their heightened risk for CHD, there is a need to identify culturally competent instruments to measure PA among AA women. Additionally, the limited studies evaluating self-report instruments solely on AA women may contribute to the lack of understanding about effective interventions to improve PA specifically in this high-risk population. The third manuscript (Chapter 4) addresses this gap by examining PA interventions in an exclusive sample of AA women at high risk for CHD. This last manuscript demonstrated limited feasibility of telephone support interventions specifically in the peer-led group – to improve PA in a randomized sample of AA women. Moreover, this final study provided an estimate of variability of outcome measures to inform future large scale randomized clinical trials.

Limitations

There are several limitations to each of the studies in this dissertation. For the first manuscript, participants in the study were concurrently receiving additional health services from

the WWP because of their high risk for CHD. It is possible that their responses to the interview may have been influenced by their existing relationship with the WWP. Response bias may have occurred because the interviewer works in the same organization and is familiar with the participants in the study. Although, a high proportion of participants are AA female employees, the findings may not accurately represent the views of AA women in general. Lastly, the qualitative nature of the study limits generalizability of findings to other populations.

The second manuscript, an integrative review of self-report instruments, may be limited by the scope of investigation as defined by the publication dates, key terms and databases used in the literature search. It is possible that other relevant studies on self-report instruments used in AA women exist but are unavailable for public use. Although a number of validation studies of self-report measures were included, none were conducted solely on AA women. Thus, results of the review may not demonstrate the accurate validation of instruments used to measure PA specifically among AA women.

Finally, the last manuscript included a randomized sample of 20 AA women. The small sample size, short study duration of 12 weeks, and the timing of the study may have limited the demonstration of significant differences in PA and secondary outcome measures between the two groups. The lack of professional training and experience in telephone counseling by the peer coach may have contributed to the low adherence among the peer-led group. Pedometers provide a valid measure of PA but non-compliant users can easily counterbalance their accuracy. Additionally, 10,000-pedometer step count per day may not be an attainable goal for sedentary high-risk populations. Although both received similar training on telephone support, the peer coach in the study lack formal training in organizational skills and health counseling compare to the professional nurse. The difference in counseling skill level may have contributed to the small

differences in PA and psychosocial measures. Lastly, the social support instrument has not been validated for use in telephone support interventions. Thus, the instrument may not be responsive to measuring outcome changes in this study.

Future steps

This dissertation provides preliminary data for future research on PA and its impact in improving overall health outcomes specifically among AA women at high risk for CHD. Improving PA in high-risk populations is challenging particularly among AA women. AA women have the highest prevalence of risk factors for CHD and yet, are one of the most difficult to reach groups. Identifying effective interventions to improve PA and ideal settings, such as worksite wellness programs, to offer these interventions are significant steps toward improving health outcomes in this understudied population.

In the setting of worksite wellness program, the findings in this dissertation support the importance of understanding the experience of high-risk employees with PA. With a large proportion of AA women participants in the study, the findings from the first manuscript revealed that physical limitations due to pain and weakness were the predominant barrier to PA. Unlike previous studies, this finding is unique but not unexpected because participants in the study are considered high-risk for CHD. All participants have multiple chronic health conditions and risk factors for CHD that impeded their participation in PA. Participants identified close family relationship as the biggest motivating factor for PA. Future research should investigate whether interventions primarily aimed at alleviating the physical symptoms associated with chronic illness in this population would improve participation in PA. Additionally, this research should also examine if incorporating the role of family, as a motivating factor during health counseling would improve engagement in PA and adoption of health behaviors.

To maximize the health benefits of PA, valid instruments that can accurately measure PA among AA women in the context of CHD need to be identified. The second manuscript evaluated 14 self-report instruments used to measure PA in AA women in the context of CHD. Findings revealed modest validity and highlighted the need for future research focusing on investigating psychometrically valid and culturally competent instruments for use specifically among AA women.

The last manuscript in this dissertation examined telephone support approaches to improve PA among AA female employees at high risk for CHD. The last manuscript demonstrates the feasibility of telephone support interventions, provided by a nurse versus a peer coach, to improve PA among AA women participating in the WWP. Bandura's social cognitive theory, and specifically, the self-efficacy model should provide the framework for future studies examining the most effective intervention to improve PA in high-risk populations. Self-efficacy is influenced by four sources of information: performance outcome, vicarious experience, verbal persuasion, and physiological feedback. The interaction of these four factors with the individual determines his or her self-efficacy to accomplish a task. As a predictor of PA, self-efficacy should guide clinical trials to examine whether telephone support intervention delivered by a professional nurse versus a trained peer coach would be more effective in improving PA.

Although not significant, changes in secondary outcome measures showed a positive trend towards improvement in health outcomes. These findings could inform future clinical trials investigating the most effective telephone support intervention to improve PA among AA women at high risk for CHD.

Contribution to Nursing Science

This body of work provides a greater understanding of PA as it relates to the experience of AA women at high risk for CHD, importance of valid PA measures specifically for AA women, and approaches to improve PA among high-risk AA women taking into account the role of WWP. This work highlights the increasing health benefits of PA and the urgency of addressing the negative effects of physical inactivity in vulnerable, minority populations. This dissertation is unique for its focus on the understudied, hard to reach, and yet high-risk AA women.

The results of this dissertation, as demonstrated in the three manuscripts, contribute to the state of science by: 1) identifying interventions that address the barriers to PA and bolster motivation to engage in PA, 2) identifying valid self-report instruments to measure PA, and 3) examining telephone support interventions to improve PA and health outcomes, among AA women at high risk for CHD in the setting of WWP. Advanced practice nurses (APNs) and nurse scientists play an important role in promoting and highlighting the health benefits of PA. With knowledge about the PA experience of AA women with regards to barriers and motivators to participation, APNs can help design interventions specifically for high-risk AA women and implement processes to facilitate engagement with PA in various settings. APNs should conduct comprehensive health assessments including review of lifestyle behaviors, and family health risks and should recommend measures to educate the public about importance of PA in modifying health risks. APNs should take the lead in raising awareness about the health risks of physical inactivity and the positive health outcomes of PA independent of other health conditions. Nurse scientists can investigate the validity of additional instruments used to measure PA in AA women or construct psychometrically reliable and culturally competent PA

instruments for use in AA women. Nurse scientists should continue to focus in the identification, development, and testing of innovative health interventions to improve PA specifically for high-risk populations. To help guide public health policy, APNs should conduct high-level studies such as randomized clinical trials and comparative effectiveness research to provide stakeholders with scientific evidence to make informed decisions about healthcare.

PA will continue to take a prominent role in health promotion and disease prevention in the coming years. There will be increased focus on incorporating behavioral health counseling and structured PA regimens as standard health promotion practices in various settings. Prescriptions for PA or exercise programs will become routine during primary care visits replacing pharmacological prescriptions for diseases resulting from physical inactivity. Given the disparities in CHD, it is essential to continue efforts to identify interventions to improve PA and reduce risk for CHD among AA women. This dissertation illuminates the overall need for adequately powered and controlled clinical trials to examine the most effective intervention to improve PA and evaluate health outcomes among high-risk, hard to reach minority populations.

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Appendice A: eIRM Recruiting Letter

Date: November 19, 2014

Dear:

You are being invited to participate in a study about a wellness program to improve physical activity by using telephone "coaching" in addition to the use of pedometer among African American women employees with one or more risk factors for heart disease. You are being asked to volunteer for this study because you have expressed interest in improving your health by participating in the Self Cares program.

The purpose of this study is to determine the likelihood that an adequate number of volunteers can be recruited to participate, can follow the program, and can continue to participate in the program for 12 weeks. The study will also look at changes in your physical activity level, risk for heart disease, and diabetes. In consideration for your participation, a compensation package is available. Declining to participate in the study will not in any way affect your membership in the Self Cares program.

Please let me know by November 26th (Wednesday) of your interest to participate in the study by contacting me at this number 725-5123 (please leave a voicemail) or by sending an email to cwells@selfregional.org. Please respond as soon as possible because there is limited space for the study. With your permission, we will refer you to John Paguntalan, a nurse practitioner at Self Regional Healthcare and the primary researcher, to contact and tell you more about the study. You may also directly contact him at 554-3421 or email him at jpaguntalan@selfregional.org.

Sincerely,

Cathy Wells, RN
Manager
Employee Health and Wellness

MUSC
MEDICAL UNIVERSITY of SOUTH CAROLINA
IRB Number: «ID»
Date Approved ««_attribute154»

Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT
Physical Activity Telephone Support Intervention in African American Women At-Risk for Coronary Heart Disease: A Worksite Feasibility Study

1. PURPOSE AND BACKGROUND:

You are being asked to volunteer for a research study. The purpose of this study is to examine the feasibility of physical activity (PA) telephone support intervention related to recruitment, adherence to protocol, and retention of eligible participants in a 12-week study period. You are being asked to participate in this study because you have expressed interest in improving your health through participation in the Self Cares Program, the Self Regional Healthcare worksite wellness program (WWP). Declining to participate will in no way influence your participation in the Self Cares Program. The primary investigator (PI) in charge of this study is John Paguntalan, APRN-BC. The study will involve approximately 20 volunteers.

2. PROCEDURES:

If you agree to participate in this study, the following will happen:

1. You will be asked to confirm that you are an African American female employed either full-time or part-time, have a risk factor for heart disease, have low pedometer step count, and have access to a telephone. You will also be asked to confirm that you are not pregnant (if there is a question or possibility of pregnancy, a urine pregnancy test will be performed); and have no plans to relocate, resign, or retire in the next 12 weeks. If the above information shows that you are eligible for the study, you will be randomly assigned to one of the two groups. This means that you have a 50/50 chance of being in either group. Each group will have a different telephone coach.
2. At the start of the study, you will meet your assigned telephone coach at a designated time and location at work. Your telephone coach will then call you once every two weeks at a specified time and place that you both agreed as suitable. Your coach will provide you with encouragement and monitor your activity. Some of the telephone conversation will be recorded to evaluate how well your telephone coach is following the telephone support protocol.

3. You will be asked to complete measurements related to your height and weight at a specified location at work at the start of the study, 6 weeks and 12 weeks. You will also be asked to provide a blood sample at the start of the study and at 12 weeks to assess your total cholesterol to measure your risk for heart disease and blood sugar to measure your risk for diabetes. You must fast for at least 12 hours (i.e., no food or water) prior to each of the two measurement visits. Approximately 32 ml of blood will be drawn for laboratory testing, which equates to ~2 tablespoons (16ml) each visit. These measurements will be used to examine changes that occurred as a result of you participating in the physical activity telephone support program over a 12-week period.
4. You will be asked to enter or upload your pedometer steps to a designated computer in the hospital every week. If you need additional training, a member of the worksite wellness program is available to teach you how to upload your pedometer steps into designated computers in your work area. A help-line is also available to assist you in case you have difficulty uploading your pedometer steps to the computer.
5. You will be asked to list down your physical activity on a paper form every day for the next 12 weeks. You will also be asked to complete a paper survey describing how much time you spend on certain types of activity on an average weekday once at start of the study, 6 weeks, and 12 weeks.
6. You will be asked to complete a paper survey describing how helpful the encouragement/support from your telephone coach in increasing your physical activity once at the start of the study, 6 weeks, and 12 weeks.
7. You will be asked to complete a paper survey measuring your confidence to accomplish your physical activity goal once at baseline, 6 weeks, and 12 weeks. Finally, all completed paper forms and surveys at the start of the study, 6 weeks, and 12 weeks will be submitted to John Paguntalan.

3. **DURATION:**

Participation in the study will take 12 weeks.

4. **RISKS/DISCOMFORTS:**

1. Potential risks to the participants are minimal. The risks of venipuncture include temporary discomfort from the needle stick; bruising, infection, or fainting could occur.
2. Steps are being taken to ensure your privacy and confidentiality will be maintained. However, loss of confidentiality is a potential risk.

5. **BENEFITS:**

There may be no benefit from participating in this study. However, this program may help others because it has the potential to provide the proper guidance for a healthy lifestyle that is often omitted from worksite setting.

6. **COSTS:**

You will not be charged for any of the study procedures.

7. **PAYMENT TO PARTICIPANTS:**

In return for your time and effort, you will be given $10 gift certificate at the start of the study, $50 gift certificate at 6 weeks, and a choice of $50 gift certificate or a free *Fitbit* (pedometer) at 12 weeks.

Payments that you receive for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

8. **ALTERNATIVES**

You have the alternative not to participate in the study. If you choose not to participate in this study, the PI is happy to refer you to Employee Health how to go about obtaining any of the measurements collected in this study. Declining to participate in the study will in no way influence your participation in the Self Cares Program.

I. DISCLOSURES

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study and the Self Regional Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should seek immediate help and contact the PI of research study. The PI will help facilitate your treatment at Self Regional Healthcare treatment. The hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future employment, medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact the Principal Investigator **John Paguntalan, APRN-BC, 864-554-3421**.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

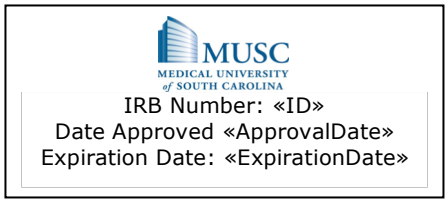
I agree to participate in this study. I have been given a copy of this form for my own records.

If you wish to participate, you should sign below.

Signature of Person Obtaining Consent _____

Date _____

Signature of Participant _____ Date_____



Appendice C: Self-Efficacy for Exercise Scale

This scale is designed to gather information about your confidence about being able to exercise on a regular basis. For the purpose of this study, exercise can include walking, aerobics, bicycling, jogging, swimming, and any other forms of physical activity.

How confident are you right now that you could exercise three times a week for 20 minutes if:

	Not Confident	Very Confident
1. the weather is bothering you	0 1 2 3 4 5 6 7 8 9 10	
2. you were bored by the activity	0 1 2 3 4 5 6 7 8 9 10	
3. you felt pain when exercising	0 1 2 3 4 5 6 7 8 9 10	
4. you had to exercise alone	0 1 2 3 4 5 6 7 8 9 10	
5. you did not enjoy doing it	0 1 2 3 4 5 6 7 8 9 10	
6. you were too busy with other activities	0 1 2 3 4 5 6 7 8 9 10	
7. you felt tired	0 1 2 3 4 5 6 7 8 9 10	
8. you felt stressed	0 1 2 3 4 5 6 7 8 9 10	
9. you felt depressed	0 1 2 3 4 5 6 7 8 9 10	

Appendice D: Social Support for Physical Activity Scale

This scale is designed to gather information about support you get from other people about your physical activity. The following is a list of things people may say or do to someone who is trying to do physical activity on a regular basis. For the purpose of this study, a third column for your assigned coach is added.

Please rate each question. Under "Family" rate how often somebody living under the same household has said or done what is described in the last 6 weeks. Under "Friends" rate how often your friends and co-workers has said or done what is described. Under "Coach" rate how often your assigned coach has said what is described. In this study, the coach is not going to do any activities with you other than telephone interaction.

Please write one number from the rating scale in each space:
1 = none
2 = rarely
3 = a few times
4 = often
5 = very often
0 = does not apply

	Family	Friends	Coach
1. Did physical activities with me			
2. Offered to do physical activities with me			
3. Gave me helpful reminders to be physical active			
4. Gave me encouragement to stick with my physical activity program			
5. Changed their schedule so they can do physical activities with me			
6. Discussed physical activities with me			
7. Complained about the time I spend doing physical activity			
8. Criticized me or made fun of me for doing physical activites			
9. Gave me rewards for being physically active			
10. Planned for physical activities on recreational outings			
11. Helped plan events around my physical activities			
12. Asked me for ideas on how they can be more physically active			
13. Talked about how much they like to do physical activity			

Appendice E: Participant Progress Notes

Participant_____ Date_____

Accomplishment from last contact:

Comments from last contact:

New health concerns/questions:

New physical activity goals/ for how many weeks:

Other notes:

Next call date and time:

Coaches, this is your record keeping. Use this as guide when coaching participants and monitoring their progress

Appendice F: Physical Activity Scale

This scale is designed to gather information about how physically active you are on an average weekday.

In the physical activity scale you see some examples of different levels of physical activity. Try to assess how much time you spend on each level on an average weekday. Start with level 1 and continue downward.

Example: If you normally sleep 8 hours, you should mark the 8-hour box of level 1. If you watch TV for an hour and a half, you should mark the 30-min box and the 1-h box of level 2. If you are not active on all activity levels, you should leave levels unmarked.

Please note that the total number of minutes and hours on an average weekday and nightshould equal to 24 hours.

Examples	Minutes	Hours	Time spent
1. Sleep, rest	□□□ 15 30 45	□□□□□□□□□□ 1 2 3 4 5 6 7 8 9 10	
2. Sitting quietly, watching TV, listening to music or reading	□□□ 15 30 45	□□□□□□□□□□ 1 2 3 4 5 6 7 8 9 10	
3. Working at a computer or desk, sitting in a meeting, or eating	□□□ 15 30 45	□□□□□□□□□□ 1 2 3 4 5 6 7 8 9 10	
4. Standing, washing dishes or cooking, driving a car or truck	□□□ 15 30 45	□□□□□□□□□□ 1 2 3 4 5 6 7 8 9 10	
5. Light cleaning, sweeping floors, food shopping with grocery cart, slow dancing or walking downstairs	□□□ 15 30 45	□□□□□□□□□□ 1 2 3 4 5 6 7 8 9 10	
6. Brisk walking, bicycling to work or for pleasure, painting or plastering	□□□ 15 30 45	□□□□□□□□□□ 1 2 3 4 5 6 7 8 9 10	
7. Gardening, carrying, loading or stacking wood, carrying light object upstairs	□□□ 15 30 45	□□□□□□□□□□ 1 2 3 4 5 6 7 8 9 10	
8. Aerobics, health club or fitness center exercise, chopping wood, or shoveling snow	□□□ 15 30 45	□□□□□□□□□□ 1 2 3 4 5 6 7 8 9 10	
9. More effort than no. 8: running, racing on bicycle, playing soccer, or tennis	□□□ 15 30 45	□□□□□□□□□□ 1 2 3 4 5 6 7 8 9 10	
Total hours in a weekday and night			24 hours

Appendice G: eIRB HIPAA

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to the Medical University of South Carolina (MUSC) to use or disclose (release) your health information that identifies you for the research study described here:

Physical Activity Telephone Support Intervention in African American Women At-Risk for Coronary Heart Disease: A Worksite Feasibility Study

The purpose of this study is to examine the feasibility of telephone support physical activity (PA) intervention related to recruitment, adherence to protocol, and retention of eligible participants in a 12-week study period.

The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Health insurer or payer in order to secure payment for covered treatment;
- Parents of minor children <16 years old. Parents of children 16 years old or older require authorization from the child; or
- Federal and state agencies and MUSC committees having authority over the study such as:
    - The Institutional Review Board (IRB) overseeing this study;
    - Committees with quality improvement responsibilities;
    - Office of Human Research Protections;
    - Food and Drug Administration;
    - National Institutes of Health; or
    - Other governmental offices, such as a public health agency or as required by law.

MUSC is required by law to protect your health information. By signing this document, you authorize MUSC to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

You do not have to sign this authorization. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, MUSC may still use or disclose (release) health information already

obtained about you as necessary to maintain the integrity or reliability of the research study. If you revoke this Authorization, you may no longer be allowed to participate in this research study. To revoke this Authorization, you must write to:

John Paguntalan, Primary Investigator, Self Regional Healthcare, 1325 Spring Street, Greenwood, SC 29646

You will not be allowed to see or copy the information described on this Authorization as long as the research study is in progress. When the study is complete, you have a right to see and obtain a copy of the information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

You will be given a copy of this Authorization. This Authorization will expire at the end of the research study. If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at 843-792-8744.

Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form.

_____

Signature of Research Participant ages 16 & above* Date

_____

Research Participant's Personal Representative** Date

_____

Printed Name of Research Participant (or representative, if applicable)

*If the research participant is 16 to 18 years of age, signatures of both the research participant and the personal representative are required.

A personal representative can be defined as a person authorized under state or other law to act on behalf of the individual in making health care related decisions. For example, a court-appointed guardian with medical authority, a health care agent under a health care proxy or a parent acting on behalf of an unemancipated minor.

NOTICE OF PRIVACY PRACTICES

MUSC Organized Health Care Arrangement (OHCA)

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESSS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

The Medical University of South Carolina and its affiliates (including but not limited to the Medical University Hospital Authority, MUSC Physicians, and MUSC Physicians Primary Care) participate in a clinically integrated health care setting. As a result of this clinical integration, these organizations function as an Organized Health Care Arrangement (OHCA) as defined by the Health Insurance Portability and Accountability Act (HIPAA). For purposes of this notice, the members of the MUSC OHCA are collectively referred to in this document as "MUSC." W**e collect or receive this information about your past, present or future health condition to provide health care to you, to receive payment for this health care, or to operate the hospital and/or clinics.**

HOW WE MAY USE AND RELEASE YOUR PROTECTED HEALTH INFORMATION (PHI)

A. The following uses do NOT require your authorization, except where required by SC law:

1. **For treatment.** Your PHI may be discussed by caregivers to determine your plan of care. For example, the physicians, nurses, medical students and other health care personnel may share PHI in order to coordinate the services you may need.

2. **To obtain payment**. We may use and disclose PHI to obtain payment for our services from you, an insurance company or a third party. For example, we may use the information to send a claim to your insurance company.

3. **For health care operations.** We may use and disclose PHI for hospital and/or clinic operations. For example, we may use the information to review our treatment and services and to evaluate the performance of our staff in caring for you.

4. **For public health activities.** We report to public health authorities, as required by law, information regarding births, deaths, various diseases, reactions to medications and medical products.

5. **Victims of abuse, neglect, domestic violence.** Your PHI may be released, as required by law, to the South Carolina Department of Social Services when cases of abuse and neglect are suspected.

6. **Health oversight activities.** We will release information for federal or state audits, civil, administrative or criminal investigations, inspections, licensure or disciplinary actions, as required by law.

7. **Judicial and administrative proceedings.** Your PHI may be released in response to a subpoena or court order.

8. **Law enforcement or national security purposes.** Your PHI may be released as part of an investigation by law enforcement.

9. **Uses and disclosures about patients who have died.** We provide coroners, medical examiners and funeral directors necessary information related to an individual's death.

10. **For purposes of organ donation.** As required by law, we will notify organ procurement organizations to assist them in organ, eye or tissue donation and transplants.

11. **Research.** We may use your PHI if the Institutional Review Board (IRB) for research reviews, approves and establishes safeguards to ensure privacy.

12. **To avoid harm.** In order to avoid a serious threat to the health or safety of a person or the public, we may release limited information to law enforcement personnel or persons able to prevent or lessen such harm.
13. **For workers compensation purposes.** We may release your PHI to comply with workers compensation laws.
14. **Marketing.** We may send you information on the latest treatment, support groups and other resources affecting your health.
15. **Fundraising activities.** We may use your PHI to communicate with you to raise funds to support health care services and educational programs we provide to the community. You have the right to opt out of receiving fundraising communications with each solicitation.
16. **Appointment reminders and health-related benefits and services.** We may contact you with a reminder that you have an appointment.

B. You may object to the following uses of PHI:

1. **Hospital directories.** Unless you object, we may include your name, location, general condition and religious affiliation in our patient directory for use by clergy and visitors who ask for you by name.
2. **Information shared with family, friends or others.** Unless you object, we may release your PHI to a family member, friend, or other person involved with your care or the payment for your care.
3. **Health plan.** You have the right to request that we not disclose certain PHI to your health plan for health services or items when you pay for those services or items in full.

C. Your prior written authorization is required (to release your PHI) in the following situations:
You may revoke your authorization by submitting a written notice to the privacy contact identified below. If we have a written authorization to release your PHI, it may occur before we receive your revocation

1. Any uses or disclosures beyond treatment, payment or healthcare operations and not specified in parts A & B above.
2. Psychotherapy notes.
3. Any circumstance where we seek to sell your information.

WHAT RIGHTS YOU HAVE REGARDING YOUR PHI
Although your health record is the physical property of MUSC, the information belongs to you, and you have the following rights with respect to your PHI:

A. The Right to Request Limits on How We Use and Release Your PHI. You have the right to ask that we limit how we use and release your PHI. We will consider your request, but we are not always legally required to accept it. If we accept your request, we will put any limits in writing and abide by them except in emergency situations. Your request must be in writing and state (1) the information you want to limit; (2) whether you want to limit our use, disclosure or both; (3) to whom you want the limits to apply, for example, disclosures to your spouse; and (4) an expiration date**.**

B. The Right to Choose How We Communicate PHI with You. You have the right to request that we communicate with you about PHI in a certain way or at a certain location (for example, sending information to your work address rather than your home address). You must make your request in writing and specify how and where you wish to be contacted. We will accommodate reasonable requests.

C. The Right to See and Get Copies of Your PHI. You have the right to inspect and receive a copy of your PHI (including an electronic copy), which is contained in a designated record set that may be used to make decisions about your care. You must submit your request in writing. If you request a copy of this information, we may charge a fee for copying, mailing or other costs associated with your request. We may deny your request to inspect and receive a copy in certain very limited circumstances. If you are denied access to PHI, you may request that the denial be reviewed.

D. The Right to Get a List of Instances of When and to Whom We Have Disclosed Your PHI. This list may not include uses such as those made for treatment, payment, or health care operations, directly to you, to your family, or in our facility directory as described above in this Notice of Privacy Practices. This list also may not include uses for which a signed authorization has been received or disclosures made more than six years prior to the date of your request.

E. The Right to Amend Your PHI. If you believe there is a mistake in your PHI or that a piece of important information is missing, you have the right to request that we amend the existing information or add the missing information. You must provide the request and your reason for the request in writing. We may deny your request in writing if the PHI is correct and complete or if it originated in another facility's record.

F. The Right to Receive a Paper or Electronic Copy of This Notice: You may ask us to give you a copy of this Notice at any time. For the above requests (and to receive forms) please contact: Health Information Services (Medical Records), Attention: Release of Information / 169 Ashley Avenue / MSC 369 / Charleston, SC 29425. The phone number is (843) 792-3881.

G. The Right to Revoke an Authorization. If you choose to sign an authorization to release your PHI, you can later revoke that authorization in writing. This revocation will stop any future release of your health information except as allowed or required by law.

H. The Right to be Notified of a Breach. If there is a breach of your unsecured PHI, we will notify you of the breach in writing.

HEALTH INFORMATION EXCHANGES

MUSC, along with other health care providers belongs to health information exchanges. These information exchanges are used in the diagnosis and treatment of patients. As a member of these exchanges, MUSC shares certain patient health information with other health care providers. Should you require treatment at another location that is a part of one of these exchanges, that provider may gather historical health information to assist with your treatment. You have the option of saying that this cannot be done. If you choose not to take part in these alliances, please contact the MUSC Privacy Office at 792-4037.

HOW TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you think your privacy rights may have been violated, or you disagree with a decision we made about access to your PHI, you may file a complaint with the office listed in the next section of this Notice. **Please be assured that you will not be penalized and there will be no retaliation for voicing a concern or filing a complaint. We are committed to the delivery of quality health care in a confidential and private environment.**

PERSON TO CONTACT FOR INFORMATION ABOUT THIS NOTICE OR TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you have any questions about this Notice or any complaints about our privacy practices please call the Privacy Officer (843) 792-4037, the Privacy Hotline (800) 296-0269, or contact in writing: HIPAA Privacy Officer / 169 Ashley Avenue / MSC 332 / Charleston SC 29425. You also may send a written complaint to the Office of Civil Rights. The address will be provided at your request.

CHANGES TO THIS NOTCE

We reserve the right to change the terms of this Notice at any time. We also reserve the right to make the revised or changed Notice effective for existing as well as future PHI. This Notice will always contain the effective date. You may view this notice and any revisions to it at: http://www.musc.edu/privacy.

EFFECTIVE DATE OF THIS NOTICE

This Notice went into effect on April 14, 2003.
Revised September 2013.

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