Published in final edited form as:

Contemp Clin Trials. 2010 January ; 31(1): 92. doi:10.1016/j.cct.2009.09.006.

Heart Healthy and Ethnically Relevant (HHER) Lifestyle Trial for Improving Diet and Physical Activity in Underserved African American Women

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Abstract

Background—African American women are at increased risk for CVD morbidity and mortality relative to white women. Physical inactivity and poor dietary habits are modifiable health behaviors shown to reduce CVD risk. Community health centers have the potential to reach large numbers of African Americans to modify their risk for CVD, yet few lifestyle counseling interventions have been conducted in this setting.

Methods—The HHER Lifestyle trial is a randomized controlled trial to compare the effects of a standard care intervention (provider counseling, nurse goal setting, and educational materials) to a comprehensive intervention (standard care intervention plus 12 months of telephone counseling and tailored print materials) on changes in physical activity and dietary fat consumption in financially disadvantaged African American women at 6 and 12 months. Secondary outcomes are body mass index, central adiposity, and total cholesterol. Potential mediators of outcome are self-efficacy for overcoming barriers, social support, and decisional balance.

Results—African American women (N=266; 130 standard care, 136 comprehensive intervention) 35 years and older from nine clinics within two community health centers were enrolled. Most participants were overweight or obese with existing chronic health conditions.

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Conclusion—The HHER Lifestyle trial is unique in that it targets financially disadvantaged African American women from community health centers, incorporates a standard care intervention into a routine clinical appointment, and includes a comprehensive process evaluation. The design will allow us to examine the added effect of regular telephone counseling and tailored print materials to a primary care provider and nurse intervention.

Keywords

lifestyle intervention; cardiovascular risk reduction; physical activity; exercise; diet; nutrition; underserved population; African American; women; health disparities; primary care

Introduction

Cardiovascular disease (CVD) is the leading cause of death for women in the United States [1]. Prevalence rates for CVD are higher in African American women (49%) than white women (35%) [1]. African American women also are disproportionately affected by high rates of hypertension (47%), overweight (80%), obesity (51%), diabetes (13%) [1] and CVD risk factors that are preventable and largely attributable to lifestyle behaviors [2]. Lower socioeconomic status among African Americans is a contributing factor to these and other health disparities [3,4].

Community health care centers are unique primary care clinical settings that hold promise for reducing disparities because they provide the largest proportion of comprehensive primary health care services to medically underserved and vulnerable populations. About 66% of health care center patients are minorities, 90% have incomes 200% below the federal poverty line, and 39% have no health insurance [5,6]. Community health care centers are community-based and patient-driven organizations that provide services to all persons, regardless of ability to pay. Community health centers are excellent settings for health professionals to counsel people on lifestyle factors, because those professionals are trusted sources of health information whose messages can reach a population that is underserved and more likely to suffer from chronic diseases.

Current evidence indicates that behavioral interventions implemented in health care centers can produce small but significant improvements in CVD risk factors including increased smoking cessation, improved diet, increased physical activity, and weight loss [7]. Based on this evidence, various health organizations and agencies recommend behavioral counseling within such primary care settings to promote healthy diet and physical activity, especially for individuals who are overweight/obese or have chronic diseases [8–13]. Yet, these interventions are not being delivered in routine clinical practice [14–17], especially in underserved areas, so many persons receiving care are not benefiting from advances in behavioral counseling. Health care providers report a number of barriers to implementing behavioral interventions into routine practice including lack of time, reimbursement issues, inadequate training and skills, and lack of organizational support [18]. Furthermore, few studies conducted in primary care settings have targeted underserved populations such as African American women [19]. Thus, previous studies do not evaluate whether lifestyle interventions are effective for underserved African American women in a health care setting.

In response to this evidence and gaps in the literature, the primary aim of the Heart Healthy and Ethnically Relevant (HHER) Lifestyle trial was to test the effectiveness of a theory-based standard care intervention (brief primary care provider counseling, nurse-assisted goal-setting, community resource guide, and educational materials) versus a comprehensive intervention (standard care intervention plus 12 months of telephone counseling and monthly tailored print materials) on increasing moderate-intensity physical activity and reducing dietary fat and

cholesterol consumption in financially disadvantaged African American women. The culturally appropriate intervention was designed to circumvent many of the common obstacles to providing counseling and sustaining behavior change. The present article provides an overview of the study design, theoretical framework, intervention protocol, outcome measures, process evaluation, and baseline data for the HHER Lifestyle trial.

Methods

Study Design and Aims

The HHER Lifestyle trial is a randomized controlled trial designed to assess the effectiveness of a culturally appropriate, theory-based intervention to reduce dietary fat and increase moderate-intensity physical activity in primary care settings among underserved African American women. Community health center primary care providers and their nurses were trained to implement a standard care intervention for each participant during a routine clinic visit. After implementation of the standard care intervention, half the participants were randomized to receive either the additional comprehensive intervention components or no additional formal intervention (see below for randomization allocation procedures). The primary study outcomes were hours per week of moderate-to-vigorous intensity physical activity and dietary fat intake. The study was funded by the National Heart, Lung and Blood Institute (HL073001) and is registered in clinicaltrials.gov (NCT00860444). The study protocol was approved by the institutional review board at the University of South Carolina on February 27, 2004.

Setting and Recruitment of Providers

Enrollment of study participants was limited to a two year period, beginning May 2005 and ending in April 2007, to have sufficient time to follow each participant for 12 months. Final 12 month assessments occurred in May 2008 and study results are anticipated to be published in 2010. Participants were recruited from nine community clinics within two federally funded community health care centers (in Columbia, SC and Orangeburg, SC). These community health centers were selected because their patient profiles matched the priority population that was the target of the HHER Lifestyle trial and because the principal investigator (DPM) had experience collaborating with both health centers in previous studies [20–22]. Based on reports provided by the participating community health care centers, patients were predominantly minorities (70% African American), on Medicaid/Medicare (70%), and self-pay or uninsured (25%), and the leading diagnoses for these adult patients were hypertension, diabetes, and other CVD-related conditions.

At study onset, all primary care providers and nurses in the selected clinics were invited to a kick-off dinner or lunch aimed at recruiting them to participate. As new health care professionals joined the clinics, they were contacted by HHER research staff and invited to join the study. Thirty providers were invited to participate. Seventeen providers (57%) agreed to participate and completed the required training. Among nurses, 28 were invited to participate and 16 (57%) agreed to participate and completed the required training. A detailed description of health care provider and nurse recruitment, training and study participation is available elsewhere [23]. A brief overview is provided in the intervention section.

Recruitment of Study Participants

On a weekly basis, the involved community health care centers used their computerized patient scheduling system to identify African American women ages 35 years or older who had non-urgent medical appointments scheduled with a participating primary care provider in the upcoming two to three months. At least four to eight weeks prior to the scheduled medical appointment, a personalized recruitment letter, study brochure, and a postage-paid refusal

postcard were mailed to patients from the referring clinical site. The letter briefly introduced the study, invited participation, and let patients know that they would be contacted by telephone. If the patient did not wish to participate or be contacted, the letter instructed her to return the refusal postcard provided. Two weeks after the recruitment letter was mailed, if a refusal postcard was not received, HHER research staff attempted to contact participants by telephone to conduct an eligibility screening. Once a participant was contacted, the research assistant briefly described the study and obtained verbal consent to perform the eligibility screening.

Patients were eligible for the study if they met the following criteria: (a) self-identified African American woman aged 35 years or older, (b) no physical disability or orthopedic problem that would prevent walking goals from being met, (c) non-life-threatening blood pressure level at baseline assessment ($< 160/95$), (d) no insulin controlled diabetes, (e) not pregnant or planning to become pregnant during study period and (f) able and willing to complete survey instruments and assessment procedures. The Physical Activity Readiness Questionnaire (PAR-Q) [24] was also used to screen for potential medical contraindications to physical activity, including heart conditions, hypertension, cardiac medications, bone and joint problems, chest pain during activity or rest, loss of balance, or dizziness. Patients who endorsed any of these PAR-Q items were not automatically excluded but required primary care provider approval to participate. For those who remained eligible after telephone screening and were interested in participation, a baseline assessment was scheduled at least one week prior to their medical appointment, and a recruitment packet that included an informational letter, a consent form, a self-administered questionnaire, a reminder card, and a HHER magnet was mailed.

Patients who completed the baseline assessment were required to attend their scheduled medical appointment to be enrolled in the study. At the medical appointment each patient received the standard care intervention (described in the standard care intervention section). After HHER research staff received confirmation from the clinic that the patient attended her appointment, the patient was then randomized to receive either the comprehensive intervention group or no additional formal intervention. Randomization.

A stratified randomization procedure with blocking was used to balance randomization within primary care provider for every four patients. A series of blocked treatment assignments with equal allocation into two groups (i.e., standard care and comprehensive intervention) was generated by the study statistician (CA) in advance of the trial and placed in a notebook accessible to the HHER research staff member responsible for administering the treatment allocation process. An excess number of assignments was generated for each stratum (e.g., provider) and used sequentially as accrual proceeded. Primary care providers, nurses and research assistants responsible for data collection were blind to treatment assignment. Study participants were notified of their treatment assignment by a mailed letter (sent after their primary care visit). Those randomized to the comprehensive intervention also received an intervention notebook and pedometer (described in more detail in the comprehensive intervention section). A brief follow-up phone call was made to each participant to confirm receipt and ensure understanding of the randomization letter and to instruct the participant on next steps. No participant expressed dissatisfaction with treatment assignment directly to study personnel. There was not potential for cross-over in the study design.

Intervention

Theoretical Framework—The HHER Lifestyle interventions were modeled in part after PACE [25] and the Activity Counseling Trial [26], two primary-care-based interventions that successfully increased physical activity in adult women. Similar to those trials, the HHER Lifestyle trial used an integrated theoretical approach to promote physical activity and a low-fat diet among women. Several adaptations to these existing interventions were deemed

necessary. First, financially disadvantaged African American women experience unique barriers to lifestyle change that needed to be more fully addressed. These barriers include unsafe physical environments which impede walking [27–31], lack of physical activity opportunities and resources [27,30–33], food insecurity and limited availability of low-cost healthy food options [34–38], transportation difficulties [27,39], family responsibilities and social role constraints [27,31,40–42], and cultural beliefs regarding food, physical activity, and a healthy body weight [39,41,43,44]. The health educators who delivered the comprehensive intervention had previous experience with underserved populations and received additional training to be sensitive in identifying and addressing these barriers on calls. Print materials also emphasized ways to overcome these barriers, provided resources for free or low-cost programs and facilities, and included recipes with low cost ingredients and foods common in the diet of Southern African American women. Second, print intervention materials had to be at the appropriate reading level for this underserved population. Thus, all print materials (existing or newly developed) were written at less than an eighth grade reading level [45]. Third, a best practice in interventions with ethnic minorities is to design intervention materials that are tailored to the population, at both a surface and deep level [46]. Thus, intervention materials depicted photos of African American women and content was pilot-tested to address the perceived needs and barriers of the populations [47]. We included components commonly used in interventions in African American communities including the use of “real life stories” (i.e., testimonials) of other program participants. Fourth, our intervention extended previous existing interventions based on recommendations made in several literature reviews [12,18]. For example, primary care providers, nurses, community resources, and health educators were involved in intervention delivery. The intervention was delivered in a routine clinical appointment to enhance generalizability of the approach, and thus had to be simple and relatively efficient. Finally, the population and setting (community health centers) necessitated unique methods that were tested in this study. For example, conducting home visits and requiring no additional travel for intervention delivery were viewed as important for accessing and engaging the population through this setting.

Intervention strategies were grounded in the Transtheoretical Model [48] and Social Cognitive Theory [49]. According to the Transtheoretical Model, individuals make behavioral changes in a series of stages, and movement from one stage to the next is related to cognitive and behavioral processes of change, decisional balance, and self-efficacy. This model considers a person’s readiness for change, allowing intervention strategies to be matched to both cognitive readiness for change and current behavior. This model is appealing for primary care settings, as it is patient-centered and does not use a “one-size-fits-all” or prescriptive approach [12].

In Social Cognitive Theory, key behavior change strategies include self-regulation (self-monitoring, goal setting, problem-solving, and self-reward), enhancing self-efficacy through small gradual changes, seeking social support, and building behavioral competence. The constructs in both models were targeted in the interventions in order to promote long-term lifestyle changes in physical activity and diet.

Intervention Overview—Components of the intervention are shown in Figure 1. HHER research staff notified the clinic of the patient’s study participation and her stage of readiness for change for both physical activity and diet (based on the baseline assessment) via weekly faxes. All participants received the standard care intervention that included stage-based behavioral counseling from their primary care provider, nurse-assisted goal setting, a community resource guide of free or low cost programs and facilities, and ethnically tailored educational materials during their appointment. Comprehensive intervention participants, in addition to receiving the standard care intervention, also received 12 stage-matched and ethnically tailored newsletters, an in-depth introductory telephone call, and up to 14 brief telephone counseling calls from HHER research staff over a 12-month period. All contacts

were designed to be relatively brief and low-cost to enhance generalizability to routine clinical care. Telephone counseling was chosen over in-person meetings because it is more flexible, avoids transportation problems common in this population, and has been shown to be effective in a variety of populations [50].

Standard Care Intervention—All women enrolled in the HHER Lifestyle trial received the standard care intervention prior to randomization. Primary care providers were trained to give brief (two-to-four minute) stage-matched counseling for both physical activity and dietary fat intake during the patient's scheduled medical appointment. Nurses were trained to engage participants in brief (5-to-10 minute) stage-matched goal-setting and provide them a community resource guide and ethnically tailored educational materials related to physical activity and diet.

Provider and Nurse Training—Primary care providers were given a CD-ROM that provided training for the HHER Lifestyle program, a supplemental training manual, and a pocket-sized, laminated counseling tool. The training was approved by the Continuing Medical Education Organization at the University of South Carolina School of Medicine for 7.5 continuing medical education credits (primary care providers). It was also approved by the South Carolina Area Health Education Consortium for 7.2 continuing education units (nurses). The CD-ROM, which was self-paced to accommodate health care provider schedules, contained five modules. Module 1 included educational information about the benefits of physical activity and a low-fat diet and current recommendations for both [51,52]. It also highlighted ethnic disparities in health and barriers to lifestyle change. Module 2 emphasized clinical guidance and recommendations for lifestyle counseling and provided training in using patient-centered counseling and goal-setting based on the participant's stage of readiness for change. Because intervention strategies are similar for pre-contemplation and contemplation and action and maintenance, providers and nurses were trained to view participants in one of three stages: Stage 1 (not ready for change), Stage 2 (beginning to change), or Stage 3 (making changes). Collapsing stages also made the intervention easier to remember and deliver. Module 3 focused on the logistics for how to deliver the standard care intervention in clinics. Module 4 contained three videos demonstrating stage-matched, patient-centered provider counseling for pseudo-patients in different stages of change. Module 5 provided a video demonstrating nurse goal-setting and two text-based scripts of goal-setting sessions. At the completion of training, primary care providers completed post-tests (10 items each for Modules 1 to 3) and a training evaluation.

HHER research staff provided each clinic with color-coded folders (based on stage of change) for the nurse liaison to select for participants. The folders contained a stage-appropriate diet goal sheet, a walking goal sheet, a local physical activity and dietary community resource guide, two ethnically-tailored educational materials (walking and low fat) [47], and information about reading food labels and the DASH diet [53,54]. Primary care providers and nurses also received a pocket-sized, laminated trifold counseling tool, that contained information about the study steps, a counseling flow chart, information for easily assessing stage of change (one for physical activity and one for dietary fat), and suggestions for counseling topics for each stage of change (e.g., social support, overcoming barriers, setting goals).

Comprehensive Intervention—After participants attended their primary care visit where the standard care intervention was delivered, participants who were randomized to the comprehensive intervention group subsequently received 12 months of telephone-based counseling and monthly, tailored, stage-matched and ethnically relevant newsletters provided by a health educator employed by the project. The telephone counseling was modeled after Stanford University's Active Choices program, a manualized behavior change program designed to increase moderate intensity physical activity. Active Choices has been shown

efficacious in increasing physical activity in randomized clinical trials [55–58] and more diverse settings and populations [59]. The Active Choices intervention includes an in-person counseling session followed by brief regular telephone counseling (every other week for the first two months and monthly thereafter). For the HHER Lifestyle trial, it was adapted in two major ways: the initial counseling session was delivered by telephone (as opposed to in-person), and nutrition counseling was integrated so that the telephone calls and tip sheets targeted both physical activity and a low-fat diet. Tip sheets were modified to be less than an eighth grade reading level, physical activity tip sheets were added based on the needs and barriers of the population, and nutrition tip sheets were created (e.g., “Eating on a Budget.”). Thus, the HHER comprehensive intervention consisted of one in-depth overview counseling phone call followed by 14 brief counseling calls (the first four calls delivered every other week, the rest delivered monthly). Comprehensive intervention participants were mailed an intervention notebook with materials to reference in the telephone calls, a pedometer with instructions and a photograph regarding proper device placement, a serving size reference card for major food groups, and monthly calendars to track physical activity and dietary goals and progress.

The introductory telephone call was designed to last approximately 60 minutes. The purpose of this call was to outline major study goals relative to physical activity and diet, establish rapport with the study participant, provide education about physical activity and diet and current recommendations, help participants set short- and long-term physical activity and low-fat dietary goals (based on history, preferences, and current behaviors and behavioral readiness), review tips for exercising safely and preventing injury (including recognizing warning signs and symptoms), provide stretching tips, instruct participants in using the pedometer and calendar, and schedule follow-up telephone calls.

The subsequent 14 counseling calls were designed to last approximately 20 minutes each. The first portion of these calls assessed current physical activity and dietary practices relative to the last call’s goals, stage of readiness for change for each behavior, and injuries or illnesses since the last call. The health educator then selected stage-appropriate topics for discussion based on topics and barriers raised by the participants and/or past call history. As is recommended in Active Choices, topic-specific tip sheets were mailed to participants after the call if the health educator deemed the sheets useful. Call duration and topics discussed were recorded in an Access database.

After each telephone call (or after scheduled calls if the participant could not be reached), participants were sent a newsletter that was tailored to their stage of readiness for change based on stage during the most recent telephone call. The four-page color newsletter contained the following sections: HHER Lifestyle Program updates, health hotline (each month addressed a different disease such as hypertension and stroke that was related to physical inactivity and poor diet and was prevalent among African American women), real-life story (testimonial that highlighted a HHER participant), walking corner, physical activity interactive learning, nutrition interactive learning, nutrition notes, nutrition tips, and a tasty “heart smart” recipe of the month. The walking corner, nutrition notes, and the interactive learning sections were stage-matched, and all content in remaining sections were the same for all women. The newsletters were designed to be ethnically relevant by portraying African American women, highlighting foods and recipes more common among African Americans women in the south (e.g., corn bread, sweet potato casserole, spicy mixed greens, oven fried chicken) using inexpensive ingredients, and including barriers and benefits commonly cited by African American women. For example, barriers included identifying safe environments to be active, choosing in-season and low-cost healthy ingredients, and overcoming barriers raised by family members to eating healthy. Benefits included the importance of social support from family, friends, and church members, the importance of community and being a role-model to children and others in one’s

family and community, and reducing one's risk of health conditions prevalent in the African American community.

Outcomes

Based on our previous experience [20,21], transportation is a significant barrier to participation in research studies in low-income populations. Thus, we conducted assessments in participant homes to minimize participant burden. Participants were evaluated at baseline, six months, and 12 months. The purpose of the baseline assessment was to gather information on the participant's medical history (including blood pressure) to determine if the participant remained eligible for the study, obtain informed consent and assess primary outcomes.

At each assessment, HHER research staff obtained physical measurements (blood pressure, weight, waist circumference, and capillary blood), and conducted interviewer-administered instruments. Participants were given an Actigraph accelerometer and physical activity log and instruction on their use. They were asked to wear the monitor for one week and return it and the log by mail in a postage paid envelope provided.

A description of primary outcome, secondary outcomes, and potential mediating variable measures and citations for validity and reliability are presented in Table 1. Participants received a \$20 incentive after completion of each assessment. Initially we provided the entire incentive as a lump sum at the end of the baseline assessment at the participant's home. Because return of accelerometers proved difficult and no-show rates at scheduled medical appointments were high, we modified the incentive structure such that women received \$10 after completing each home visit and received an additional \$10 upon HHER research staff receipt of the accelerometer. At baseline participants received an additional \$10 for attending the scheduled medical appointment.

Primary Outcomes—The primary outcomes for this study were minutes/week of moderate to vigorous physical activity and self-reported dietary fat. Physical activity as measured by accelerometers was our a priori primary outcome; however, collecting accelerometers in this sample proved very challenging. Many women did not wear the accelerometer and we had a sizeable number of women who did not return them. Thus, before study enrollment ended and within the first four months of conducting the six month assessments, we replaced this outcome with moderate to vigorous intensity physical activity as measured by the measured by the Community Health Assessment Physical Activity Survey (CHAMPS) [60]. We continued to collect accelerometer data, however, over the course of the study. Diet was assessed with the New Leaf Dietary Risk Assessment (DRA), which is an indicator of the extent to which diets are low/high in saturated fat and cholesterol [61].

Secondary Outcomes—The secondary outcomes for this study were body mass index, central adiposity as measured by waist circumference, and total cholesterol.

Mediating Variables—Consistent with our theoretical models, we hypothesized that changes in physical activity and diet would be mediated by self-efficacy for overcoming barriers to physical activity [62,63] and diet [64], social support for physical activity and diet [65], and decisional balance (balance of the pros and cons of change) for physical activity [66] and diet [20]. Although it would have been ideal to measure all constructs included in Social Cognitive Theory [49] and the Transtheoretical Model [48], this was not feasible given the setting, sample, and participant burden. Thus, we selected those constructs shown to be most consistently associated with physical activity and dietary behavior.

Process Evaluation

Process evaluation assessed implementation fidelity (goal setting, provider counseling, and intervention counseling) and intervention dose (the number of intervention counseling sessions received). The process evaluation also was designed to gather information to provide feedback to the investigators on the effectiveness of training. The process evaluation assessed factors that determine whether the intervention was delivered and received as intended. If primary outcomes are not achieved, process evaluation data will provide information on the extent to which the intervention was implemented as intended, whether the target group actually participated in the intervention, and whether there were other similar programmatic efforts occurring in the environment that dampened the intervention effects.

Primary care providers and nurses were asked to audio-record all HHER-related counseling and goal setting. HHER health educators also audio-recorded all introductory and follow-up counseling calls. Four forms were used to evaluate participant encounters with providers, nurses, and health educators (separate forms for the introductory session and for phone counseling). Process evaluator(s), trained on procedures and use of the forms, conducted the process evaluation. The evaluator made judgments regarding whether activities were covered, partially covered, not covered, or not applicable as indicated on the specific forms. Evaluator judgments were based upon whether the provider/nurse/health educator covered all aspects of the activity (covered), covered some aspects (partially covered), or omitted or failed to mention aspects (not covered). In the event there were items that did not pertain to the situation, NA (not applicable) was used.

Sample Size and Power Calculations

Effect size estimates and standard deviations for the proposed study were based on the Southeastern Cholesterol Project (for the Dietary Risk Assessment) [67] and the Assessment of Moderate Intensity Activity in Minority Women: Cross-Cultural Activity Participation Study (CAPS) [68]. In CAPS, accelerometer data indicated that African American women engaged in 10.3 ± 10.7 minutes/day of moderate to vigorous physical activity. In the Southeastern Cholesterol Project [67] total DRA scores for African American women ranged from 21.9 ± 1.1 to 23.1 ± 1.1 . We planned for a Type I error rate of 0.05 and 80% power to detect differences between groups across time. With a sample size of 125 participants per group, we had 80% power to detect differences corresponding to 0.18 standard deviations or 2.52 min/day MVPA and 0.11 units on the DRA between treatment groups across time. Similarly, this sample size has 80% power to detect change corresponding to 0.25 standard deviations or 3.59 min/day and 0.15 units on the DRA from baseline to follow-up in a single group. Therefore, we powered the study to detect small differences in the primary dependent variables between groups and across time based on standards set by Cohen and Cohen [69]. Assuming comparable attrition rates of 20% for each group, we inflated our recruitment goal to 156 participants per group for a recruitment goal of 312.

Statistical Analysis

The primary outcomes of interest are MVPA (min/wk) and DRA-score at midpoint (6 months) and end of study (12 months). Typical patterns for behavioral intervention effects are curvilinear (i.e., strong short term effects that attenuate over time). Therefore we felt that it was important to assess outcomes at a midpoint. Thus, the primary hypotheses are that women assigned to the comprehensive intervention group will have higher levels of physical activity (hours per week of moderate intensity physical activity) and lower dietary fat consumption (as indicated by scores on the Dietary Risk Assessment). The hypotheses will be tested by comparing the difference in treatment effect at six- and 12-months using mixed linear models. Independent variables will include intervention group, baseline level, and selected prognostic factors including age, education, income, employment status, and BMI measured at baseline).

Differences in primary outcome measures between the two groups, adjusted for baseline scores, will be used to assess treatment differences from baseline to follow-up. Interactions between treatment condition and time also will be conducted to determine if the intervention effect differs significantly over time, reflecting, for example, possible decay or improvement in counseling skills. Model assumptions will be assessed using standard residuals-based diagnostic procedures, and normalizing or variance-stabilizing transformations will be made as appropriate.

Similar analytic methods involving mixed model ANCOVA will be used for testing treatment-group differences with respect to the secondary outcome measures, including weight loss, cholesterol, and intervention mediators.

MacKinnon's [70] approach to assessing mediation will be used to test for the indirect effects of each hypothesized mediator. The mediator models involve conducting two regression models. The first model will regress change in the hypothesized mediator on intervention group (α coefficient path). The second model will regress change in the outcome variable (physical activity or diet) on intervention group and change in the hypothesized mediator (β coefficient path). To assess the magnitude of the effect for each potential mediator, asymmetric confidence limits based on the distribution of the product will be constructed using the PRODCLIN program [71]. This method considers the non-normal distribution of the mediated effect by constructing upper and lower confidence limits based on the distribution of the product of two normal random variables [70,72]. This approach has been shown to be more powerful than other analytic approaches in simulation studies [72].

Results

Participant Recruitment

Figure 2 shows the flow of participants through the recruitment phase of the study. A total of 1,623 recruitment letters were mailed to obtain the final sample of 266 participants (16% yield). Only 34% of those targeted could be contacted by phone prior to their scheduled medical appointment. The most common reasons for not contacting patients were time and non-working phone numbers. Approximately two-thirds of these patients could not be reached because they did not answer their phone or did not return messages, within the two week period required to complete baseline assessment prior to the scheduled medical appointment. The other one-third had wrong or disconnected telephone numbers. Among the 553 that were contacted by phone, most completed the telephone screening (86%). Baseline assessments were conducted with 350 patients and 266 of these (76%) ultimately enrolled and were randomized. The most common reasons for not enrolling were not attending their scheduled clinic visit and not obtaining provider clearance to participate.

Participant Characteristics

Demographic and health-related baseline characteristics of the study sample are presented in Table 2. Standard care and comprehensive intervention participants differed only on one measure: standard care participants had significantly higher waist circumference measures than comprehensive intervention participants. Most participants were aged 35 to 64 years, with only a small percentage aged 65 years or older. Close to one-third were married, with a larger percentage divorced or separated. The sample was roughly split between those with a high school education or less and those who attended at least some college. Most participants had incomes less than \$30,000, consistent with the focus of community health centers, and just over half of participants were employed. Hypertension was the most commonly diagnosed chronic disease, followed by diabetes and high cholesterol. The vast majority of participants were overweight or obese. The average blood pressure readings were in the pre-hypertension

range and the average waist circumference measurement was in the substantial risk category. Average cholesterol readings were in the desirable range.

Table 3 presents the baseline values for the primary outcomes. Standard care and comprehensive intervention participants did not differ on these measures. Participants scored slightly lower (i.e., indicating a lower fat, lower cholesterol diet) as compared to a clinic-based study conducted with low-income women in North Carolina [67,73].

Discussion

Ethnic and racial disparities in CVD and other diseases are marked [1,74]. Cardiovascular-related morbidity and mortality among African American women pose serious challenges to the health of our society. While physical activity and dietary change are critical for reducing CVD risk, health behavior change is difficult. Interventions that can be incorporated into settings that have broad reach, such as primary care settings, are appealing. Interventions that are moderately effective but reach large numbers have greater potential to improve health than highly effective interventions that reach small numbers [75–78].

The HHER Lifestyle trial will address important gaps in our understanding of interventions to promote physical activity and dietary change in primary care settings. There are a number of unique aspects of this trial. First, it targets a high-risk, underserved population of financially disadvantaged African American women seeking care at community health centers. Financially disadvantaged African American women, with few exceptions [67,79–82], have not been the target of clinic-based physical activity and dietary interventions even though they experience disproportionate health burdens. Of the studies that have targeted underserved women, only one focused exclusively on African American women and it was limited to those with Type 2 diabetes [80], only one incorporated clinician counseling into a routine visit [82], and two were not randomized designs [79,82]. Furthermore, primary care providers delivered a component of the intervention in only two of the studies [67,82], and while two of the studies included community health centers as sites [67,80,82], two were done exclusively in public health departments [79,81], and none were conducted exclusively in community health centers. Thus, our study uses a unique approach to test a lifestyle intervention in an understudied population and setting. Community health care centers provide an excellent opportunity to reach this population to test interventions that promote the adoption and maintenance of dietary and physical activity behaviors. Indeed, we were successful in reaching our intended population of financially disadvantaged African American women with high risk for adverse CVD outcomes.

Second, the standard care intervention is incorporated into a routine clinical appointment, a practice that has been recommended for increasing the generalizability of primary care interventions [12,18,83]. The standard care intervention was designed to be brief and easy to implement, thus likely feasible within the constraints of real world practice. Furthermore, training primary care providers and nurses via a self-paced CD-ROM and providing continuing education credit proved to be an efficient and practical training modality. We trained these health care providers in the use of behavioral strategies and in patient-centered counseling that took into account the patient's readiness for change, a practice recommended by the American College of Preventive Medicine [12]. We also used a multidisciplinary model in which primary care providers deliver brief lifestyle counseling and then other health professionals and community resources are incorporated to augment this counseling. This approach has been recommended to lessen time burdens for primary care providers [84] and help link individuals with community resources [85,86]. By examining the added impact of telephone counseling rather than in-person sessions, we believe the comprehensive intervention is more

generalizable and is consistent with recommendations to test the effectiveness of telephone counseling for physical activity and diet in more representative populations and settings [50].

Third, primary care providers, nurses, and health educators were asked to audio record their HHER Lifestyle encounters. This aspect of the trial will allow us to better understand the quality, content, and duration of the intervention, something that is rarely addressed in primary care interventions. By using a standard care intervention as opposed to a usual care intervention, we will be able to determine whether brief provider counseling combined with nurse goal setting results in behavior change as well as the impact of additional, more intensive telephone counseling.

Finally, we are using well-validated primary and secondary outcome measures and are also including measures to assess mediation. Relatively few lifestyle intervention studies in general assess mediation [87], and far fewer exist in the primary care literature [88,89].

There are limitations in the research design that should be noted. First and foremost is the reliance on a self-report measure for the physical activity primary outcome. Although we had planned to use objectively measured physical activity (accelerometers) as one of the primary study outcomes, we had difficulty getting participants to comply with the instructions for wearing them and the return rate was less than desired. Constraints in the recruitment timeline that centered on a scheduled clinic visits limited our ability to ask participants to re-wear accelerometers prior to their scheduled medical appointment in instances where wear time was inadequate. In addition, given the high cost of accelerometers we decided not to re-issue monitors to participants that had previously lost one. Thus given the potential for large amounts of missing data, we decided to use a well-validated self-report measure, which was intended to be a secondary outcome, as our primary outcome. Although we acknowledge that the potential for bias in self-report, we have minimized this limitation by selecting a measure that has strong psychometric properties, is sensitive to detecting change in intervention studies and has been used with ethnically diverse samples [57,59,60,90,91]. HHER participants reported an average of around 3.5 hours per week of moderate to vigorous intensity physical activity on the CHAMPS, a value that is only somewhat higher than other studies recruiting underactive older adults [59]. Because the CHAMPS uses ranges to estimate physical activity (e.g., “less than 1 hour per week” is coded as 0.5 hours per week), the estimates should not be interpreted as precise values. Instead, changes over time will be more important to consider.

Although the potential for multiplicity exists given that the HHER Trial has two primary outcomes measured repeatedly over time in two study conditions, we have been careful to pre-specify the analytic approach. To guard against type III error, we will utilize repeated measures analysis of variance to takes advantage of all of the longitudinal data collected simultaneously. This approach is robust when missing data exist.

In summary, despite recommendations from professional and national organizations [8–12, 92], primary care providers deliver physical activity and dietary counseling in routine clinical encounters at suboptimal levels [14–17]. A sizeable number of studies have examined the efficacy of behavioral interventions in primary care settings, yet few address external validity [18]. Our study provides an important opportunity to evaluate the effectiveness of culturally appropriate, theory-based, health-care-center-based physical activity and dietary counseling for CVD risk reduction in financially disadvantaged African American women.

Acknowledgments

The project described was supported by Award Number R01HL073001 from the National Heart, Lung, And Blood Institute. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Heart, Lung, And Blood Institute or the National Institutes of Health. We are especially grateful to all

of the women who participated in this study. We also thank the providers and nurses at the Eau Claire Cooperative Health Center and Family Health Center, Inc. for their participation as well as their time and feedback regarding the study protocols. We acknowledge the substantial contributions of staff who have participated in HHER Lifestyle Program: Tiffany N. Barker, Alisa Brewer, Shamika Brown, Tina Devlin, Elizabeth Fallon, Elizabeth Fore, Monetha Gaskin, Desiree Hammond, Genova McFadden, Edena Meetze, Keri Norris, Jennifer Salinas, Lisa Wigfall.

This study was funded by the National Heart Lung and Blood Institute (HL073001).

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Figure 1.
Intervention Flow chart

Figure 2.
Recruitment Flow Chart

Table 1

Description of Primary and Secondary Outcome Measures and Hypothesized Mediators

Variable	Description	Measure/Definition	Full range	References
<i>Primary Outcomes</i>				
Community Healthy Activities Model Program for Seniors (CHAMPS) Physical Activity Questionnaire ^a	Interviewer administered, self-report measure includes activities typically undertaken in the course of the day that are physical in nature, and recreational activities that provide physical activity. The frequency of activity is assessed in times per week, and duration is classified using six categories ranging from “less than 1 hr/wk” to “9 or more hrs/wk.”	Hours per week in moderate- and vigorous-intensity physical activities (MVPA)	0–28	Stewart, 2001[60]Harada, 2001[93]
		Hours per week in light-, moderate-, and vigorous-intensity physical activities (Total Physical Activity)	0–51	Stewart, 2001[60]Harada, 2001[93]
New Leaf Dietary Risk Assessment (DRA)	Interviewer administered, 52 item frequency questionnaire to assess dietary fat and cholesterol. Each item is scored from 0–2, a lower score indicating a more healthful dietary pattern (lower saturated fat and cholesterol). Scores from all questions are summed for a total DRA score.	Weekly consumption frequency for meats; side dishes/snacks; dairy/eggs; spreads/dressing/oils and total.	Meats: 0–32 Side Dishes: 0–24 Spreads: 0–24 ^b Dairy: 0–24 Total DRA: 0–104	Ammerman, 1991[61]
<i>Secondary Outcomes</i>				
Body Mass Index (BMI)	Weight was measured (to the nearest 0.1 kg) using a SECA brand scale with the participant in light clothing	weight (kg)/height(m ²)	Normal: 18.5–24.9 Overweight: 25–29.9 Obese: ≥30	Poirier, 2006[94]

Variable	Description	Measure/Definition	Full range	References
	and no shoes. For purposes of calculating body mass index, height (measured to the nearest 0.1 cm) was measured using a stadiometer at baseline only.			
Central Adiposity	Measured with the participant standing using a tape measure. Waist circumference was measured twice; if the value is different by more than 0.25 in then the measure was repeated and the mean of the two closest values was used.	inches	Normal risk: < 34 Increased risk: 31–34 Substantial Risk: ≥35	Grundy, 2005[95]
Total Cholesterol	Cholesterol esters present in serum (non-fasting) were ascertained by fingerstick using Boehringer Mannheim (Roche Diagnostics)/ Hitachi 911 Analyzer.	mg/dL	Desirable: < 200 Borderline: 200–239 High: ≥ 240	NCEP Expert Panel, 2001[96]
<i>Mediators</i>				
Barriers-based Self Efficacy for Exercise	14-item, interviewer-administered instrument of perceived confidence to engage in physical activity when barriers are present. Responses range from 0%=not at all confident, 100%=absolutely confident.	Higher score indicates higher degree of confidence	0–100	Garcia, 1991[62]
Self-Efficacy for Low-fat Diet	8-item, interviewer-administered instrument assesses self-efficacy for	Higher score indicates higher degree of confidence	NegAffect: 0.99–3.96 Pos Affect: 0.88–3.52 Availability: 0.97–3.84	Chang, 2003[64]

Variable	Description	Measure/Definition	Full range	References
	eating a low-fat diet in three domains: positive affect, negative affect and availability. Responses range from 1= Not at all confident to 4=Very confident. Scores are weighted sums			
Social Support for Physical Activity	15-item, self-administered survey of perceived social support from both family and friends for exercise/PA. Responses range from 1=None, 5=Very often.	Higher scores on each indicate greater social support	15–75	Sallis, 1987[65]
Social Support for Low-fat Diet	19-item, self-administered survey of perceived social support from both family and friends for eating low fat foods. Responses range from 1=None, 5=Very often.	Higher scores on each indicate greater social support	19–95	Sallis 1987[65]
Decisional Balance for Physical Activity	13 item, self-administered survey of perceived benefits (pros) and perceived barriers (cons) of regular exercise/physical activity. Responses range from 1=Not important, 5=Extremely important. Scores are standardized.	A <i>positive</i> decisional balance indicates the pros outweigh the cons (std pros – std cons)	7–36 pros 6–30 cons	Marcus, 1992[66]
Decisional Balance for Low-fat Diet	8 item, self administered survey, adapted from Marcus (1992), of perceived	A <i>positive</i> decisional balance indicates the pros outweigh the cons (std pros - std cons)	4–20 pros 4–20 cons	Parra-Medina, 2002[20]

Variable	Description	Measure/Definition	Full range	References
	benefits (pros) and perceived barriers (cons) of eating low fat diet. Responses range from 1=Not important, 5=Extremely important. Scores are standardized.			

^aMVPA and total physical activity were highly positively skewed at pretest and somewhat skewed at posttest. A square root transformation successfully normalized these variables.

^bThe original DRA spreads score is the sum of 12 items (range 0–24). Due to instrumentation error 2 items from the spreads score were dropped and replaced with the participant mean for the remaining items in order to keep with the original Total DRA range 0–104 and spread range 0–24.

Table 2

Baseline Characteristics of HHER Study Participants

Characteristic	Comprehensive n ^a (%)	Standard Care n ^a (%)	<i>p</i> ^b
N=266	136 (51.2)	130(48.8)	
<i>Demographic</i>			
Age			
35–49	63 (47.0)	64 (49.6)	0.39
50–64	59 (44.0)	48 (37.2)	
65+	12 (9.0)	17 (13.2)	
Marital Status			
Married/Living together	43 (31.9)	43 (33.1)	0.58
Divorced/Separated	50 (37.0)	56 (43.1)	
Not married	15 (11.1)	12 (9.2)	
Widowed	27 (20.0)	19 (14.6)	
Education			
Less than 12	26 (19.4)	25 (19.4)	0.21
12 Years	49 (36.6)	37 (28.7)	
Some college or degree	54 (40.3)	55 (42.6)	
Some graduate or degree	5 (3.7)	12 (9.3)	
Income			
Missing	20 (14.7)	13 (10.0)	0.32
\$0–9,999	29 (25.0)	20 (17.1)	
\$10,000–19,999	29 (25.0)	35 (29.9)	
\$20,000–29,999	22 (19.0)	29 (24.8)	
\$30,000+	36 (26.5)	33 (25.4)	
Employment status			
Unemployed	25 (18.5)	25 (18.2)	0.91
Employed (FT/PT)	78 (57.8)	71 (54.6)	
Disabled (P/T)	15 (11.1)	18 (13.9)	
Retired	17 (12.6)	16 (12.3)	
<i>CVD risk factors</i>			
Smoking Status			
Current Smoker	29 (21.9)	20 (15.9)	0.23
Quit	15 (11.4)	22 (17.5)	
Never Smoked	88 (66.6)	84(66.6)	
Physician Diagnosed Hypertension	78 (58.2)	84 (64.6)	0.29
Physician Diagnosed Diabetes	113 (36.3)	102 (33.1)	0.27
Physician Diagnosed High Cholesterol	49 (36.3)	43 (33.1)	0.58
Body Mass Index			
Normal, 18.5–24.9 kg/m ²	16 (12.4)	13 (10.6)	0.08
Overweight, 25–29.9 kg/m ²	31 (24.0)	17 (13.8)	

Characteristic	Comprehensive n ^a (%)	Standard Care n ^a (%)	<i>p</i> ^b
Obese, ≥ 30 kg/m ²	82 (63.6)	93 (75.6)	
Systolic blood pressure, mean $\pm$ s.d.	132.9 $\pm$ 21.5	135.3 $\pm$ 23.9	0.42
Diastolic blood pressure, mean $\pm$ s.d.	76.4 $\pm$ 10.6	78.5 $\pm$ 10.9	0.13
Total Cholesterol, mean $\pm$ s.d.	127.1 $\pm$ 56.5	121.8 $\pm$ 56.1	0.54
Waist Circumference, mean $\pm$ s.d.	39.8 $\pm$ 6.6	42.7 $\pm$ 9.6	0.01

^a n's may vary due to missing data

^b Differences in proportions evaluated using χ^2 (two-tailed) and means using t-test.

Table 3

Values for Primary Outcomes by Treatment Group at Baseline for the HHER sample

	Comprehensive mean $\pm$ sd	Standard Care mean $\pm$ sd	P
<i>Dietary Risk Assessment Scores</i>			
Meat score	11.35 $\pm$ 3.99	10.79 $\pm$ 3.69	0.24
Side Dish score	9.56 $\pm$ 2.95	10.25 $\pm$ 3.29	0.08
Dairy score	5.01 $\pm$ 2.84	5.04 $\pm$ 2.81	0.91
Spreads score	6.08 $\pm$ 3.28	6.04 $\pm$ 2.91	0.89
Total DRA score	32.01 $\pm$ 9.06	32.11 $\pm$ 8.51	0.93
<i>CHAMPS Physical Activity Score</i>			
MVPA, hours/week	3.5 $\pm$ 4.8	3.9 $\pm$ 4.3	0.46
Total, hours/week	10.3 $\pm$ 7.7	10.8 $\pm$ 8.0	0.65