Contemporary Clinical Trials 47 (2016) 340–348

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

Rationale, design, and baseline findings from HIPP: A randomized controlled trial testing a home-based, individually-tailored physical activity print intervention for African American women in the Deep South

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ARTICLE INFO

Article history:
Received 21 December 2015
Received in revised form 22 February 2016
Accepted 28 February 2016
Available online 2 March 2016

Keywords:
Physical activity
Health disparities
Home-based interventions
African American women

ABSTRACT

African American women report high rates of physical inactivity and related health disparities. In our previous formative research, we conducted a series of qualitative assessments to examine physical activity barriers and intervention preferences among African American women in the Deep South. These data were used to inform a 12-month Home-based, Individually-tailored Physical activity Print (HIPP) intervention, which is currently being evaluated against a wellness contact control condition among 84 post-menopausal African American women residing in the metropolitan area of Birmingham, Alabama. This paper reports the rationale, design and baseline findings of the HIPP trial. The accrued participants had an average age of 57 (SD = 4.7), a BMI of 32.1 kg/m^2 (SD = 5.16) with more than half (55%) having a college education and an annual household income under $50,000 (53.6%). At baseline, participants reported an average of 41.5 min/week (SD = 49.7) of moderate intensity physical activity, and 94.1% were in the contemplation or preparation stages of readiness for physical activity. While social support for exercise from friends and family was low, baseline levels of self-efficacy, cognitive and behavioral processes of change, decisional balance, outcome expectations, and enjoyment appeared promising. Baseline data indicated high rates of obesity and low levels of physical activity, providing strong evidence of need for intervention. Moreover, scores on psychosocial measures suggested that such efforts may be well received. This line of research in technology-based approaches for promoting physical activity in African American women in the Deep South has great potential to address health disparities and impact public health.

1. Introduction

To date, African Americans have the highest death rate and shortest survival of any racial/ethnic group in the U.S. for most cancers [1]. Among women, existing racial disparities are largely due to breast and colon cancers. According to the American Cancer Society (ACS), African American women have mortality rates that are 44% higher for colorectal cancer and 39% higher for breast cancer than White women [1]. Disparities such as these necessitate intervention, and sedentary lifestyle is one of the few modifiable risk factors for breast and colon cancer [1]. Numerous observational studies indicate that regular moderate-to-vigorous physical activity can reduce the risk of developing colon cancer by 25–40% [2–7] and breast cancer by 20–80% [8–11] in adults. Larger risk reductions (average 41%) were observed in three studies focused on African American women [9,11]. While the exact mechanisms have yet to be determined, physical activity may influence breast and colon cancer risk indirectly by promoting weight control or directly by altering biologic pathways related to breast and/or colon cancer (e.g., concentrations of insulin, adipocytokines, sex steroid hormones; gene expression) [3,4,10,12].

Due to its cancer-protective effects, at least 30 min of moderate-to-vigorous physical activity on 5 or more days of the week is recommended by the ACS [13]. Despite these recommendations, most Americans remain sedentary [14] with national survey data indicating particularly low levels of regular leisure-time physical activity in African American women (19.8%) [1]. As sedentary behavior may contribute to existing cancer disparities, interventions aiming to increase physical activity among African American women are needed. Past efforts to promote physical activity in

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http://dx.doi.org/10.1016/j.cct.2016.02.009
1551-7144/

general (and as a strategy for reducing cancer risk) among African American women have typically involved center- or clinic-based programs [15–17], which have limited reach and may be difficult for many individuals to attend. Home-based interventions minimize many barriers to interventions commonly cited by African American women (e.g., childcare and monetary costs) [18].

Our research team has developed and tested a computer expert system [19–22] that individually tailors self-help print materials based on constructs from the Social Cognitive Theory [23] and Transtheoretical Model [24]. This program can be mail-delivered and now specifically addresses the physical activity intervention needs and preferences of African American women, as identified by our formative research (11 focus groups with the target population in rural and urban counties across Alabama). [25] A one-month demonstration trial (N = 10 African American women recruited in Birmingham, AL) was previously conducted to vet the resulting theory-based individually-tailored physical activity intervention. Results showed participant satisfaction and increased motivational readiness for physical activity in 70% of the participants, as well as 90% retention. Moreover, there was almost a doubling of moderate-to-vigorous physical activity from baseline (M = 89.5 min/week, SD = 61.17) to 1 month (M = 155 min/week, SD = 100.86; p = .056) [25]. Building on these promising findings, the current study will test the Home-based Individually tailored Physical activity Print (HIPP) intervention for African American women in the Birmingham, AL metropolitan area against a wellness contact control condition. The purpose of the current paper is to describe the rationale, design, and baseline findings of this study.

2. Methods

2.1. Design

The HIPP study is an ongoing randomized controlled trial (N = 84) of a 12-month computer-tailored physical activity intervention for cancer risk reduction compared to a wellness contact control condition among African American women. Addressing key areas derived from Bowen and colleagues' framework for feasibility studies [26] (see Table 1), we hypothesize that participant satisfaction questionnaire/interview data, recruitment, retention, and adherence will demonstrate the acceptability and demand for the HIPP intervention among African American women. As for limited efficacy testing, we expect increases in physical activity from baseline to six months (7-Day Physical Activity recall interviews, accelerometers) will be greater in the intervention arm as compared to the control arm. Moreover, we anticipate that arm differences at 6 months will be sustained at 12 months.

Secondary aims include exploring differences between groups on changes in functional exercise capacity (6 min walk test), body mass index (BMI), waist circumference, and percent body fat (estimated by bioelectrical impedance); associations between changes in physical activity and changes in these variables; and potential moderators (e.g., education) and mediators (Social Cognitive Theory and Transtheoretical Model constructs directly targeted by the physical activity intervention) that are associated with intervention efficacy. Blood draws at baseline, six months, and 12 months will allow for hormone assays (e.g, insulin, leptin, free estradiol, and other circulating biomarkers implicated in cancer pathways) and exploratory studies of gene expression.

2.2. Setting and sample

The study is being conducted at the Clinical Research Unit at the University of Alabama at Birmingham (UAB) Center for Clinical and Translational Science. Human subjects approval was obtained from the UAB Institutional Review Board and the trial is registered with ClinicalTrials.gov (NCT02574689). Participants are women between the ages of 50–69 from the Birmingham, AL metropolitan area who self-identified as African American and/or Black. Post-menopausal women were recruited for the current study to avoid problems associated with timing of the menstrual cycle when measuring hormones and because there is more evidence for an inverse association between physical activity and breast cancer risk in postmenopausal women

Table 1
Key areas of focus for feasibility studies and how they were addressed in the current study.

Key area[a]	Definition	Outcomes of interest	Assessed in this study?
Acceptability	Is a new program suitable, satisfying, or attractive to participants?	Satisfaction, intent to continue use, perceived appropriateness	Yes. By participant satisfaction surveys, exit interviews, recruitment
Demand	Is a new program likely to be used?	Actual use, expressed interest or intention to use, perceived demand	Yes. By participant satisfaction surveys, exit interviews, adherence, retention
Implementation	Can a new program be successfully delivered to intended participants in some defined, but not fully controlled, context?	Degree of execution, success or failure of execution	No. This study was conducted in a rather controlled context. Please see discussion for future directions.
Practicality	Can a program be carried out with intended participants using existing means, resources, and circumstances and without outside intervention?	Amount/type of resources needed to implement; factors affecting ease or difficulty of implementation; efficiency, speed, or quality of implementation; positive/negative effects on target participants; ability of participants to carry out intervention activities; cost analysis	Somewhat. We will be able to comment on positive/negative effects on participants (improved physical activity). Future directions include cost analyses, which have already been conducted on similar programs in different populations and support practicality [69]. See discussion for future directions.
Adaption	To what extent does an existing program perform when changes are made for a new format or with a different population?	Degree to which similar outcomes are obtained in new format, process outcomes comparison between intervention use in two populations	Somewhat. We will be able to compare findings with our participants to past studies using similar interventions in different populations.
Integration	To what extent can a new program be integrated within an existing system?	Perceived fit with infrastructure, perceived sustainability	No. Program was implemented by research staff in current study. Please see discussion for future directions.
Expansion	To what extent can a previously tested program, process, approach, or system be expanded to provide a new program or service?	Costs to organization and policy bodies, fit with organizational goals and culture, positive or negative effects on organization, disruption due to expansion component	No. Please see discussion for future directions.
Limited efficacy	Does the new program show promise of being successful with the intended population, even in a highly controlled setting?	Intended effects of program or process on key intermediate variables, effect-size estimation, maintenance of changes from initial change	Yes. We will examine group differences in changes in physical activity from baseline to 6 and 12 months. Data will be used to estimate effect sizes for future power analyses.

[a] Adapted from Bowen and colleagues [26].