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Community-based participatory research to design a faith-enhanced diabetes prevention program: The Better Me Within randomized trial

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ABSTRACT

Reducing obesity positively impacts diabetes and cardiovascular risk; however, evidence-based lifestyle programs, such as the diabetes prevention program (DPP), show reduced effectiveness in African American (AA) women. In addition to an attenuated response to lifestyle programs, AA women also demonstrate high rates of obesity, diabetes, and cardiovascular disease. To address these disparities, enhancements to evidence-based lifestyle programs for AA women need to be developed and evaluated with culturally relevant and rigorous study designs. This study describes a community-based participatory research (CBPR) approach to design a novel faith-enhancement to the DPP for AA women. A long-standing CBPR partnership designed the faith-enhancement from focus group data (N = 64 AA adults) integrating five components: a brief pastor led sermon, memory verse, in class or take-home faith activity, promises to remember, and scripture and prayer integrated into participant curriculum and facilitator materials. The faith components were specifically linked to weekly DPP learning objectives to strategically emphasize behavioral skills with religious principles. Using a CBPR approach, the Better Me Within trial was able to enroll 12 churches, screen 333 AA women, and randomize 221 (M_{age} = 48.8 ± 11.2; M_{BMI} = 36.7 ± 8.4; 52% technical or high school) after collection of objective eligibility measures. A prospective, randomized, nested by church, design will be used to evaluate the faith-enhanced DPP as compared to a standard DPP on weight, diabetes and cardiovascular risk, over a 16-week intervention and 10-month follow up. This study will provide essential data to guide enhancements to evidence-based lifestyle programs for AA women who are at high risk for chronic disease.

1. Background

Reducing obesity is strongly associated with reductions in diabetes and cardiovascular risk [1]. Modest weight loss in the diabetes prevention program (DPP) trial was associated with a 58% reduction in diabetes risk [2]; however, the DPP has shown reduced effectiveness in African American (AA) populations [3,4] that also experience higher rates of obesity [5], diabetes [6], and hypertension [7,8] compared to Caucasians. Faith based organizations (FBO), such as churches, have been extensively involved in the delivery of health programs in AA communities. Programs have been implemented through faith-placed, secular programs held at an FBO, and faith-based, which integrates faith-based activities such as scripture into health programming [9]. A large review of FBO weight loss studies in AA found that faith-placed programs resulted in greater weight loss than faith-based programs that integrated faith elements, indicating that additional research is needed to identify best practices [9]. Further, a review of DPP program translations for AA found reduced effectiveness; approximately half of the expected weight loss from the original study [3]. Taken together, more research is needed to develop effective enhancements to health programs for AA [9,10].

One approach that may improve the effectiveness of health programs for AA is community-based participatory research (CBPR). CBPR works to build an equitable partnership between the community, and research team, with a long-term commitment to develop the relationship through co-learning leading to mutual trust and respect [11]. In the context of CBPR, community members and leaders work together on all aspects of the research study leading to quality research, community

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empowerment, and sustainable programs with lower rates of attrition and synergy over time [12,13].

Psychosocial and physiological factors can also influence the effectiveness of health programs. For example, allostatic load, a composite of several biological measures representing dysregulation due to prolonged exposure to stress, has been shown to increase the "wear and tear" on the body [14], with data showing allostatic load is higher in AA as compared to White females [14,15]. Further, the influence of sex hormones such as estradiol on stress responses is not fully understood and could alter responses to intervention [16–18]. The reduced effectiveness of diabetes prevention programs in AA may be multifactorial requiring a systems approach to implementation and evaluation.

The Better Me Within (BMW) trial aims to address the lack of effectiveness of diabetes prevention programs in AA females by integrating a CBPR approach to design and implement a randomized trial of a faith-enhanced diabetes prevention program in the FBO setting. The design allows for comparison of faith-based as compared to faith-placed approaches along with mediators and moderators of outcomes. This paper describes study development, methodology, recruitment, and baseline demographics of the study sample.

2. Methods

2.1. Study aims

The primary aim of the BMW trial is to evaluate the impact of a CBPR developed faith-enhanced diabetes prevention program (e.g., faith-based) as compared to a standard diabetes prevention program (e.g., faith-placed) on weight in AA overweight females at 16-weeks post-intervention, and at 10-month follow-up. Secondary aims include evaluating changes in diabetes risk (hemoglobin A1c and fasting glucose), cardiovascular disease risk (blood pressure, LDL and HDL cholesterol), and health behaviors (physical activity and diet) at 16-weeks between the faith-enhanced DPP and standard DPP conditions, and how psychosocial factors such as self-efficacy and spiritual health locus of control, and physiological factors such as cortisol and estrogen, influence changes in primary and secondary outcomes.

2.2. Study development

The CBPR partnership that guided the development and implementation of the BMW trial had been in existence for approximately 10 years. The partnership included researchers, individuals trained in public health, and a Community Advisory Board (CAB) of several pastors and first ladies from the Southern Sector of Dallas, TX. Based on the findings of a large NIH funded study (GoodNEWS trial) to improve cardiovascular risk guided by this CBPR partnership [19,20], it was determined that weight management was the next community health priority to address. Formative work was conducted through focus groups to evaluate AA women's needs, preferences, and barriers to weight management, along with preferences and opinions of church leaders including pastors, first ladies, and pastor associates.

Seven focus groups with 64 AA adults including 53 female congregation members (mean age = 44.0 (SD = 11.3) years; 95% African American) from six congregations, and 7 pastors and 4 first ladies (mean age = 56.3 (SD = 13.6) years; 100% African American) were conducted in the Southern Sector of Dallas, TX, an urban, low-income, primarily ethnic minority community. The purpose of the focus groups was to determine the perspectives of church leaders and church members on the relationship between faith and health, as well as, weight loss and maintaining a healthy lifestyle, to guide the development of a faith-enhanced lifestyle program. Gathering input directly from community members, in addition to community leaders, has been shown to improve the outcomes of behavioral interventions [10]. Using directed content analysis [21] to group participant statements, the following broad categories were identified: 1) Connections between faith beliefs and health, 2) Attitudes, values and motivations for weight management, 3) Hurdles to healthy weight, and 4) Elements for successful weight loss. Specific strategies from these themes included 1) focus on diabetes and chronic disease prevention, 2) address food habits and motivation, 3) pastor involvement in the program was critical but needed to be realistic from a time perspective, and 4) emphasize connections between faith and health. These findings were presented to the CAB and used to develop the faith-enhanced weight management program for the Better Me Within trial.

2.3. Study design

The BMW trial is a prospective randomized community-based, nested design. Churches were randomized to either a standard diabetes prevention program (faith-placed) or a faith-enhanced diabetes prevention program (faith-based) over 3 years, starting in January of 2014, and completing in December of 2016. Each year, 4 churches were recruited and randomized to treatment condition, for a total of 12 churches. Small churches were paired during the randomization process within each cohort to ensure one received the standard DPP, and the other the faith-enhanced DPP, as church size can influence study implementation. A limitation of this approach is church size was only accounted for at the cohort level. Baseline data collection was completed in July of 2016. The Institutional Review Board at The University of North Texas Health Science Center approved the study. Informed consent was collected from each study participant prior to enrollment.

2.4. Church recruitment

The CBPR partnership recruited churches from October of 2013 to February of 2016. Church inclusion criteria included 1) church size $>$ 100 members, 2) primarily African American parishioners, 3) willingness of pastor or senior leadership to be involved in program delivery, 4) church member willing to serve as a facilitator (e.g., health coach), and 5) space to conduct weekly group meetings. Pastors and first ladies from the CAB led initial recruitment efforts by contacting churches within their social and professional networks. Once a church demonstrated interest, the project director and CAB partner would meet with church leadership to provide an overview of the program. During this meeting the purpose of the BMW trial was described as well as the roles and responsibilities of the church and study program. A commitment by the pastor reserved a spot in the study. The pastor then selected a woman or women from the congregation to serve as the health coach (es), and coach training was scheduled. This was repeated each year until a total of 12 churches were enrolled in the study.

2.5. Participant recruitment

Pastors and health coaches received flyers and program factsheets to distribute at church events and to interested church members. Participants were pre-screened by telephone or at face-to-face events by study staff, and were then invited to a baseline measurement event at their corresponding church. Informed consent was collected at baseline measurement events along with objective measures of eligibility (e.g., weight, height, hemoglobin A1c). Participant eligibility requirements included 1) identify as AA, 2) female, 3) 18 years of age or older, 4) parishioner at enrolled church, 5) overweight or obese (BMI $\geq$ 25), and 6) willingness to participate in a 10-month study. Exclusion criteria included 1) currently attending a weight loss program, 2) diagnosed diabetes, 3) medical condition that interfered with physical activity or dietary changes, and 4) plans to move in the next 10 months. Individuals who were not eligible to participate were invited to attend the sessions if room was available to meet the preferences of the CBPR partnership.