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The WORD (Wholeness, Oneness, Righteousness, Deliverance): design of a randomized controlled trial testing the effectiveness of an evidence-based weight loss and maintenance intervention translated for a faith-based, rural, African American population using a community-based participatory approach



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ABSTRACT

Background: The positive effects of weight loss on obesity-related risk factors diminish unless weight loss is maintained. Yet little work has focused on the translation of evidence-based weight loss interventions with the aim of sustaining weight loss in underserved populations. Using a community-based participatory approach (CBPR) that engages the strong faith-based social infrastructure characteristic of rural African American communities is a promising way to sustain weight loss in African Americans, who bear a disproportionate burden of the obesity epidemic. Objectives: Led by a collaborative community—academic partnership, The WORD aims to change dietary and physical activity behaviors to produce and maintain weight loss in rural, African American adults of faith.

Design: The WORD is a randomized controlled trial with 450 participants nested within 30 churches. All churches will receive a 16-session core weight loss intervention. Half of the churches will be randomized to receive an additional 12-session maintenance component.

Methods: The WORD is a cultural adaptation of the Diabetes Prevention Program, whereby small groups will be led by trained church members. Participants will be assessed at baseline, 6, 12, and 18 months. A detailed cost-effectiveness and process evaluation will be included.

Summary: The WORD aims to sustain weight loss in rural African Americans. The utilization of a CBPR approach and the engagement of the faith-based social infrastructure of African American communities will maximize the intervention's sustainability. Unique aspects of this trial include the focus on weight loss maintenance and the use of a faith-based CBPR approach in translating evidence-based obesity interventions.

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1. Introduction

Obesity is a significant public health problem that disproportionately affects underserved groups. Within the U.S., African Americans [1] and southern rural residents [2] bear

* Corresponding author. Tel.: +1 501 526 6720. E-mail address: khk@uams.edu (K.H.K. Yeary). some of the highest burdens of the obesity epidemic. Weight loss improves obesity-related risk factors, and weight loss interventions have shown improvements in these outcomes. However, the positive effects of weight loss interventions diminish unless weight loss is maintained, suggesting an important role of maintenance. Several multi-center efficacy trials of lifestyle modification for obesity have reported sustained weight loss for diverse groups [3,4]. However, little

work has translated evidence-based weight loss and maintenance interventions to regular settings, such as the community [5]. To effectively address obesity disparities, evidence-based weight loss and maintenance interventions translated for rural African American groups in the community are needed.

Given their geographic and social placement in African American communities, African American churches are excellent venues for the delivery of community-based, obesity treatment interventions [6]. Churches provide ease of access not available from programs located in medical or other less central and ubiquitous settings. The church's ability to bring some people together on a regular basis can also encourage consistent and continual attendance to a weight loss maintenance intervention [7,8]. In addition, the strong social networks within Black churches and between African American churches and their communities [6,9] provide a rich social context, which is important in weight maintenance [10]. Embedding an obesity treatment intervention in this rich social context may be sufficient to sustain weight loss, without the addition of a weight maintenance intervention component. Engaging the religious and spiritual beliefs in the African American culture may also enhance long-term motivation for weight control [11,12].

Numerous studies have successfully used African American churches as intervention sites to change obesity-related health behaviors, [13–17] but few have specifically tested obesity control programs. The faith-based weight loss studies reported in the literature have shown promising results, [18–22] but are few in number and have been conducted without long-term follow-up. To date, there have been no evidence-based, rigorously designed, community-based obesity control programs with a maintenance component for rural African American groups [11].

A community-based participatory research (CBPR) approach builds on the complementary strengths and insights of community and academic partners to facilitate the development of interventions that are relevant for underrepresented groups [23] and to maximize the effects of research addressing health disparities. The WORD (wholeness, oneness, righteousness, deliverance) is a faith-based weight loss and maintenance effectiveness trial for rural African American adults that uses a CBPR approach. To date, there have been no obesity interventions with the aim of sustaining weight loss in African American communities of faith. The WORD also contributes to the paucity of studies examining the effectiveness of evidence-based lifestyle obesity interventions in practice [5] by translating the Diabetes Prevention Program, DPP [24], which has shown sustained weight loss in diverse groups [3,4]. Further, to the authors' knowledge, few DPP-based randomized clinical trials (or effectiveness trials) have been conducted using a CBPR approach. This paper describes the study development, purpose, and methods. Currently The WORD is in the beginning of the recruitment process, so the subsequent description will reflect the study's current timeframe.

2. Methods

The WORD is funded by the National Institute of Minority Health and Health Disparities, National Institutes of Health, through the Arkansas Center for Health Disparities. The study is approved by the University of Arkansas for Medical Sciences (UAMS) Institutional Review Board and registered in clinicaltrials.gov (NCT02169947).

2.1. Setting and population

The WORD will recruit 30 African American churches in the Arkansas portion of the Lower Mississippi Delta. The Lower Mississippi Delta is a predominately rural region bordering the Mississippi River in Arkansas, Louisiana, and Mississippi [25]. The region has a high prevalence of poverty, with 16–22% of households having incomes below the federal poverty level [26]. The residents of the Arkansas Delta are primarily African American and Caucasian [25]. It is well established that rates of chronic disease are higher in the Delta than in the rest of the nation, [27] with Delta counties having higher rates of obesity compared to non-Delta counties [28]. Compared to non-Delta Arkansas counties (66.6%), Arkansas Delta counties have an obesity rate of 69.8% [29], which is slightly higher than the national average (69.0%) [30].

2.2. Community-based participatory partnership

The study builds on a nearly 10-year partnership between K.Y. and the Faith Task Force, a group of community leaders who strive to connect faith and health to improve the health of congregations. Instituted in 2005 and led by J.T., the Faith Task Force represents over 30 diverse faith-based organizations, state organizations, and community organizations in the Arkansas Delta. The Faith Task Force has collaborated with the University of Arkansas for Medical Science researchers in the areas of obesity, racism and birth-outcomes, cardiovascular health, and cancer prevention. The WORD study was built upon a county-wide health assessment of African American churches in the Delta that identified obesity as an issue of community interest, and on two previously conducted pilot studies that assessed culturally appropriate weight loss strategies for underserved African American church-going populations [31,32]. Consistent with CBPR principles [23], identification of weight loss as a priority community issue, development of the intervention, study design, and proposed evaluation and dissemination plans were conducted collaboratively between community and academic partners. The study also includes a community subcontract whereby J.T. serves as the principal investigator (community PI). The application of the nine core CBPR principles delineated by Israel et al. [33] in The WORD is outlined in Table 1.

2.3. Study aims

The primary aim of the study is to assess the effectiveness of a weight loss + maintenance intervention compared to a weight loss only intervention, with the primary outcome of weight loss maintenance and the secondary outcomes of physical activity and dietary intake (i.e. fruit, vegetable, fat, and fiber intake). Both groups will receive a 16-session weight loss intervention program. The weight loss + maintenance group will receive an additional 12-sessions directed at weight maintenance. Successful weight loss maintenance is defined as maintaining weight loss for a minimum of one year [34]. The weight loss + maintenance intervention is hypothesized to result in less weight regained compared to the weight loss only intervention at 12 and 18 month follow-up (6 and 12 months after the 16-session weight loss intervention program). The secondary aim of the study is to conduct a comprehensive

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