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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

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include the focus on weight loss maintenance and the use of a faith-based CBPR approach in translating evidence-based obesity interventions.

Keywords

Randomized clinical trial; Community-based participatory research; obesity; rural; African American; faith-based; weight loss

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 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.

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).

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].

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.

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 process evaluation and assess the cost-effectiveness of the maintenance component in terms of potential life years and quality adjusted life years gained. Information on cost-effectiveness has the potential to translate evidence on comparative effectiveness into practice as it will provide useful information to future researchers and practitioners wishing to replicate the program in similar populations.

Theoretical Framework, Study Design, and Randomization

The project's overall conceptual framework, is based on Social Cognitive Theory (SCT);[35] and social support and network models [36], all of which focus on the dynamic interaction between individuals, their environment, and their behavior. Aspects of behavioral weight loss methods address the physical environment (e.g. stimulus control for weight loss) as well as increasing social support for behavior change. The project further builds on the social environmental components (peers, friends, family) of SCT, and the engagement of social relationships through a lay health advisor model for weight loss and maintenance. Engaging and building upon current social networks through the training of those indigenous to the community is hypothesized to lend to greater cultural sensitivity in intervention delivery, facilitate changes in community or peer-group norms, and promote sustained weight loss. Likewise, utilizing lay health advisors will target several components of SCT, including the trained community member serving as a model for observational learning and the ability of lay health advisors to convey greater salience for behavior change to influence outcome expectations.

To assess the effect of the Weight Loss + Maintenance intervention on weight loss maintenance, a randomized controlled design is being used with the church as the unit of randomization and individuals nested within church. The Weight Loss Only intervention will serve as the control arm. Each church (n=30) will enroll 15 African American adults for a total of 450 participants across the study churches (with 450 participants nested within 30 churches). Recruitment and randomization will be conducted on a rolling basis in four waves, whereby 6 churches will be enrolled in wave 1, and 8 churches enrolled in each of the subsequent three waves. Anthropometrics and self-reported health behaviors and

psychosocial variables will be assessed in all participants (including control) at baseline, 6, 12, and 18-months.

Church and WORD Leader (lay leader) Selection, Recruitment, and Retention

The Community PI and his staff are engaging their extensive faith-based networks across the Arkansas Delta to meet with pastors and make formal presentations about the study. In the presentations, interested pastors are asked to recommend potential lay leaders (WORD Leaders) from their congregations to lead the intervention sessions after completing the required study training. Qualifications for WORD Leaders include ability to travel and an interest in promoting health within a faith-based context. Congregation members interested in being WORD Leaders are then given a formal presentation about roles and expectations by the Community PI and his staff. Pastors and WORD Leaders who agree to participate in the study are asked to sign church and WORD Leader agreements, respectively, that provide a framework for roles and expectations for all parties.

To ensure retention in the study, the Community PI will maintain regular contact with the churches to offer any support needed for enrolled churches. The WORD Leaders will serve as the primary contact for enrolled churches and the Community PI or his staff will be in contact with WORD Leaders on at least a biweekly basis. At least one member of the research team will also talk to WORD Leaders by phone after each intervention session, whereby WORD Leaders will be given the opportunity to express any support the church may need. Churches will be given incentives for supporting participant recruitment (\$100 for meeting recruiting goals) and data collection (\$100 for each assessment point). WORD Leaders' alternate contact information (e.g., addresses, phone numbers of individuals who may be contacted in the event that participants change residences or phone numbers) will be collected to be used in follow-up of WORD Leaders. WORD Leaders will also be given incentives (\$100 per session) for delivering intervention sessions.

Participant Selection, Recruitment, and Retention

The WORD Leaders will be primarily responsible for advertising the study to potential participants using flyers, church bulletins, announcements from the pulpit, and word of mouth. All recruitment materials were co-created by the community and academic investigators on the research team. WORD Leaders will invite those who are interested in the study to a group orientation, where the Community PI and his staff will provide a study overview and administer a screening instrument. The self-administered screening instrument will ask participants a series of yes/no questions to determine initial eligibility, including whether they are African American, generally healthy, taking insulin, had a stroke in the past 6 months, and other questions related to study eligibility. The self screener also includes the Physical Activity Readiness Questionnaire (PAR-Q) to assess a participant's readiness for physical activity. Potential participants will also be asked for their name and contact information if they are interested in participating in the study. For interested participants who are eligible per the self screener, academic staff will then administer a detailed screening interview by phone where potential participants will be asked to report demographic information, weight, whether they are currently participating in a weight loss program, whether they have any health conditions or disabilities that keep them from

walking for exercise, medications they are currently taking, and other questions related to study eligibility. Potential participants who are still eligible after the detailed phone screening interview will be scheduled for a baseline assessment visit, where actual weight and height will be obtained by a trained study staff member to confirm weight eligibility. Participant data will be collected at the church associated with each participant's intervention group. Informed consent and weight and height data will be collected individually in a private area. The baseline assessment survey will be self-administered in a group setting in the church. Given that the unit of randomization is the church, control and intervention arms will be kept separate from one another at all data collection points.

A goal of 15 participants per church will be recruited (to ensure an adequate sample size) to form each intervention group. If fewer than 15 participants are recruited by a church due to small membership or other factors, smaller churches will be combined to obtain an adequately-sized intervention group, more than 15 participants will be recruited in churches that are able to over-recruit, and additional churches will be recruited as necessary.

To ensure retention in the study (intervention session attendance and data collection), participants' alternate contact information will be collected to be used in follow-up of enrolled participants. WORD Leaders will also be trained to build supportive relationships with participants and encourage intervention session attendance and data collection visit attendance. Incentives will be given to participants at data collection visits (\$25 at 6 months, \$30 at 12 months, \$50 at 18 months). Participating churches will also be given incentives to support participant attendance at data collection visits.

Participant Inclusion and Exclusion Criteria

African American adults (aged 18 and older) who are overweight [Body Mass Index (BMI) $> 25 \text{ kg/m}^2$] will be eligible for the study if they are free of medical problems for which participation in a weight loss program with an exercise component might require medical supervision; have not had a heart attack or stroke in the past 6 months; are not currently on medication that might affect weight loss or require medical monitoring (insulin); are not pregnant, lactating, or pregnant in the last 6 months; are not enrolled in another weight loss program, have never had weight loss surgery and have not lost more than 10% body weight in the previous 6 months; and do not have a clinically significant medical condition or any condition that makes it unlikely for them to be available for 18 months. Participants will also agree to complete the program assigned to them. Further, only one participant per household will be allowed to enroll in the study; each participant will have the option to bring one additional household member with them to intervention group sessions. The additional household member will need to meet eligibility criteria and sign a confidentiality agreement, but will not be allowed to enroll in the study.

Intervention

The DPP[24] was adapted using information from two previous pilots K.Y. conducted with rural African American communities of faith[31, 32], whereby community partners collaborated with academic partners to design culturally appropriate weight loss curricula. The WORD shares the same components of the DPP (e.g. keeping track books, instructional

curriculum, etc.) but differs from the DPP in *how* the intervention components are delivered, the *content* of the intervention components, and the *process* through which the intervention content was adapted. Regarding intervention component delivery, The WORD differs from the DPP by: 1) delivering the intervention in a church setting; 2) using a small group format; 3) and training community members to deliver the intervention. Regarding the content, The WORD differs from the DPP by integrating spiritual beliefs and components of Social Cognitive Theory and Social Support and Networks Theory throughout the curriculum. For instance, self-efficacy is addressed in the intervention by emphasizing how strength to achieve study goals can be drawn from God. This message will be reinforced through asking participants to self-monitor time engaged in their faith. Each session includes opening prayer, a Bible study that connects faith beliefs with health, and a closing prayer that petitions God for help to achieve specific study goals. Participants will also be paired to be each other's prayer partners to support each other throughout the time between intervention sessions. Given the importance of the spiritual messages in adapting the DPP, detailed information about the spiritual messages incorporated into each session is included in Table 2. The process through which The WORD was adapted in intervention delivery and content was done using a CBPR approach that included community and academic investigators, which ensured a product that was salient to the target population. Specific project decisions that arose from the CPBR process are delineated in Table 1.

Group meetings will be held weekly for 1.5 to 2 hours for 16 sessions and will be conducted in participating churches. Typically with holidays and inclement weather, the 16 sessions are anticipated to be conducted over an approximate 6-month time frame. Sessions will be led by WORD Leaders and begin with a private weigh-in and a recap of the previous session, with the exception of the first session, which gives an overview of the intervention. There is then a 40-minute behavioral module focused on making dietary and physical activity changes through drawing on strength from one's faith, followed by a Bible study that connects faith and health, and on-site physical activity. An interactive approach rather than a didactic lecture format will be used, emphasizing group discussion. Details on the WORD Group Intervention Sessions, associated learning and behavioral objectives, and spiritual messages are delineated in Table 2. The on-site physical activity will consist of walking for 30 minutes. Each church will be given a walking DVD and WORD Leaders will lead their group. Communication from WORD Leaders will motivate attendance. In addition to the weekly sessions, WORD Leaders and group participants are anticipated to interact with each other through church functions as both the WORD Leaders and group participants will be associated with the participating church hosting the intervention. WORD Leaders will also be instructed to contact participants who miss a session to encourage making up the information covered from the session, in addition to continued group attendance.

Participants in the Weight Loss + Maintenance condition will meet monthly for 12 months after the conclusion of the Weight Loss Only intervention for the maintenance component of the program. Maintenance sessions will be approximately 1 hour per session and encourage participants to continue practicing strategies associated with weight maintenance (e.g. self-monitoring, stimulus control, goal setting and problem solving, relapse prevention) in the context of connecting faith with health. Participants will be encouraged to develop a level of

mastery in practicing weight control strategies such that they will be able to be more independent in their weight control efforts. The on-site 30 minutes of physical activity will also be continued in the same manner conducted in the Weight Loss Only intervention. Details on the maintenance sessions are delineated in Table 2.

WORD Leader Training—A training-of-trainers model that incorporates didactic education, experiential learning, trainee practice, and written and verbal feedback will be used to train WORD Leaders to facilitate the intervention. Study staff (aka “Master Trainers”) with Masters degrees in Public Health and experience in training community members in behavioral weight loss interventions will be training WORD Leaders for the trial. The training builds knowledge about obesity and health, obesity-related health behaviors (i.e. healthy nutrition, physical activity), behavioral change for weight loss based on the study protocol through experiential learning, and the connection between faith and health. The training builds skills in group facilitation, leadership, communication, and behavior change promotion. Training of WORD Leaders will consist of initial training prior to group implementation, followed by booster trainings that continue and overlap with four months of group implementation. The initial training prior to group implementation consists of 28 hours of total training time spread across 6 weeks. After completion of the initial training, WORD Leaders will be given a certification exam to become certified WORD Leaders for the project. The latter portion of the training in the form of booster sessions will overlap with intervention implementation to provide ongoing support for WORD Leaders and provide them with group implementation experience while still in training so that questions and issues that arise as a result of their group-leading experiences can be addressed in subsequent training sessions. WORD Leaders will also complete Human Subjects certification with the support of the Community PI and his staff.

Certified WORD Leaders will be considered study employees under the community subcontract and given stipends for leading WORD groups. They will be under the direct supervision of the research team. The research team will offer ongoing support and feedback to the WORD Leaders, clarifying content and implementation strategies, and monitoring the intervention so it is delivered according to protocol. Conference phone calls will occur between WORD Leaders and at least one member of the research team after each intervention session is delivered. The Master Trainers will also observe WORD Leaders delivering intervention sessions to provide feedback and ensure intervention fidelity. Master Trainers will observe WORD Leaders once before the third session is delivered using an observation checklist, that will assess coverage of session content, clarity of delivery, engaging delivery, delivery within time constraints, answering participant questions, facilitating participant interactions, what went well, and what could be improved upon. If corrective feedback is necessary, Master Trainers will observe WORD Leaders on multiple occasions as needed.

Measures

Study staff will call participants to schedule data collection visits at baseline, 6 months, 12 months, and 18 months. Study staff will work with WORD Leaders and participating churches to schedule data collection visits through attempting to schedule data collection

before or after already scheduled group meetings. WORD Leaders will encourage attendance to data collection visits. Data will be collected at the church where the participant's intervention group will meet. Actual weight and height data will be collected individually in a private area. The survey will be self-administered in a group setting in the church.

Unless specified below, all measures will be assessed at baseline, 6, 12, and 18 months:

Sociodemographic factors will be assessed by self-report at baseline only and will include gender, age, education, marital status, and household size.

Percent change in weight from baseline at 12 and 18 months is the primary endpoint. Participants will be measured in light clothing to the nearest 0.5 lb (0.2 kg) using a calibrated digital scale. Height (without shoes) will be measured to the nearest 0.5 cm using a stadiometer at baseline only. Weight and height will be used to compute a continuous measure of BMI (kg/m^2).[37]

Health behaviors are secondary endpoints. Dietary intake will be assessed with the 2011 BRFSS fruit and vegetable consumption measure[38] that was adapted for self-administration and the Fat- and Fiber-related Diet Behavior Questionnaire[39]. Physical activity will be assessed using an adapted version of the Paffenbarger Physical Activity Questionnaire (PAQ) that has been validated in African American communities of faith[40].

Psychosocial variables are hypothesized as mediating or moderating variables. Scales by Sallis and colleagues[41] that assess social support for diet and physical activity change will be used. Self-efficacy for health behaviors will be assessed through scales from Sallis and colleagues[42]. Religiosity will be assessed through items and scales that measure denomination, religious attendance, private religious practices[43], daily spiritual experiences [44], spiritual coping[45], perceived sacredness of the body[46], congregation support[47], spiritual locus of control[48], and the extent to which congregation members hear weight-related messages from the pulpit[49].

Other variables will include sweetened beverage intake[38, 50] and the social context module from the 2011 BRFSS, which was adapted for a self-administered format[38]. To assess the potential cost effectiveness of the intervention, the investigators will use the SF12 Health Instrument that can be converted into an SF6D score. The SF6D score is a preference-weighted health outcome that can be used to measure QALYs gained from the intervention. Use of the metric cost per QALY gained allows comparison across disparate interventions to determine their cost-effectiveness in relation to a pre-specified threshold such as the common \$50,000 per QALY.

Evaluation

Cost-Effectiveness Evaluation—A cost-effectiveness evaluation will be conducted following the guidelines from the US panel on cost-effectiveness in health and medicine. [51] The cost-effectiveness evaluation will have two primary objectives: a micro-costing model will be developed to estimate the incremental cost of conducting the Weight Loss +

Maintenance intervention relative to Weight Loss Only intervention and an incremental cost-effectiveness evaluation will be conducted based on the cost per life year and QALY gained for the Weight Loss + Maintenance group relative to the Weight Loss Only group. To assess the cost of intervention delivery (taking a health system perspective), all resources provided with the intervention, excluding research costs, will be priced and summed to generate total costs. Total costs will be divided by the number of participants to generate per person estimates. Algorithms for mapping BMI into life years lost according to age and race profiles have been established[52] and used in cost-effectiveness evaluations of weight loss programs.[53, 54] Because life years gained from the intervention occur in future periods, all costs and outcomes will be discounted to present value terms using a 3% discount rate.

The measurement of QALYs in addition to life years gained should provide useful information as rural, African-American populations are understudied with respect to preference-based measures. Further, the few studies that have estimate QALYs gained from a weight loss intervention tend to show small effects. Additional data from at risk populations and with maintenance programs are needed to better understand cost-effectiveness profiles for weight loss interventions[55, 56].

Process Evaluation—Process evaluation associated with health interventions has increased considerably over the past 20 years, in part because of the growing complexity of behavioral interventions, including interventions with multiple components addressing multiple levels of the ecological model, across multiple sites for multiple groups [57]. As church-based interventions become increasingly complex, process evaluation becomes even more crucial in advancing research and practice[58]. Process evaluation can shed light on why some interventions produced the intended results, and why others did not, and provide valuable insights about significant, modest, or null findings[57].

The 7 key components of process evaluation defined by Linnan and Steckler [57] will be included in The WORD's process evaluation to document context, reach, dose given, dose received, fidelity, implementation, and recruitment (Table 3).

Sample Size Calculations—Data from one of the pilots upon which The WORD was built was used to conduct power calculations.[31] With an overall sample of 450, the power ranges from 85-91% to detect the hypothesized difference of 2kg between the group means at 18 months, depending on the attrition rate. In previous research studies conducted by the study team, retention rates have ranged from 80-93% at 18-months; therefore if a similar assumption is made, the study would have 85% power for 20% attrition in order to detect a difference of 2kg between the group means at 18 months when the standard deviation is 5.5kg and the intracluster correlation is 0.02 using a simple linear regression model with a significance level of 0.05. At a 20% attrition rate, there would be 93% power to detect a difference of 2.3kg between the group means at 18 months.

Data from one of the WORD pilots [31] also showed a significant between-group difference in the secondary outcome of physical activity of 5.5 METS (SD=9.25 METS) for the total physical activity and 4.2 METS (SD=7.4 METS) for the moderate physical activity, which are both considered large effects (Cohen[59]). The sample of 15 churches per group with 15

individuals per church achieves 99% power to detect the effect found in the pilot for both total physical activity and moderate physical activity. The sample size achieves 80% power to detect the mean difference as small as 2.9 METS for the total physical activity, and 2.3 METS for the moderate physical activity while holding the assumed standard deviations constant at mentioned levels and using a simple linear regression model with the intracluster correlation of 0.02.

Outcome Analyses—Preliminary analyses will include the generation of descriptive statistics and assessment of treatment group differences at baseline, as well as examination of treatment drop-out and missing data patterns' impact on treatment effects.

The study's primary hypothesis is that randomization of participants to the Weight Loss + Maintenance intervention will produce greater reductions in weight at the 12 and 18 month maintenance stage, compared to participants in the Weight Loss Only group. The predictor variable is assignment to the Weight Loss Only or Weight Loss + Maintenance group and the outcome is percent weight change from baseline to 12 and 18 months. Analyses of our primary outcome variable (percent baseline weight change at 12 and 18 months) will be done in accordance with the intent-to-treat principle. Our primary analytical approach will use an ANCOVA-like linear regression model and mixed model for continuous measures to model the mean outcome levels and covariance structures in the Weight Loss Only and Weight Loss + Maintenance groups. Using these models, treatment effects will be estimated and tested by comparing group-specific means at 12 and 18 months while conservatively adjusting for the baseline differences and weight loss at 6 months.

The study's secondary hypotheses are that randomization of participants to the Weight Loss + Maintenance condition will result in greater energy expenditure from total and moderate physical activity, as well lower dietary fat intake behaviors, higher fiber intake behaviors, and higher fruit and vegetable intake at 12 months and primarily at 18 months. Similar to the analytical approach for the primary outcome, an ANCOVA-like linear regression model and mixed model for continuous measures will be applied, with the treatment group assignment as the main covariate of interest. The simple model is going to be further expanded in order to adjust the main association but also to investigate the relationships between other covariates and secondary outcome measures.

As a virtue of the study design, clustering of participants within the churches is introduced. Mixed linear models will be used to account for correlations within church clusters. Fit by restricted maximum likelihood and implemented in SAS Proc Mixed, this method is powerful and accommodates the complex covariance structures that may arise. This method is also robust to moderate departures from multivariate normality.[59]

Data Dissemination Plan

Dissemination of research findings to the participating faith communities is an essential component of the CBPR approach.[60] In order to continue the inclusive and transparent nature of this research effort, the community and academic investigative team will work together to create and develop a community organizing strategy for providing timely and useful information to the participating faith communities on a rolling basis, which will

include flyers, community forums, and independently organized meetings and information sessions. WORD Leaders at each site will serve as the local contacts. Project results will be disseminated to academic audiences through scientific manuscripts, conferences, and an intervention manual with program materials that would be useful to future practitioners.

Summary

The WORD is the culmination of 9 years of collaborative work between community and academic partners, whereby the community identified the issue of obesity, co-led the pilot studies upon which The WORD was built, and co-created the design of the current large-scale trial. The CBPR approach utilized by the partnership to translate an evidence-based obesity intervention (i.e. DPP) is innovative (to the authors' knowledge, few DPP efficacy trials have been conducted using a CBPR approach) and fills the gap identified by the church-based health intervention literature for collaborative approaches[61]. The CPBR approach also enabled the identification and incorporation of religious and spiritual elements throughout the intervention, which answers the call for spiritual sensitivity when designing church-based interventions[7, 61, 62].

The WORD is also innovative in other ways. To date, there have been no obesity interventions with the aim of sustaining weight loss in African American communities of faith. The proposed study will test the effectiveness of a faith-based weight loss and maintenance intervention for rural African American adults using a community-based participatory approach.

Although several multi-center trials have shown sustained weight loss in diverse groups,[3, 4] there is a paucity of studies examining the effect of these evidence-based interventions in practice.[5] Thus, the effectiveness of an evidence-based lifestyle obesity intervention that has been shown to produce sustained weight loss in diverse groups (DPP[24]) will be assessed through translating the DPP for rural African American communities.

Enlisting social support is one strategy shown to improve weight maintenance; so embedding obesity treatment intervention in a social-support-rich context, such as the church, may be sufficient to sustain weight loss, making the addition of a weight maintenance component unnecessary or less cost-effective. Therefore, The WORD is also innovative in that it will be testing the added benefit of a weight maintenance component on sustained weight loss in an intervention placed in a social support rich context.

The WORD will also explore factors associated with weight maintenance in an underserved population, which will contribute to future approaches to improve the health of groups bearing a disproportionate burden of the health consequences of obesity.

Findings from the proposed study will also contribute to the evidence on the cost-effectiveness of maintenance components for weight loss. Weight loss programs that result in significant weight regain immediately following program close-out are not cost-effective; thus understanding whether weight loss maintenance can improve cost-effectiveness profiles is important.[54]

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Table 1
Application of Community-Based Participatory Research (CBPR) Principles 1 in The WORD

CBPR Principle	Application of CBPR Principles in The WORD
The community is the unit of identity	The African American faith community in the Delta is the unit of identity and is engaged as a partner
The strengths and resources within the community are built upon	The social networks within the faith community and particular cultural beliefs will be engaged and built upon through the training of lay health advisors (WORD Leaders) to deliver the intervention, the incorporation of cultural beliefs in intervention materials, and community investigators leading recruitment efforts
There are collaborative, equitable partnerships in all phases of the research	A community subcontract with a community PI is present to promote equal power sharing; the issue of obesity was initially identified by the community through a prior survey of churches; community investigators meet regularly with academic investigators for all project-related decisions
Co-learning and capacity building is promoted among all partners	Academic partners received formal training in community-based participatory research; community partners received training in research methodology; regular team meetings facilitate co-learning of research principles and community values
The balance between research and action is integrated and achieved	The research question of whether a weight loss maintenance intervention is efficacious is balanced with the action to combat obesity in rural African American faith communities
An ecological model of health and local relevance of public health problems are emphasized	The issue of obesity was identified by the community as a relevant local public health problem in a previous survey of Delta churches
Systems development is involved through a cyclical and iterative process	Both academic and community partners took part in a CBPR workshop to strengthen the partnership; regular team meetings where both community and academic partners participate to make project-related decisions facilitates systems development
Findings and knowledge gained are disseminated to all partners and all partners are involved in the data dissemination process	Cost and outcome data will be disseminated through community forums, community brochures/flyers, scientific manuscripts, and scientific conferences
There is long-term process and commitment	The academic and community PIs have been working together on federally-funded community-based public health research for over 9 years

¹ Israel B, Schultz AJ, Parker EA, Becker AB, Allen AJ, Guzman JR. Critical Issues in Developing and Following Community Based Participatory Research Principles. In: Minkler M, Wallerstein N, editors. Community-Based Participatory Research for Health. San Francisco: Jossey-Bass; 2003, p. 53-76.

Table 2
WORD Group Sessions; Associated Learning and Behavioral Objectives; and Spiritual Messages

Session Number	Session Title	Learning and Behavioral Objectives	Spiritual Messages
1	Welcome to The WORD	To provide an overview of The WORD Intervention, including the program goals and basic information about weight loss. A focus on the role of faith in making healthy changes is emphasized.	Being physically healthy is also a part of keeping the body pure, of being a temple for God's Spirit. Taking care of your physical body by being healthy is a spiritual act of worship.
2	Energy In, Energy Out: Calories	To learn how calories are related to eating and physical activity; and learn how calories are related to a healthy weight	Emphasize helpful, lawful and spiritual things with God. Your body is bought with a price, paid for by Jesus. Therefore glorify God in all that you do including what you eat.
3	Zap the Fat	To learn how to keep track of fat grams, and its usefulness in weight loss. To receive personal fat gram goal, and to practice calculating the fat grams of example foods.	From the beginning God did not want man to eat too much fat or blood. God originally wanted man to eat plants, like fruits and vegetables.
4	Active in God	To provide the WORD activity goal. Discuss the importance of physical activity and how to increase current levels of physical activity. Make an initial activity plan for the next week including 60 minutes of physical activity.	How to deepen one's relationship with God through physical activity.
5	Eat Less Calories	To learn how to weigh and measure foods, and how to record them using the WORD track books. Learn three ways to eat less fat and fewer calories.	How to use our bodies to glorify God with spiritual praise.
6	Healthy Eating	To learn the importance of eating vegetables and fruits, and about how much and what type of vegetables and fruits to eat daily. To learn importance of eating enough fiber and what types of food are high in fiber.	We can glorify God by taking care of our bodies, by eating healthy.
7	Walk with Him	To discuss barriers to physical activity, and learn different ways to find time to be active. To discuss lifestyle activity.	We are called to live in a way that is consistent with how God tell us to treat this body. His word will build spiritual growth, as one grows and learns, a change of lifestyle will take shape.
8	Find the Qs: Cues to Healthy Behavior	To learn about cues for physical activity, eating, and spirituality. How to find cues for physical activity, eating, and spirituality in one's home and day-to-day life. To learn to use cues to promote healthy behaviors.	Our body is God's temple. God wants us to be in good health Physically and Spiritually.
9	Break the Chains: Problem Solving	To learn the five steps of problem solving. To practice the steps using a problem the group member is experiencing now with meeting the program goals.	To know that it is wise to seek God's help to break chains and problem solve by trusting in the Lord and acknowledging Him in all we do.
10	Eating Out	To learn the four keys of eating healthy when eating out. To provide examples and practice the four keys in real-life settings.	To learn that strength to eat healthy comes from Christ
11	Replacing Lies with Truth	To learn about lying thoughts and how to replace them with truthful thoughts. To practice replacing lying thoughts with truthful thoughts.	Believers must put off remaining sinful deeds and instead be continually renewed into the Christ likeness to which they are called. This also means to stop lying to oneself about health or healthy lifestyle.
12	Stopping Slips	To learn about slips and how to get back up after a slip. To learn how to stop slips from happening and make an action plan to correct them.	As Christians, we will fall. We will slip, but God calls us to rise back up again and to try. The difference between the righteous and the wicked are not that the righteous never fall, but that they get back up again.

Session Number	Session Title	Learning and Behavioral Objectives	Spiritual Messages
13	Be HOLY: Remaining Active in God	To discuss how to keep the physical activity plan fun and interesting. To learn about aerobic fitness. To learn how to be HOLY in terms of remaining active in God (how hard are you working when active, how often are you active, how long are you active, saying yes to aerobic activities).	Taking care of your body can be hard work; therefore one must be active Spiritually and Physically. Good physical works cannot produce salvation; however all of our works should be evidences of God-empowerment.
14	Find the Social Qs!	To learn about social cues for physical activity, eating, and spirituality. To find social cues for physical activity, eating, and spirituality in their homes and day-to-day lives. To learn to use social cues to promote healthy behaviors.	We can glorify God by eating healthy and by being healthy. If we don't spend time with God, spiritually we will be dry too. It is important to sow good things into our lives so we can have good fruit later on.
15	Managing Stress	To learn how to prevent and cope with stress so that it does not impact healthy eating and physical activity. To create action plans to manage stress.	When in fear, anxiousness, or dissatisfaction, we must always seek and turn to the peace of God, for Peace. God has the power to transform our minds concerning our health and we must trust in him.
16	Persevering: Maintaining Healthy Changes	To review the changes made while being a part of the WORD program. To learn tips to maintain healthy changes.	If you know that it is right and good to be healthy, but do not do it, it is sin. God wants wholeness for You. He wants the best for You. The best means being healthy.
Maintenance Sessions			
17	Being a New Creation	To learn how to be a new creation in Christ during this changing time. To review how to set weekly goals remembering CHRIST.	God's plan is fully furnished with His power and ability, His grace and wisdom, His blessing and provision.
18	Setting Goals of FAITH	To learn how to set goals of FAITH with God's help. To review the principles for setting helpful goals and then set a specific behavioral goal related to diet or physical activity that they will try to achieve during the next month.	Whatever you do, don't lean on your own understanding-acknowledge God, pray to Him, be willing to listen to Him and He will direct your paths.
19	Yield Not to Temptation at Holidays and Special Events	To learn how to resist temptations to overeat during holidays and special occasions through prayer. To learn how to Plan ahead, Pray ahead and Practice ahead.	Through reflection and prayer God can help us with the challenges of eating healthy and being active during holidays and vacations.
20	Mindful Eating	To identify the ways the body tells us when food is needed. To recognize the difference between hunger, appetite and satiety. To identify ways on how to be more aware of food cues.	The spirit indeed is willing and the flesh is weak; the spirit always wants us to do what is right; the flesh goes beyond the limits of the spirit.
21	You Are How You Eat	To learn about the different types of eaters. To review things that get in the way of healthy eating and being active. To connect negative thoughts to emotions that trigger eating too much and lack of physical movement.	The scripture says examine yourself first, and then partake in your everyday eating. We need to examine ourselves and see what we are eating, see what we are drinking and be careful of what we eat and drink. We need to do some self-examination.
22	Train up Your Muscles	To review the long-term WORD Activity goal. To understand the health benefits of aerobic exercise and strength training. To know how to start a simple strength training program.	Stresses that we need to be in charge of our vessels use strength exercises by the grace of God to build up our muscles and our strength.
23	Social Support for Physical Activity	To explore the importance of social support in each participant's weight loss journey as well as the role social support will play in continued weight maintenance. To identify sources of social support for exercise. To learn to identify and ask for the types of support that would be most helpful.	We are not alone. We have the support of our brothers and sisters in Christ. Prayer is a powerful way to support on another. Pray that your fellow group members meet their physical activity goals, have the motivation to exercise when they don't feel up to it, and pray that they lean on the strength of God when they physically tired and worn.
24	Supermarket Smarts	To learn to identify strategies to make healthy choices at the supermarket. To practice the steps in planning one week of	If we sow bad choices and fall into temptations at the grocery store, our lives will have a greater chance of being full of disease. If we don't

Session Number	Session Title	Learning and Behavioral Objectives	Spiritual Messages
		meals. To learn how to begin the grocery list from the meal plan	spend time with God, spiritually we will be dry too. It is important to sow good things into our lives so we can have good fruit later on.
25	Trusting in God to Make Reduced Energy Density Eating Work for You	To solidify by review, what makes up the Caloric Density of food. To learn how to use food labels to determine caloric density. To identify ways to boost foods with a low caloric density.	Consider what you eat, no matter who you are with and take the time to consider not only what you are eating and but how much you are eating. God will help you regulate your mind to know when you've eaten enough.
26	Count Up the Cost	To discuss the importance of accuracy in keeping track and evaluate ways to increase accuracy. To review the foods guide pyramid and ways to maintain a balanced diet while choosing foods low in caloric density.	We stay on track by looking forward to a more meaningful life in health because of our hope in Christ Jesus
27	Healthy Eating for Life	To learn the importance of eating less fat. To learn about which fats to decrease in your diet and which fats to include in your healthy diet. To review quick tips for how to include fat in a healthy diet.	Whether you eat or drink, or whatever you do, do it all to the glory of God. It is important to remember that our bodies are temples where God lives and we must care for it like God cares for us.
28	Becoming a Weight Maintenance Pro	To learn the strategies of successful weight maintenance as identified through the National Weight Control Registry. To identify how similar their behaviors are to those of Registry members and incorporate weight maintenance strategies used by Registry members into their own maintenance plans.	We must remember that when trying to achieve a healthy weight and become physically active the "race" is not given to the swift or the strongest but to those who endure and lean on the Lord.

Table 3
Process Evaluation for The WORD

Process Evaluation Component	Question Addressed	Measure
Context	What aspects of the church or community-level environment can influence implementation of intervention components?	Church environment checklist
Reach	To what extent do participants attend the intervention sessions?	WORD Leader Log (Attendance) Resource Team Calls
Dose Delivered	To what extent were the intervention components delivered?	WORD Leader Log (Sessions delivered) WORD Group Meeting Notes Resource Team Calls
Dose Received	To what extent are participants engaged in the intervention? To what extent was the intervention received by participants?	WORD Leader Log (Attendance, WORD Track Books completed, weight at each intervention session)
Fidelity	To what extent did the WORD Leaders deliver the intervention according to protocol?	Session Observation Check-List Resource Team Calls WORD Group Meeting Notes
Implementation	To what extent was the intervention implemented by WORD Leaders and received by participants as intended?	WORD Leader Log (Attendance, WORD Track Books completed, weight at each intervention session, sessions delivered) Session Observation Check-List WORD Group Meeting Notes Resource Team Calls
Recruitment	What recruitment strategies were effective at the church and participant levels? What is the recruitment yield at the church and participant levels? How many people need to sign-up and attend orientation to meet recruitment goals?	"How WORD Leaders Recruited group members" form WORD Church and Word Leader Recruitment Log "I'm Interested" Sign-up sheet Orientation Sign-in sheet Orientation Questions asked