Official Title: Developing a Lifestyle Intervention to Reduce Body Weight for Obese African American Men Living in the Rural South

NCT #: NCT05530980

Date: 12/19/2023

Protocol

The primary objective of this study to test the feasibility and acceptability of a theoretically-based 12-week behavioral weight management intervention tailored to Black men living in the rural South. A total of 15 Black men living in Orangeburg County South Carolina or neighboring rural counties will be recruited. Primary outcomes of interest for this single group pretest-posttest feasibility study include the number of Black men who express interest in the study, the number who are eligible/ineligible, the length of time needed to enroll the desired sample size, attendance, and attrition. Change in weight and weight-related behaviors (physical activity and dietary behaviors) will be secondary outcomes and will be measured at baseline and upon completing the intervention. Participants who complete the intervention will be invited to complete a post-intervention focus group interview to provide feedback on the intervention (e.g., motivation for participating, program effectiveness and enjoyment, facilitators and barriers to participation, recommended improvements). This interview may be held virtually or in-person based on participant preferences. The interview will be audio-recorded and transcribed by a professional transcriptionist.

Many participants in the qualitative study that informed the development of the intervention noted that safety and convenience were two important considerations in program planning. In addition, men noted a preference for programs that incorporated physical activity during meeting sessions. Based on these considerations and the status of the COVID-19 pandemic at the time the intervention was developed, publicly available walking track/outdoor areas were deemed to be a feasible and acceptable location for intervention delivery. In the event of inclement weather, meeting sessions will be held at a local YMCA.

The table below shows a general overview for each of the core 12-week sessions. In brief, participants will be taught core principles of weight loss and behavior change. Participants will be provided with Fitbits and will be asked to self-monitor their physical activity throughout the program. In addition, they will be asked to create Fitbit accounts and to support and compete with other men in the program. Participants will also be asked to track their dietary intake using either paper-based tracking forms or a method of their choice (e.g., food tracking app such as MyFitnessPal). A simple kitchen scale will be provided to those needing one to facilitate accurate dietary tracking. Participants will also be highly encouraged to monitor their weight throughout the program using a bathroom scale. A bathroom scale will be provided to those needing one. YMCA memberships will also be offered for the duration of the study or financial support to cover YMCA memberships will be provided to help participants reach physical activity goals.

Sample Meeting Session

Activity	Description	Duration
Welcome & educational session	Content addressed by facilitator; facilitated discussion of content	10 minutes
Progress reports & social support	Participants provide update on weekly progress (e.g., PA, diet, weight)	10 minutes
Warmup walk with socialization	Timed walk around track, field, or other PA destination; opportunity for socialization with peers and facilitator	10 minutes
Competitive activity	Group-based competitive activity (specific activities to be planned with participants but may include receiver drills, 40-yard dash, 2-hand touch football, pushups, etc.)	15 minutes
Cooldown walk with socialization	Timed walk around track, field, or other PA destination; opportunity for socialization with peers and facilitator	5 minutes
Wrap-up and future planning	Q/A session about content; next week goal setting	10 minutes

Surveys/Instruments

Anthropometric measures (weight, body mass index, and waist circumference) will be measured during in-person visits at baseline, approximately 1 week after completing the intervention, and approximately 3 months after completing the intervention. Weight and height will be measured using a portable digital scale and stadiometer, and waist circumference will be measured using anthropometric measuring tape. Blood pressure will be measured in duplicate using a portable automatic monitor. Moderate-vigorous physical activity (MVPA) will be assessed using Actigraph accelerometers worn on the wrist. Dietary intake will be assessed at each time point using three 24-hour dietary recalls performed by the PI or research assistant using the Nutrition Data System for Research software. Several psychosocial factors will be assessed. Social support for exercise will be assessed using a 13-item scale developed by Sallis and colleagues, and self-efficacy for exercise using a 16-item Self-Efficacy for Exercise Questionnaire adapted from Garcia and King. Motivation for healthy eating will be assessed using 15 items of the Treatment Self-Regulation Questionnaire (TSRQ), and motivation for physical activity will be assessed using the 24-item Motivation for Exercise Scale. Motivation for weight loss will be assessed using an 8-item weight control motivation scale developed by Stotland and colleagues. Environmental support for PA will be assessed using the 33-item Rural Active Living Perceived Environmental Support Scale (RALPESS). Subscales of the Neighborhood Environment Walkability Scale (NEWS) will be used to assess neighborhood surroundings and neighborhood safety. Relatedness to others in physical activity will be assessed using a 6-item scale developed by Wilson & Bengoechea. A standard sociodemographic questionnaire will be used to assess various variables of interest including participants' age, living arrangements, education, income, and

insurance status. A generic medical history questionnaire will be used to assess various acute and/or chronic conditions that participants may have.

Upon completion of the 12-week program, an acceptability survey will be administered to participants along with the other post-intervention measures. A focus group interview will be held soon after program completion for participants to provide feedback on the intervention (e.g., motivation for participating, program effectiveness and enjoyment, facilitators and barriers to participation, recommended improvements).