

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

Statistical Analysis Plan

Data on the number who express interest in the study will be tracked using a simple Microsoft Excel spreadsheet. Data on those who are eligible/ineligible will be collected using an eligibility form and an enrollment tracking spreadsheet. The length of time needed to enroll the desired sample size will be determined based on the first day of recruitment efforts until all men have provided signed informed consent. Attendance rates will be calculated as the number of sessions attended/total sessions, and >75% attendance will be deemed acceptable. Attrition will be determined by examining the number of rural men who enrolled versus completed the weight loss intervention, and <20% attrition will be deemed acceptable. Simple descriptive statistics will be used for data analysis of primary study outcomes.

Changes in secondary outcomes from baseline to 4 and 6 months will be examined using repeated measures ANOVAs. A two-tailed level of significance at .05 will be used for all analyses.