Changes in Weight and Physical Function for Older African American Women in a National, Nonprofit, Community-Based, Peer-Led, Weight Loss Program

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Purpose of the Study

The proposed research is based on evidence that weight loss in frail, overweight, older individuals can improve their physical function and the hypothesis that a low-cost, nonprofit, community-based, peer-led weight loss program with a national infrastructure can provide effective weight loss for an under-served, vulnerable population. If it works in an under-served population, it could be expected to work in the overweight, older, frail population at large because the program, by design, adapts to the needs of its specific members. Since overweight, older individuals with decreased physical function are susceptible to adverse geriatric outcomes – hospitalizations, falls, worsening disability, and worsening mobility – this study will provide evidence for a program that has the potential to reduce long-term negative health outcomes among all older individuals.

Primary aim: Determine real-world effectiveness of community-based, dietitian-facilitated weight loss program on weight.

Hypothesis: Compared to the wait-list control arm, participants in the intervention arm will lose more weight.

Secondary aims: Determine the real-world effectiveness of a community-based, dietitian-facilitated weight loss program on CVD risk factors (S1); physical function (S2);healthcare utilization (S4)

Hypotheses: Compared to the wait-list control arm, participants in the intervention arm will have (H1) greater improvements in blood pressure, waist circumference, hemoglobin A1c, and lipids; (H2) greater improvement on the short physical performance battery, 8-foot up and go, 30-second chair stands, and isometric hand grip; (H3) greater improvements in 36-item short form survey (SF-36), and (H4) fewer outpatient and emergency department visits and inpatient stays.

Background & Significance

Although elderly frail individuals are often depicted as cachectic white women, they are more likely to be overweight African American women with cardiovascular disease (CVD) risk factors. Excess weight contributes to many chronic medical conditions, including diabetes, hypertension, and congestive heart failure, which are incorporated in the definition of the “frailty phenotype”, therefore excess weight and frailty are positively linked. Older, frail individuals are a significant burden for the healthcare system. Compared to their non-frail counterparts, the rate of hospitalizations, falls, worsening disability, and worsening mobility, is two to five times higher; and their mortality rate is six times higher.

Furthermore, frailty can lead to decreased health, loss of independence, and nursing home placement. Since older African American women have the highest rates of both excess weight and frailty, we are targeting this vulnerable group. Evidence shows that older African American women are most affected by chronic weight-related medical conditions and, thereby, have a high likelihood of being dependent on others for their care after the age of 65.

Poor physical function is a characteristic of frailty, and several weight loss interventions have shown that overweight, older adults can achieve both weight loss and improved physical function through diet and exercise. Unfortunately, these programs are difficult to disseminate broadly for at least one of three reasons: 1) they are led by individuals with specialized training; 2) they do not have infrastructure for dissemination; and 3) they are too expensive for many elderly individuals. Since excess weight and frailty are interrelated, there is a critical need for a pragmatic, affordable intervention that effectively achieves weight loss and improves physical function in overweight, frail, older African American women that could be easily disseminated across the nation. If found, such an intervention could address their excess weight and frailty and possibly lower their healthcare costs by reducing the need for high cost utilization.

Unfortunately, the "academia to community" approach to weight loss intervention development has failed African American women. African American women lose less weight than other groups in standard programs; culturally tailored adaptations are not successful; and programs lack infrastructure for dissemination. We designed a "community to academia" approach. We will test a community-based weight loss program that 1) has preliminary evidence of benefit; 2) is acceptable to older African American women; 3) is affordable for participants; and 4) can be broadly disseminated quickly. In overweight, frail older African American women, we will conduct the first randomized trial using an existing community-based, dietitian-facilitated weight loss program with a national infrastructure Take Off Pounds Sensibly (TOPS), to determine its real-world effectiveness on weight change (Primary Aim [P1]) and CVD risk factors (Secondary Aim 1 [S1]); physical function (Secondary Aim 2 [S2]) and quality of life (Secondary Aim 3 [S3]); and healthcare utilization (Secondary Aim 4 [S4]).

Although TOPS meetings are peer-led and the other two are dietician-led, the dietary components are similar. However, all three interventions have qualitatively different exercise components. Villareal's exercise component was supervised by a physical therapist,13 while the Bales/Starr intervention only encouraged regular physical activity. TOPS recommends the 2018 Physical Activity and Dietary Guidelines for Americans (150 minutes of moderately vigorous or 75 minutes of vigorous activity per week). For this intervention, one-third of the programs will address physical activity and support the Physical Activity Guidelines. This is a Stage III trial – one where an efficacious intervention is adapted for testing in a community setting. Collectively, the diet and exercise components of the TOPS program, are a pragmatic version of the Villareal and Bales/Starr interventions. It is also important to note that the diet only arms in both the Villareal and Bales/Starr interventions showed both weight loss and improved physical function. Therefore, we expect the TOPS intervention will show both weight loss and improved physical function with its pragmatic approach according to the 2018 Dietary Guidelines.

Design & Procedures

Feasibility Survey:

A feasibility survey will be performed to determine if the study can be performed virtually and if participants would be interested in partaking in TOPS if it were done virtually or over the phone. We have a goal of 150 surveys.

The community sites will assist by handing out or mailing residents a study flyer to introduce the telephone survey. A letter from the research team and site liaison will also be given to residents explaining the purpose of the study, why their name, phone number, and address may be shared with Duke, allow them the option to opt-out from being contacted, and how to contact the study team or site liaison if they have questions about the survey. Community sites will either provide Duke a list of residents to be called, or simply allow residents to contact Duke themselves if they have interest in completing the telephone survey.

Participants that complete the survey will be screened for eligibility of African American women, aged 55 and older. If they complete the 30-45 minute survey they will be compensated with a $25 gift card.

Participants who completed the initial survey and did not answer our additional Covid-19 vaccine questions will have the opportunity to be re-consented then asked our additional questions for another $10 gift card.

The telephone survey will not be recorded, answers will be directly entered into REDCap. We predict no more than 150 surveys will be completed.

If study sites request results of the feasibility study, we will share our summary of data analysis.

In-Person Study:
A 6 month 1:1randomized trial with a wait-list control will be used to determine the changes in weight, physical function, CVD risk factors, and healthcare utilization for older African American women with decreased physical function in the TOPS program. The control group will receive the intervention at the end of the study.

Using a 1:1 randomization model, after baseline measurements are obtained, participants will be randomized to either the intervention (TOPS Now) or waitlist control (TOPS Later) arms of the study. The TOPS Now participants will start TOPS meetings immediately. The TOPS meetings will be held weekly for 6 months and will include a private weigh-in and group-based education sessions on one of 26 pre-selected topics. At the same time the TOPS Later participants will receive information about the USDA MyPlate Program and the current Physical Activity and Dietary Guidelines for Adults. Participants in both plans will complete assessment by the study team, which will include will include measurements of weight, physical function, blood tests and surveys of healthcare utilization at baseline, 3, and 6 months. At the end of the 6 months we will provide vouchers for all participants to join their local weekly TOPS chapter meetings. The total length of time participants in both study arms will be on study is up to 8 months (to allow for the waiting period for randomization and completion of final study evaluations.)

There is minimal risk to the participants. Weight loss has been shown to be safe in overweight, older individuals. Additionally, this study will enroll participants into Take Off Pounds Sensibly (TOPS). The TOPS program is being used in non-medical settings throughout the United States and Canada and poses minimal risk to participants. Individuals must have a body mass index of 27 or greater to participate in the current study. The minimal risk for individuals who participate in this study is greatly outweighed by

potential health benefits that may accrue and by the importance of the scientific knowledge that may result from this work. Should previously undetected evidence of chronic kidney disease or hypothyroidism be identified during screening and testing, subjects will be referred to the care of their physician for further evaluation.

The rationale for these aims is that the successful completion is expected to provide evidence that a community-based weight loss program with a national infrastructure can help a vulnerable, under-served population lose weight and improve their physical function. For older overweight individuals, this could improve their CVD risk factors, quality of life, enhance their health; reduce their healthcare utilization, illness, and disability; and decrease their adverse geriatric outcomes. After completing these aims, we expect that we will have proven that the community-based weight loss program can improve both weight and physical function among older, overweight African American women. This also could help other demographic groups with excess weight and poor physical function. Eventually, it could help older adults maintain their health and independence in the community.

Selection of Subjects

List inclusion/exclusion criteria and how subjects will be identified.
Study population. Inclusion Criteria. Participants must meet the following criteria: 1) English speaking, African American women aged ≥55; 2) BMI ≥27 kg/m2; 3) stable body weight (no weight loss of greater than 10 lbs for 6 months prior to study); 4) Patient must have a primary care provider and provide contact information

Feasibility survey: We predict no more than 150 surveys will be completed. Participants will be screened for eligibility of: African American women, aged 55 or older to complete the telephone survey.

Conditional Inclusion Criteria. Participants with type 2 diabetes on insulin or sulfonylureas will be allowed to participate in the study only if their providers agree to manage the changing medications requirements associated with possible weight loss by signing and returning a “Permission to Participate” form. Patients with history of bipolar or schizophrenia, provider must sign "Permission to Participate" form. PCPs or oncologists of participants with cancer or a history of cancer treatment within the past 12 months, other than basal cell skin cancer or squamous cell skin cancer, will have 10 days to agree to their patient's participation in the study.

Exclusion Criteria. 1) Women with type 2 diabetes on insulin or sulfonylureas without provider approval; 2) Participants whose provider exercises the opt out option; 3) Participants with history of bipolar or schizophrenia without provider approval. 4) current cancer diagnosis other than basal cell skin cancer or squamous cell skin cancer; 5) use of medications thought to affect metabolism; body weight, energy expenditure, or appetite; 6) Eating disorder; current moderate to severe symptoms of depression; dementia; neurological conditions causing functional limitations; 7) unstable medical illness such as unstable angina, recent MI, or congestive heart failure class III-IV; 8) terminal medical conditions 9) Currently enrolled in a weight loss program

Subject Recruitment and Compensation

Planned Recruitment. Participants will be recruited through Duke MyChart, The Bales-Starr registry of individuals who have agreed to be contacted for further research, community sites such as: churches, communities centers, medical facilities and/or senior centers in North Carolina (NC).

Screening. Potential participants interested in joining the study may attend an information session to learn more about the study. Information sessions may be held at the study site and presented with a powerpoint. Once consented participants may complete the screening and baseline assessments. Individuals who call the study line, will be screened by study staff via telephone to determine eligibility.

Study participants will receive a ClinCard to receive study payments after they complete the study assessments at baseline, 3, and 6 months. They will receive $50 at baseline, $75 at 3 mo. $100 at 6 mo.

Participants interested in completing the survey will be screened to make sure they are African American women, aged 55 or older. If they complete the survey they will be mailed a $25 gift card. Participants who completed the initial survey and did not answer our additional Covid-19 vaccine questions will have the opportunity to be re-consented then asked our additional questions for another $10 gift card.

Study Interventions

Participants enrolled at study sites that are randomized to the TOPS Now group, will start the study intervention, TOPS Weight Loss program within a few weeks of consenting to take part in the study. Participants will meet one hour weekly for a duration of 6 months. These weekly meetings will be facilitated by dieticians. TOPS Inc. offers tools, training and programs for healthy living and weight management, with exceptional group fellowship and recognition. Founded in 1948, TOPS has been helping and supporting members to take off and keep off pounds sensibly for nearly 70 years.

Weekly meetings include private weigh-ins and professionally prepared, informational chapter programs, featuring up-to-date information on nutrition, exercise and healthy lifestyles. Programs provide positive reinforcement and motivation to adhere to food and exercise programs.

To ensure intervention fidelity, TOPS dietician facilitators will be trained to deliver program content as written and will be in communication with TOPS leaders as necessary.

Participants randomized to the TOPS Later Group, will start the TOPS Weight Loss program at a later date, (in approximately 6 months) since they are assigned to the waitlist control group. This group will receive the waitlist control materials from a dietician, which include the My Plate, and the current Physical Activity and Dietary Guideline handouts to be utilized during the first 6 months of the study. TOPS Later participants will begin their TOPS Weight Loss program and meet one-hour weekly for a duration of 6 months.

During the approximately 8 month period of study enrollment all participants will meet with study staff to complete "checkups" which will include body measurements, physical function assessments, and surveys. These visits will take place at baseline, 3, and 6 months from the time of enrollment. The total length of time participants will be on study is up to 8 months.

Risk/Benefit Assessment

Risks: There is minimal risk to the subjects. Weight loss has been shown to be safe in overweight, older individuals. Additionally, this study will recruit participants into Take Off Pounds Sensibly (TOPS), a nationally available, community-based, peer-led weight loss program. The TOPS program is being used in non-medical settings throughout the United States and Canada and poses minimal risk to participants. Individuals must have a body mass index of 30 or greater to participate in the current study. The minimal risk to human subjects for participation in this study is greatly outweighed by potential health benefits that may accrue participants and by the importance of the scientific knowledge that may reasonable be expected to result from this work. Should previously undetected evidence of chronic kidney disease or hypothyroidism be identified during screening and testing, subjects will be referred to the care of their physician for further evaluation.

Medical risks of participation are minimized in two ways. After enrollment, participants' primary care providers (PCPs) will be sent a letter informing them of their patient's enrollment in the study. If the PCP does not think it is safe for the patient to participate in the study, the PCP will have up to 10 days to inform the study team, and the patient will be withdrawn from the study. Participants with diabetes on insulin or sulfonylureas will need to have a "Permission to Participate" signed by their PCP within the 10-day period, or they will be withdrawn from the study.

The study team is collecting blood for lab tests, but these will be used for outcomes, not as safety measures. However, as an added measure of safety, the study team will provide the participant and their PCP with the test results.

Physical risks of the study are minimal. Participants will be encouraged to meet the current Physical Activity and Dietary Guidelines, which will be more than participants' baseline physical activity. Therefore, possible risks are associated with increased physical activity: Decreased Blood pressure, Increased Blood Pressure, Myocardial Infarction, Low blood sugar, Bleeding, Bruising, Broken Bone, Fall, Sprain/Strain, Seizure (secondary to low blood sugar), Stroke, Subarachnoid hemorrhage (secondary to fall).

Weight loss is the goal of this study and is associated with many health benefits. There are, however, also some risks associated with greater weight loss such as altered blood parameters and decreased bone density. Additionally, some medication doses might need to be reviewed and modified given such weight loss. Study staff will monitor weight loss of each individual at the study visits and will contact and advise the PCP and participant, in writing, in cases when a participant loses ≥10% of weight.

Participants' weight loss will be monitored via REDCap. The REDCap system calculates the cumulative weight loss to determine those greater than 10% of the participant's total body weight. Participants who have ≥10% weight loss will have a populated letter generated for each participant's PCP. The letter will provide pertinent information including the cumulative weight loss pounds. The Weight Loss Threshold table created by the study statistician will look very specifically at 10, 15, 20, and 25 percent threshold points in each of the two study arms; as well as combined totals.

While we do not anticipate any adverse psychological consequences from study participation, study staff will look/listen for any unusual signs, symptoms, expressions (verbal or non-verbal), ideations that may indicate severe conflict, distress, hopelessness, depression, and suicidal or homicidal thoughts of a participant. In this case, study staff will notify the PI and follow the instructions detailed in the Safety Protocol and/or the Suicidal Protocol.

Data Management, Analysis and Statistical Considerations

For external collaborators/personnel who are NOT ENGAGED in the research but are handling de-identified or a limited data set of Duke data, include their name, role and a description of the data. Power Analysis. Based on Dr. Mitchell's previous data with older AA women, new power calculations were performed by Cynthia Coffman, PhD, the study biostatistician. The power calculations for this study are based on the primary aim (weight change) and have been updated for an individual randomized trial instead of a cluster randomized trial. We used percentage weight loss over 6 months as the primary measure, and assumed a 20% attrition rate, a standard deviation of 3.5 percentage points, and no change in weight for women in the attention-control group – all assumptions used in the original trial power calculations. Although the intervention will be delivered in a group setting, there will be rolling recruitment and those attending a group will vary from meeting to meeting so no adjustment for clustering in the intervention arm was done. Conservatively, a within-patient correlation of 0.80 was used for weight. Using the PASS 22 software (PASS 2022 Power Analysis and Sample Size Software [2022]. NCSS, LLC. Kaysville, Utah, USA, ncss.com/software/pass) procedure test for two means in a repeated measures design with a 0.05 level test to compare the average percentage weight loss over 6 months between the two study arms, a sample of n=100 women at baseline (50 each arm) would provide 90% power to detect a 2.4 percentage unit difference between arms. The original cluster randomized trial was powered at 89% to detect a 2.0 percentage unit difference between arms. We have a goal of 150 telephone feasibility surveys.

Randomization assignment. An algorithm will be built into REDCap by the biostatistician to randomly assign individuals in a 1:1 ratio to study arms. A stratified block randomization will be used with strata BMI (<35 kg/m2, ≥35 kg/m2) and 6-Minute Walk Test (<400 meters, ≥400 meters) variables. These stratification variables were chosen because of the strong interactions between excess weight and function. We expect that people with a BMI indicating Class 2 obesity would have different function than participants with a BMI ranging from 27-35 and the 400 meter 6-minute walk test is an accepted functional cut-point. The randomization sequence will be generated by a study statistician and accessible only to unblinded team members. Participants will be informed of their assignment after completing baseline assessments.

Intention to treat analysis. If a woman is initially randomized to a control cluster, but later joins an intervention cluster, her data will be analyzed as a control group individual. If a woman starts out in an intervention cluster, and does not participate in the TOPS program, her data will be analyzed as a member of the intervention group.

Dropouts. It is of interest to investigate factors that enhance or reduce the probability of participating in the TOPS program or dropping out of it. If a participant does not participate in the study-scheduled weight measurements, but has (i) at least one "chapter" weight after that time point or (ii) a measurement within 6 weeks beforehand, she will still be considered to be in the program at the time point. If neither of these criteria are met, then the participant will be considered to have dropped out at that time point.

Data & Safety Monitoring

Weight loss in overweight older adults should enhance rather than jeopardize health status, and potential serious adverse events (SAE) for participants in this project are not expected. Regardless, we will minimize potential risk by careful screening of potential participants. The individuals responsible for data safety and monitoring will be the PI, Co-investigators, the study staff (Drs. Mitchell, Bales, Starr, Gierisch, Hung; Clinical Research Specialist; and Clinical Research Coordinator).

Further data safety and monitoring will be provided by the PI. There will be several ongoing mechanisms for monitoring and reporting of adverse events: 1) ongoing participant contact via study personnel, 2) study telephone number provided to participants to report concerns related to study participation; 3) weekly meetings between the PI and study personnel. We will also check complete blood counts and basic metabolic panels every three months to monitor renal function throughout the study.

The PI will meet at least weekly with study personnel to discuss participants' reactions to the intervention, proper delivery of the intervention, and any adverse events or unanticipated problems. Monthly meetings between the investigators and the Clinical Research Coordinator will allow for ongoing progress reports, including the number of participants currently involved in the study groups, attrition rates, and scheduled data collection from participants, as well as notification and review of any adverse events. Safety monitoring for adverse events will be conducted in real time by the PI and/or Clinical Research Coordinator. The following information about adverse events will be collected: 1) the onset and resolution of the adverse event; 2) an assessment of the severity or intensity (use existing grading scales whenever possible); 3) an assessment of the relationship of the event to the study (definitely, probably, possibly or not related); and 4) action taken (e.g., none, referral to physician, start or increase concomitant medication). The PI will determine the severity of the event, will assign attribution to the event, and will monitor the event until its resolution. Any adverse events will be reported to the IRB in accordance with the Duke Human Research Protection Program's Standards of Practice.

Data Safety Monitoring Board

The National Institute on Aging has approved a Data Safety Monitoring Board to oversee the study. The DSMB will be composed of three members who are not connected with the study, except for monitoring the data. The DSMB will meet with Drs. Mitchell, Bales, Starr, Hung, and Gierisch on a semiannual basis for review of the progress of the study. The meetings are likely to be by teleconference. Reports of clinical events in the study population will be distributed in advance of the meeting. The DSMB will review clinical events to identify excess event rates in the study population over that expected based upon historical experience. We do not expect any major untoward events to occur in subjects participating in this protocol.