Feasibility and acceptability of a community-based weight loss program among African American breast cancer survivors

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Purpose of the Study

Aim 1: Examine the feasibility and acceptability of a national, low-cost, community-based, peer-led, weight loss program (Take Off Pounds Sensibly, TOPS) for overweight and obese African American breast cancer survivors in the local chapter of a national African American breast cancer support group (Sisters Network Triangle North Carolina, SNTNC).

Hypothesis 1: The TOPS format, materials, and content will be feasible and acceptable to overweight and obese African American breast cancer survivors in SNTNC.

Aim 2: Assess the weight change of overweight and obese African American breast cancer survivors after 6 months in the TOPS program to gather data for sample size calculations for a future RCT.

Hypothesis 2: Overweight and obese African American breast cancer survivors in TOPS will lose 5% of their initial body weight, which is clinically significant, within 6 months.

Background & Significance

Mounting evidence links overweight and obesity to cancer. In women diagnosed with breast cancer, obesity contributes to both breast cancer-specific and cardiovascular disease mortality. In one study, breast cancer survivors diagnosed at ≥66 years were more likely to die from cardiovascular disease than breast cancer. Therefore, obesity also plays a role in their cardiovascular mortality. Unfortunately, breast cancer treatment can exacerbate these issues because it may be associated with weight gain; increased cardiovascular events; and decreased physical function.

Compared to the general population, African American women have higher rates of overweight and obesity among those with and without breast cancer; gain more weight after they are diagnosed with breast cancer; and have worse outcomes for breast cancer mortality and cardiovascular disease. For women diagnosed with breast cancer, interventions targeting diet, weight loss, and physical activity have been associated with clinically significant weight loss; decreased mortality; reduced risk of breast cancer recurrence; and fewer cardiovascular events. Unfortunately, African American women lose less weight than other groups in standard weight loss programs.

In one randomized controlled trial, African American breast cancer survivors in an expert-led intervention – weekly didactic sessions, twice weekly supervised exercise sessions, and twice weekly text messages with community-based nutritionists and exercise trainers – lost an average of 3.6% of their weight and 44% of participants lost at least 5% of their initial weight. However, personnel increase the intervention costs, and there is no infrastructure for nationwide dissemination of this program. To decrease adverse clinical and mortality outcomes among African American breast cancer survivors, a weight management intervention with scalable infrastructure that can be implemented in low-resource settings is needed.

A national, low-cost, community-based, peer-led weight loss program (Take Off Pounds Sensibly, TOPS) can fill this unmet need. TOPS is a nonprofit, evidence-based weight loss program with a national infrastructure that offers a pragmatic option to help women diagnosed with breast cancer manage their weight. First, it includes all of the components that the NIH asserts should be included in "safe and effective" weight loss programs. Second, Dr. Mitchell's retrospective analyses showed: 1) TOPS participants lose a clinically significant amount of weight and maintain the loss for up to 7 years. Third, its peer-led, community-based structure ensures each chapter is contextually tailored for its members. For instance, in a successful pilot study, Dr. Mitchell started three TOPS chapters specifically for older African American women; and one chapter continued for almost 8 years after the study ended in 2012 (until the COVID-19 pandemic). Fourth, TOPS costs participants less than $100 per year. Finally, TOPS's nationwide infrastructure, with chapters in every state, can facilitate dissemination and implementation. However, because women with breast cancer have greater psychosocial stressors, including time-consuming treatment regimens and fear of recurrence, they may need different levels of support than those offered in standard TOPS chapters, and this study can reveal those elements and provide preliminary data for a future randomized controlled trial (RCT).

Sisters Network Triangle North Carolina (SNTNC) is an affiliate chapter of Sisters Network, Inc., a national African American breast cancer survivorship organization. SNTNC was established in 2003. Prior to the COVID-19 pandemic, SNTNC held separate monthly meetings in both Raleigh and Durham, NC. Since the pandemic, SNTNC combined the Raleigh and Durham meetings into one monthly virtual Zoom meeting. In the past, SNTNC has participated in research projects about survivorship, barriers to care, and treatment adherence.

For African American women diagnosed with breast cancer, our long-term goals are to decrease cancer-specific, cardiovascular, and all-cause mortality. The objective of this proposal is to conduct formative research to determine if the format and materials of the TOPS program are feasible and acceptable to overweight and obese African American breast cancer survivors. This project seeks to address the health disparities of overweight and obesity and cardiovascular disease among African American breast cancer survivors and benefits from the following: 1) the existing infrastructure of the SNTNC, the Raleigh/Durham chapter of a national African American breast cancer survivorship organization; 2) the successful weight loss of participants in the TOPS program; and 3) Dr. Mitchell's experience with studies of the TOPS program. The outcomes will be a) determination of the feasibility and acceptability of the TOPS program by women of SNTNC; b) recommendations the women of SNTNC have to modify the program to make it relevant to their experiences; and c) preliminary weight change data for sample size calculations for a future RCT of TOPS for weight change among this population.

This work will develop the evidence base for a scalable weight loss intervention among African American breast cancer survivors – a population with poor breast cancer and cardiovascular outcomes. If effective, these results have the potential to help increase both the survival and quality of life for this population.

Design & Procedures

Research design. Part of the study design will be the further development of study documents including TOPS programs, survey questions, and focus group scripts. The documents will not be used until full IRB approval is granted for the final drafts via amendments.

This project will be a six-month single arm study that will use qualitative and quantitative methods to measure the feasibility and acceptability of the TOPS program among African American breast cancer survivors. Qualitative methods will collect data about participants' perceptions of the program and suggestions for modification to make it relevant to them and their experiences. We will conduct up to five focus groups and up to 10 in-depth interviews. Quantitative methods will measure recruitment, retention, and weight change.

Subjects. Overweight and obese African American breast cancer survivors in the Sisters Network Triangle North Carolina (SNTNC).

Inclusion criteria:
18 years old and over
Women diagnosed with breast cancer
BMI ≥ 25 kg/m2 after completion of primary therapy (surgery, radiation, adjuvant or neo-adjuvant chemotherapy)
Regular access to a computer and internet

Exclusion criteria:
Under 18 years old
Have not had a breast cancer diagnosis
Currently undergoing infusion chemo therapy treatment
Do not have access to a computer and the internet
BMI is less than 25 kg/m2
Women whose oncology providers do not agree with their participation in a weight loss program
Participating in another weight loss program
If on insulin or sulfonylureas and provider does not agree to help manage their medications. They will need a signed provider permission form.

Study Setting. The study will be conducted via Zoom. Since the COVID-19 pandemic, SNTNC has met online. Approximately 50 to 60 women participate each month. Thus, the group is used to meeting in the virtual space. Duration. Subjects will join newly formed TOPS chapters for 6 months. Then, they will be asked to participate in focus groups to collect data about their perceptions of the TOPS program.

Recruitment and Screening. The study will enroll up to 50 women, who will be recruited through the Sisters Network Triangle North Carolina (SNTNC). Valarie Worthy, MSN, RN, is a Patient Navigator at the Duke Cancer Center. She is also the co-founder, past president, and current program manager for SNTNC and she is an enthusiastic proponent of this project. She will assist with the recruiting efforts.

Dr. Mitchell will attend up to two of the monthly SNTNC meetings, and she and Ms. Worthy will present an information session about the study via a Zoom meeting. Individuals will be invited to contact the study team to determine if they are either overweight or obese based on self-reported height and weight and calculated BMI. If women qualify based on BMI, they will be asked pre-screening questions in REDCap to determine if they are eligible to participate in the study. Based on Ms. Worthy's extensive experience recruiting participants for previous studies, we believe we will be able to complete the recruitment phase within two months.

Participants that complete the screening questions and note that they are on insulin (such as, U-100, U-200, U-300, ultra long acting, pre-mix (i.e. 70/30, 75/25), U-500 (ultraconcentrated), inhaled insulin) or sulfonylureas (such as, glyburide [DiaBeta, Glynase, PresTab, Micronase], glipizide [Glipizide XL, Glucotrol, Glucotrol XL], glimepiride [Amaryl], tolazamide [Tolinase], or tolbutamide [Orinase]) they will need to get a permission form signed by their provider. The form will be sent via email to the participant to take to their provider. The permission form will be used to notify the patients provider that they would like to participate in a weight loss study which may cause changes to their diabetes medications. The PI will not be responsible for managing their medications so the participants' provider must sign the form stating that they will agree to help manage the participants medications if needed. If the participant does not get a signed permission form or their provider does not agree to help manage their medications they will be ineligible to continue with the study. The forms will be collected, uploaded, and noted in REDCap.

Participants that attend the Zoom information session and are interested in participating in the study will be sent a link to our REDCap project. They will be able to review information about the study such as why we are doing the study, risks/benefits, and determine if they would like to continue by answering some questions. They will provide some information to identify themselves and to determine eligibility. Once eligible, participants will be able to review the e-consent. They can have as much time as needed to review, ask the study team questions via phone or email, and sign using an e-signature. After they sign they will be sent a copy of the e-consent via email that they provide. If they are ineligible, they will not be able to continue on to the e-consent.

Intervention. Participants will be invited to join new chapters of the TOPS weight loss program created for the study. Each participant will be offered a free one-year membership in the TOPS program. Participants will receive the "TOPS Plus" new member packet—one-year membership in a local TOPS chapter; My Day One: A Ready-Set-Go Guide for Healthy Living is a 24-page booklet of weight loss basics with a six-week lesson plan; a one year subscription to TOPS News, a bimonthly magazine published exclusively for TOPS members; Real Life: The Hands-on, Pounds-off Guide is a 304-page weight management lifestyle guide; Food Exchange Cards; TheraBands® Resistance Bands; My Real Progress, a 12-week food and fitness journal. TOPS Usual Procedures. The TOPS program usually consists of weekly private weigh-ins on the chapter scale, where the weight recorder notes each person's weight on their individual Weight Chart. Then, there is a group meeting, where members receive educational information on topics such as healthy eating, exercise, or behavior modification. Participants usually get a "provider-approved" weight goal. Modified COVID-19 Procedures. Because of social distancing requirements due to the pandemic, we will have to modify the usual procedures. The study will provide each participant with a scale, and members will provide the weight recorder with their weights each

week. The weight recorder will still record each person's weight on their individual Weight Chart. We will also set an initial weight loss goal of 5% of initial weight, which is considered clinically significant.

Additional Opportunity:
There is an additional opportunity for some participants to become a TOPS leader. This weight loss program requires peer leadership, which means one member of each group will be the leader. This involves reading the materials ahead of time and taking a training on TOPS leadership. Participants will receive an additional compensation for each training module completed to become a TOPS leaders.

Data collection. Focus groups and interviews. All individuals who enroll in the study will be invited to participate in 6 month focus groups and interviews, even if they did not remain in the program. Groups will be led by an experienced moderator and last for 60-90 minutes using open-ended questions to elicit the most information. Focus groups will have up to 6 participants and will be conducted via Zoom by the Behavioral Health and Survey Research (BHSR) Core, led by Laura Fish, PhD, MPH. We will conduct up to 10 individual interviews with those who are unable to participate in the focus groups. The interviews will include the same themes as the focus groups. Evidence suggests that data saturation can occur within 12 interactions, with primary themes arising as early as six. In this way, we will be able to discover factors associated with program continuation and withdrawal. Focus groups and interviews will be taped and transcribed. Both Valarie Worth's and Lola Fayanju's previous experiences with SNTNC have established these as acceptable forms of assessment with this group. All interviews will be audio recorded (via Zoom) and transcribed. All of the patient information will be stored in a secure, shared Duke drive that only the study personnel will have access to. The focus groups will be recorded and stored securely on Duke's Zoom platform, participants will be provided with a password to enter the virtual meeting. Audio will be shared to Duke Box. Notes about the interview, transcripts, and audio will be stored in Duke Box and stored in study records for at least six years after the study is done. After six years, we will destroy the records, or we will remove all information identifying participants.

Survey: All individuals who enroll in the study will be invited to complete a brief survey about their experience at the 6 month interval.

Focus group and interview guide development. Focus group and interview guides will be developed using the Framework for Reporting Adaptations and Modifications – Enhanced (FRAME), which is typically used to retrospectively document modifications that occurred during implementation. In this case, we will use FRAME to guide questions for prospective adaptations for our population of interest. Instead of asking, "What is the nature of content modifications?" we will offer options for possible modifications, such as removing, substituting, or adding elements. Focus groups and interviews will inform the adaptation and implementation of the TOPS program for African American breast cancer survivors. Weight change. Weight change will be calculated at 3 and 6 months as percentage change from initial weight. If the pandemic restrictions allow and participants are comfortable, we can consider study visits for data collection. However, we plan to provide participants with smart scales to transmit data to a secure application.

Risk/Benefit Assessment

There is minimal risk to the subjects. Weight loss has been shown to be safe in obese, 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 25 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.

Data Analysis & Statistical Considerations

Focus groups. We will import all transcripts into the Nvivo software to facilitate organization and analysis. We will use a 5-stage approach to conduct thematic analysis (familiarization; identifying a thematic framework; indexing; charting, and interpretation). Experienced qualitative researchers from the BHSR core will work with the study team to conduct the analysis. Familiarization will involve the entire research team reviewing 2-3 transcripts to identify initial coding themes to become familiar with the data. Identified themes will be used as the initial coding framework to conduct line by line coding of a single transcript. The team will meet to discuss the transcript and modify the initial framework. Next, two researchers will code the remaining transcripts. Coding will include memos for each transcript to annotated coders questions, decision about the data, and reflections on analysis. Each coder will also create an overview memo to collect observations that cut across transcripts during the coding process. After coding, the team will meet to discuss themes, sort codes, and restructure the initial framework as similarities and differences are identified. In the final stage, the team will identify major themes and associated quotes to summarize the results. We will also conduct member checking where we will ask providers and patients interviewed to provide feedback on the summarized data.

Weight change. Weight change will be calculated as last observation carried forward and completers' analyses. For both analyses, weight change will be calculated as difference between baseline weight at 3 and 6 months and as a percentage of initial weight. Weight change will also be categorized in the following groups: weight loss 0 to <5%; weight loss ≥5%; and weight gain.