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Healthy lifestyle intervention for African American uterine cancer survivors: Study protocol

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Abstract

Background—Cancer of the uterine corpus is the most common gynecologic malignancy and the fourth most common cancer in U.S. women. There is a racial disparity in the survival from endometrial cancer and this may be addressed by culturally-tailored lifestyle interventions to help African American (AA) endometrial cancer survivors lose weight or maintain a healthy weight.

Objective—The overall purpose of this pilot study is to develop and evaluate a culturally-tailored lifestyle intervention to help AA uterine cancer survivors reduce their risk of cancer recurrence and improve their quality of life through healthy eating, physical activity, and weight management. While many interventions have been evaluated to assist cancer survivors through diet and physical activity, few have focused on AA women with a uterine cancer diagnosis.

Methods—Community-engaged research principles are being followed. This study was developed with input from the Augusta University (AU) College of Nursing Community Advisory Board (CAB) and the Division of Gynecologic Oncology at the Georgia Cancer Center at AU. Weekly sessions throughout a 12-week intervention will include physical activity and lectures on improving nutritional status. The pre/post-test design includes baseline and 6-month follow-up, where participants will complete a questionnaire that assesses knowledge and attitudes about physical activity, nutrition, uterine cancer, social support, and quality of life.

Conclusions—From this pilot study, we will learn more about the feasibility and integration of healthy lifestyle interventions in this patient population, and the results can provide an opportunity for a larger-scale, multi-center study with a randomized controlled design.

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Keywords

African Americans; Uterine cancer survivors; Physical activity; Diet; Nutrition; Quality of life

1. Introduction

Cancer of the uterine corpus is the most common gynecologic malignancy and the fourth most common cancer in U.S. women. In the U.S., Black women have an 80% higher uterine cancer mortality rate than white women [1]. The 5-year survival rate of endometrial cancer patients is 64% for non-Hispanic Black women compared with 86% among non-Hispanic white women [2]. Several factors likely account for these disparities including socioeconomic status, stage-at-diagnosis, tumor characteristics, barriers to access to care, and treatment decisions [2,3]. Higher rates of comorbidities, such as obesity and diabetes, may also have a role. Compared to their white counterparts, African American (AA) patients with endometrial cancer are more likely to be obese or morbidly obese [3]. In addition, AA women who have been diagnosed and treated for uterine cancer have a higher risk of diabetes and impaired quality of life than whites [4]. Black-white differences in uterine cancer survival suggest that there are unmet needs among these survivors.

A small number of intervention studies have examined the feasibility and efficacy of lifestyle interventions aimed at increasing physical activity or improving nutritional status among uterine cancer survivors [5–8]. One additional study focused on both endometrial and breast cancer patients [9]. However, none of the studies specifically targeted AA or used interventions that were culturally tailored for African American women. Basen-Engquist et al. [5] conducted a study in which one hundred post-treatment Stage I–IIIa endometrial cancer survivors participated; only seven of the women (7%) were non-Hispanic African American. Von Gruenigen et al. [6] conducted a randomized controlled trial in early stage endometrial cancer patients (n = 45), and all but one of the participants were white. In the SUCCEED Trial, of the 75 overweight and obese endometrial cancer survivors in Cleveland, Ohio randomized to a 6-month lifestyle intervention or usual care group, only 5 of the women (6.7%) were African American [7].

Additional research is needed to examine the effects of life-style interventions among African American uterine cancer survivors. Engaging in behaviors such as physical activity, avoiding tobacco use, eating a healthy diet (e.g., a diet low in fat and high in fruits and vegetables), and learning stress-reduction techniques offers cancer survivors control over their health and may lessen their fear of disease recurrence or progression [10]. This pilot study will help to fill in current gaps in the evidence base on uterine cancer survivorship among African American women.

We hypothesize that: 1) the lifestyle intervention will correspond with a statistically significant increase in daily/weekly physical activity from baseline to six months, mediated by a decrease in perceptions of exercise barriers and improvements in physical activity knowledge and awareness 2) the lifestyle intervention will be associated with a statistically significant improvement in quality of life in pre/post-test comparisons, and that this quality of life improvement will be mediated by improvements in nutritional status.

2. Methods

2.1. Study development

In this community-engaged research study, input has been sought from the Augusta University College of Nursing Community Advisory Board (CAB), which is primarily comprised of African American women who live in Augusta and the surrounding area. The other partner in this project is the Division of Gynecologic Oncology at the Georgia Cancer Center at AU. These members offered input and guidance about recruitment of research participants and planning for the 12-week intervention including appropriate locations for the 12-week intervention, appropriate time and day for the weekly sessions, and the best approach for formatting physical activity sessions. The CAB will continue to provide input throughout the planning and conduct of this study and the dissemination of the results. This will help ensure that the intervention is culturally appropriate.

2.2. Study population

The Gynecological Oncology Program is part of the Department of Obstetrics and Gynecology at the Medical College of Georgia (MCG) at Augusta University. The program provides patient services for women across the Central Savannah Regional Area (CSRA). Gynecologic oncologists will be screening potential participants who meet the following eligibility criteria: African American; stages I or II uterine cancer survivors; at least 3-month time lapse since most recent cancer treatment; BMI > 18.5 (those not underweight); medical clearance for physical activity.

2.3. Recruitment

Prior to participant recruitment, the study will receive approval from the Augusta University IRB. Because research indicates that cancer survivors often develop recurrent or secondary malignancies and other obesity-related disorders, gyn-oncologists at Augusta University Medical Center will identify eligible patients during routine follow up visits post uterine cancer treatment. The gyn-oncology medical staff will explain the research and ascertain patient interest. Potential participants will be asked to sign a release form allowing their contact information to be provided to the research team. Participants will be mailed a letter with additional information about the study and a detailed consent form, followed by a telephone call. During the call, we will use a telephone screening protocol based on the Physical Activity Readiness questionnaire (PAR-Q) (www.csep.ca/forms). Research team members will contact potential participants to determine eligibility, further discuss the research, answer any questions, and schedule a baseline interview. We anticipate that our participants will have comorbidities. Therefore, to increase external validity and to avoid excluding individuals who would benefit from the intervention, those participants that answer “Yes” to any questions on the PAR-Q will not be excluded, but will require medical provider clearance.

2.4. Theoretical framework

The intervention will incorporate elements of the Health Belief Model (HBM), such as educational information about modifiable causes of cancer and other chronic diseases (e.g.,

the potential benefits of weight loss through healthy eating, caloric restriction, limiting alcohol intake, and physical activity) [22]. We will use the Health Belief Model as the guiding principles for the intervention. The HBM posits that a person's beliefs about a health concern, such as cancer recurrence, their perceived benefits of an action (e.g., adopting a healthy diet, engaging in physical activity, avoiding alcohol and tobacco) barriers to action, and self-efficacy explain engagement in health promoting behavior [22]. The HBM suggests that a stimulus or cue to action must be present to trigger health-promoting behavior. The lifestyle intervention will also incorporate elements of social cognitive theory [20] including goal setting, self-reporting of dietary intake self-monitoring of minutes of physical activity per day, and reinforcement of positive behaviors. Self-monitoring is strongly associated with behavior change [21]. The intervention will provide several triggers to promote healthy behaviors, and participants will be able to track minutes of daily physical activity. To increase self-efficacy, the intervention will provide information about practical steps that can be taken to lose weight or to maintain a healthy weight including menu suggestions. Other topics that will be discussed incorporate portion sizes, meal planning, food labels, grocery shopping, eating out in social situations, and improving overall diet quality. The sessions will include instructions for setting individualized goals, tracking progress, and receiving feedback. The intervention will allow users to set a weight loss goal and to self-monitor daily dietary intake toward achieving that goal and serve as a cue for action.

2.5. Intervention development

The intervention developed for this study will incorporate existing physical activity, and nutrition interventions that have been developed for uterine cancer survivors [5–8] and African American and white breast cancer survivors [10–20]. To pretest draft intervention materials, we will hold two focus group sessions with 8–10 AA uterine cancer survivors per group. We will present the draft materials to the focus group participants to solicit their feedback and input on improving the materials, including the ease and time required for completion of questionnaires. This will help to ensure that the materials are acceptable to the target population, persuasive, and more likely to be effective in changing behaviors. Members of the CAB will also be asked to review draft intervention materials in order to solicit their ideas about how to improve them.

Education and skills development to increase physical activity will be adapted from intervention materials used in previous studies of uterine cancer survivors and African American breast cancer survivors (see Table 1). During the 12-weekly group sessions, participants will have opportunities for facilitated physical activities. The goal will be to provide fitness instruction and safe and appropriate opportunities for exercising. These sessions will include a warm-up, 25 min of dance fitness, 20 min of resistance training using body weight and elastic exercise bands, a cool-down, and stretching. The exercise routine and musical playlist will be modified based on participant feedback and instructor assessment. Participants will be provided with options for decreased intensity of physical activity to accommodate individual differences. Participants will be encouraged to try several of the exercises at home and to engage in moderate intensity physical activity, like walking at least 90 min per week in between the weekly group sessions. Longer-term

changes in everyday activities such as walking, jogging, swimming, and climbing stairs rather than taking elevators will also be encouraged.

In addition to providing users with culturally-tailored healthy recipes and menu suggestions, the intervention will provide information about the importance meeting nutritional requirements by selecting foods from all the food groups with an emphasis on reducing intake of simple sugars and concentrated fats. Guidelines provided by the American Cancer Society (ACS) for nutrition and physical activity for cancer survivors will be incorporated [23]. The intervention will also utilize information, and graphics from the USDA's ChooseMyPlate program will be used as a guide to provide practical information to help consumers build healthier diets with user-friendly nutrition information [24].

Physical activity guidelines will be followed that were developed by HHS and ACS. The 2008 Physical Activity Guidelines for Americans emphasize that all adults should avoid inactivity [25]. Some physical activity is better than none, and adults who participate in any amount of physical activity gain some health benefits. For substantial health benefits, adults should do at least 150 min (2 h and 30 min) a week of moderate-intensity, or 75 min (1 h and 15 min) a week of vigorous-intensity aerobic physical activity, or an equivalent combination of moderate- and vigorous-intensity aerobic activity. Aerobic activity should be performed in episodes of at least 10 min, and preferably, it should be spread throughout the week [25]. The intervention developed and evaluated in this pilot study will focus on moderate intensity physical activity and will include health messages about the importance of routine physical activity for weight management and the potential health benefits.

Participants will receive a 12-week technology-based intervention that will use wrist-worn Fitbit Blaze PA monitoring devices (San Francisco, CA) paired with accompanying Fitbit app and web interface (see Figs. 1 and 2). Fitbit devices have the ability to measure a variety of activity-related outcomes including steps, distance, heart rate, active minutes, calories, and sleep (see Table 2). Additionally, users can access the app or web interface to track food intake, socialize with friends, and complete group challenges. Fitbit devices have shown high validity and reliability (ICC 0.71–1.00) [26–28], and a growing amount of research has successfully incorporated Fitbit use into technology-based lifestyle interventions to increase physical activity, reduce overweight/obesity, and manage chronic conditions such as cancer [29–35].

Participants will be instructed to wear a FitBit device on their non-dominant hand. A FitBit Wireless USB Dongle will first be used to register and set up the Fitbit device. Participants will then wirelessly synchronize their data on a day-to-day basis through a mobile phone or PC, and this data will be captured during the weekly interfaces. For those that do not have smartphones to synchronize FitBit activity, the dongle will ensure the information is captured during the weekly interface.

Participants will be encouraged to wear the pedometer during waking hours on a daily basis for the whole 12 week intervention period to record their daily steps and provide feedback and motivation to increase their physical activity participation. The Fitbit enhanced pedometer is designed to wirelessly synchronize with computer software to download

stored physical activity information. Participants will be encouraged to synchronize and download their data on a weekly basis. During the home visit to implement the intervention, participants will be taught how to use the Fitbit device and the associated internet based feedback and monitoring technology. The research team will have access to all de-identified participant Fitbit data and will monitor individual adherence with the intervention. Participants will receive information about how to use the Fitbit watch and how to download the app onto their smartphone in order to monitor and track their physical activity and diet. Users will also be able to track minutes of daily physical activity which will enable them to receive feedback on their activity. The women will be encouraged to call the study team to receive technical assistance with the Fitbit watch. Moreover, beginning one week after the baseline visit and throughout the 6-month intervention period, research assistants will contact enrolled women once monthly, to encourage them to continue using the Fitbit watch and to assess technical difficulties.

2.5.1. Process measures—Process evaluation measures will include the number of women (1) that attend the focus group sessions; (2) invited to participate in the study; (3) participation the study; (4) meet the eligibility criteria; (5) complete the 6-month follow-up questionnaire and (6) the number of sessions attended.

2.5.2. Outcome measures—Since feasibility issues are of interest in this pilot study, the outcomes of interest include optimal strategies for participant recruitment, the number of intervention sessions attended, and participant use of the Fitbit watch to monitor their physical activity. Other outcomes include: changes in weight (kg) and body mass index from baseline to 6 months, changes in consumption of healthy foods, decreased alcohol consumption, increased physical activity (minutes per week), changes in quality of life, and changes in knowledge, attitudes, and self-efficacy about cancer recurrence risk reduction through lifestyle changes. However, we acknowledge that, in this pilot study, the number of participants may not be large enough to detect statistically significant differences in some of these outcomes.

2.5.3. Measures

2.5.3.1. Physical activity assessment: Physical activity will be assessed with the modified Paffenbarger Harvard Alumni Questionnaire [36]. Quality of life will be assessed using the 20 item short form survey (SF-20) developed for the Medical Outcomes Study (http://www.rand.org/health/surveys_tools/mos/20-item-short-form/survey-instrument.html). The SF-20 is broken down into six domains: Physical Functioning; Role Functioning; Social Functioning; Mental Health; Health Perceptions; Pain. Exercise ability [38] and exercise barriers [39] will be assessed in the survey, while the Outcome Expectations for Exercise (OEE) scales [40] will be used to assess expectations. The BREQ-32 Questionnaire [41] will be used to better understand why the participants exercise or are motivated to engage in physical activity.

Health literacy will be measured at baseline using the Shortened Test of Functional Health Literacy in Adults (S-TOFHLA), which has been found to have good reliability and validity [37]. A Social Support Scale [42] will also be used to measure the participants' social

support for diet and exercise behaviors. The Cancer Risk Reduction and Cancer Survivorship questionnaire will be used to assess attitudes toward cancer recurrence, physical activity, and perceived behavioral control [43].

The height and weight of each participant will be measured at baseline and 6-months using a stadiometer and a digital floor scale. BMI will be calculated as weight in kilograms/height in meters squared. Body weight will be measured to the nearest 0.1 kilogram (kg) and height without shoes to the nearest millimeter by a trained research assistant.

2.5.3.2. Nutritional status assessment: We will use validated instruments to assess all outcomes. Dietary intake will be assessed using a validated food frequency questionnaire (FFQ) [44]. Detailed questions capture frequency and portion sizes of consumption of 246 individual foods and mixed items, beverages, and dietary supplements over the previous 12 months, with additional questions on food preparation. Nutrient intake will be computed from FFQ data using Nutrition Data System for Research software (Nutrition Coordinating Center, University of Minnesota, Minneapolis, MN).

2.6. Dietary assessment

Nutrient and caloric intake will be analyzed using Nutritionist Pro (Version 7.0, First Data Bank Division, Hearst Corp, San Bruno, CA).

2.7. Anthropometry and body composition

A stadiometer was used to measure height at baseline. Heights are accurate to 1 mm. A beam balance was used to determine the participants' weights. Weight was accurate to 0.1 kg. Body mass index (BMI) was calculated using the standard formula – weight (kg) divided by height²/m. Measurement of the waist circumference was done at a level midpoint between the lower rib margin and iliac crest.

The participants' body composition will be measured using the Tanita Body Composition Analyzer; Model MC 780U (Arlington Heights, IL.). Maximum weight of the analyzer is 270 kg, fat ratio 0.1% increments, and range of fat ratio 1%–75%. Body composition will be determined by using bioelectrical impedance analysis. An electrical impedance of total body water is used to calculate fat-free mass and body fat. A frequency of 50 kHz is passed from the analyzer through foot to foot and hand to hand contact with the analyzer and the individual. Percent body fat will be calculated from body fat.

At the start (baseline) of the study, height, weight, and waist circumference were measured and BMI and body fat percentage calculated. Weight and waist circumference will be measured and BMI and body fat percentage calculated every four (4) weeks.

2.7.1. Retention plan—Participants will receive a \$50 gift card for attending the baseline visit and a \$50 gift card for completing the six-month follow-up questionnaire. Data will be collected from participants at the time of the baseline visit and at 6-months. Participants will be asked to complete a self-administered questionnaire at both time points. The baseline and 6-month follow-up visit study questionnaires will be self-administered and take about 60 min to complete. Members of the research team will be available to respond to any

questions that the participants may have and to help ensure that each questionnaire is complete and has legible written responses. Before obtaining the informed consent, we will thoroughly explain the study procedures, emphasize importance of follow-up. Other strategies to improve participant retention include sending birthday and holiday cards, encouragement to contact study staff to address any barrier to compliance with the study, reminder calls, and convenient times for visits. One participant will also be eligible to win a small door prize (\$10 value) at each weekly session. This study anticipates that at least 75% of participants in the lifestyle intervention will complete the intervention sessions that focus on nutritional status and physical activity.

All data collected as part of the proposed study will be carefully monitored for completeness. The quality of the data will be maximized through pre-coded responses and computerized internal consistency checks and range checks of specified values. All information from study questionnaires and height and weight measures that is entered into computer databases will be checked for data entry errors and any discrepancies will be resolved. Data will be regularly backed up and stored in a secure location. Personally identifying information, such as names and addresses, will be kept separate from survey responses and will be kept under lock and key.

2.8. Data analyses

The general approach that will be taken for statistical analysis of the data is as follows. Initially, cross-tabulations of the data will be performed using SAS. Both chi-square and Fisher's exact tests will be used to examine the statistical significance of observed associations. Recruitment patterns will be examined by socioeconomic level (household income, education), age, and time since completion of medical and surgical therapy for uterine cancer. The number of intervention sessions attended will be examined along with participant use of the Fitbit watch to monitor physical activity and track food and beverage consumption. After cross-tabulations and exploratory analyses of the survey data are completed, characteristics of the participants will be examined, including self-reported age, education, annual household income, marital status, number of people in the household, health literacy; weight, BMI, quality of life, self-reported behaviors (consumption of fruits, vegetables, whole grains, saturated fats, added sugars, and refined grains; alcohol consumption, time spent in past week in moderate-intensity physical activity), and self-efficacy in cancer risk reduction through lifestyle changes. Paired t-tests will be used to determine the statistical significance of changes in weight, BMI, quality of life; knowledge, attitudes, and self-efficacy about cancer recurrence risk reduction through lifestyle changes; and behavioral survey items between baseline and follow-up. Linear models will be used to compare changes in these variables between baseline and 6 months while controlling for potential confounding variables. The dependent variable in the linear model to test the first hypothesis (the lifestyle intervention will correspond with a statistically significant increase in daily/weekly physical activity from baseline to six months, mediated by a decrease in perceptions of exercise barriers and improvements in physical activity knowledge and awareness) will be measured using data from Fitbit output in physical activity minutes/day and minutes/week. While controlling for participant demographics and changes in nutrition and body composition, primary predictor variables will include changes in the pre-post-test

survey at baseline and six months, to include physical activity attitudes, perceived exercise ability and exercise barriers. The second hypothesis (the lifestyle intervention will be associated with a statistically significant improvement in quality of life in pre/post-test comparisons, and that this quality of life improvement will be mediated by improvements in nutritional status) will be tested in a linear model using the change in the Quality of Life domain scores (dependent variable) at baseline and six months, with change in nutritional status (ASA24 scores) as a primary predictor, while controlling for physical activity outcomes and changes in body composition.

2.8.1. Sample size and power analysis—The targeted sample size for this pilot study was based upon our prior experience with similar studies and upon our review of the literature on similar studies that targeted white uterine cancer survivors and African American breast cancer survivors. In the study by Von Gruenigen et al. [6], weight in kg was 115.4 (SD 29.4) at baseline and 112.1 (SD 29.4) at 12-months on average in the intervention group, for a 3.5 kg decrease in weight. Using a sample size calculator for the effect size for a before-after study [45], a two-sided alpha value of 0.05, and a type II error rate of 0.2, and assuming that the SD of the change in weight (kg) is about 8–9, we estimated that a sample size of 50 uterine cancer survivors would allow for detecting a 3.5 kg decrease in weight over the intervention period. In the study by Basen-Engquist et al. [5], exercise increased from 13.64 min per week (SD 12.48) at baseline to 15.88 min per week (SD 10.64) at 6-months on average in the intervention group, for an increase of 2.24 min per week. Using a two-sided alpha value of 0.05, and a type II error rate of 0.2, and assuming that the SD of the change in physical activity (minutes per week) is about 5–6, we estimated that a sample size of 50 survivors would allow for detecting an increase in physical activity of about 2.2 min per week. We acknowledge that the sample size may not be large enough to detect statistically significant differences in some of the outcomes of interest. The study will provide important information about the feasibility of participant recruitment and feasibility of a culturally tailored, lifestyle intervention for African American uterine cancer survivors, and pave the way for a future larger-scale trial with a randomized design.

2.8.2. Limitations—Some inaccuracies in self-reported dietary information are likely. The 6-month intervention/observation period will not allow for longer term changes in healthy behaviors to be assessed.

2.8.3. Strengths—The involvement of the College of Nursing CAB is a strength of this study. CAB members will provide input to help plan and conduct the study to ensure that data collection instruments and intervention materials are culturally appropriate and meet the needs of African American women.

3. Results

The current pilot study will provide information about feasibility issues in recruitment, participation, outcome measures, quality of life improvement, and response rate at the 6-month follow-up. In the fall of 2017, we plan to apply for funding for a multiple-year, multi-center randomized controlled trial that includes other Medical Centers in the South and Southeastern US with sizeable populations of African American uterine cancer

survivors. Collaboration on a larger scale will ensure sufficient sample sizes and improve the generalizability of the intervention research findings.

4. Human subjects

The study has been approved by the Augusta University Institutional Review Board. Individuals will be excluded if clearance for their participation is not received from their gyn-oncologist or if they have a history of myocardial infarction, angina, coronary artery bypass graft surgery, coronary angioplasty, congestive heart failure; a condition that significantly limits their exercise such as active cancer treatment, peripheral arterial disease, severe orthopedic problems, or painful arthritis; or if they report a history of alcohol abuse, substance abuse, or major psychiatric illness. Women will also be excluded if they are participating in a structured weight loss program or taking weight loss medication, or if they ever had weight loss surgery.

Some women may experience pain in their lower extremities due to physical activity such as walking. Such risks will be minimized by providing women with additional options for physical activity such as swimming or stretching exercises. Further, the physical activity intervention will include a warm up and cool down and will be individualized to allow for decreased intensity.

The possible benefits of the study are weight loss through healthy eating, consuming fewer calories, limiting alcohol intake, and physical activity. Practice of healthy lifestyle intervention could continue to provide benefits to the participant.

5. Discussion

To our knowledge this study is one of few that will report the effects of a culturally-tailored lifestyle intervention developed specifically for African-American uterine cancer survivors. Previous research either did not integrate culturally tailored interventions for AA, or did not specifically target AA populations.

Rossi et al. [8] conducted a feasibility study of a physical activity intervention for obese, endometrial cancer survivors to evaluate whether the intervention improved physical activity behavior, physical function, waist circumference, and quality of life. Obese endometrial cancer survivors from Bronx, NY were assigned to either a 12-week physical activity intervention of behavioral counseling, physical activity and home-based walking ($n = 25$), or a delayed intervention control group ($n = 15$) [8]. Only 10 (38%) of the participants were non-Hispanic black. Participants reported walking 118 ± 79 min/ week at home. There were large effect sizes for the improvements in the 6-min walk test (22 ± 17 m vs. 1 ± 22 m), waist circumference (-5.3 ± 5.3 cm vs. 2.6 ± 6.7 cm), walking self-efficacy, and quality of life compared to the control group [8].

Other research used an uncontrolled pre-/post-test design. Basen-Engquist et al. [5] examined the efficacy of a home-based exercise intervention for stage I-IIIa endometrial cancer survivors in Houston, TX. Basen-Engquist et al. [5] analyzed the differential effects of the home-based intervention on obese and non-obese participants. Of the one hundred

participants, only seven of the women (7%) were non-Hispanic AA. The outcomes of interest were anthropometrics, exercise behavior, fitness, heart rate, blood pressure, and quality of life. Significant improvements were seen in exercise behavior, resting heart rate, systolic blood pressure, and multiple quality of life domains.

Von Gruenigen et al. [6] conducted a randomized controlled trial of a lifestyle intervention designed for obese endometrial cancer patients in Cleveland, Ohio, where participants (n = 45) were randomized to a 6-month intervention or usual care group. All but one of the participants were white. The intervention group received group and individual counseling. The primary outcome was weight change. Secondary outcomes included physical activity, leisure score index, and nutrient intake (3-day food records). Quantitative vitamin C and folate intake were used to assess fruit/vegetable intake. At 12 months, the intervention group lost 3.5 kg compared to a 1.4 kg gain in the control group (p = 0.018). No differences were observed in vitamin C or folate intake.

During the SUCCEED Trial, 75 overweight and obese endometrial cancer survivors were randomized to either a 6-month lifestyle intervention or usual care group, only 5 of the women (6.7%) were AA [7]. The intervention group received education and counseling for six months [7]. The first 10 sessions were held weekly and were followed by 6 bi-weekly sessions. The primary outcome was weight change at 12 months. Secondary outcomes included fruit/vegetable servings per day and physical activity. At 6-months, mean difference in weight change between the intervention and usual care groups at 6 months was -4.4 kg (95% CI -5.3, -3.5), p < 0.001 and at 12 months was -4.6 kg (95% CI -5.8, -3.5), p < 0.001. Mean difference in fruit and vegetable servings was 0.91 servings per day at 6 months and 0.92 at 12 months (p < 0.001).

The data derived from this pilot study will provide the process information necessary to implement a larger randomized control trial that will test the efficacy of the intervention. We acknowledge that the success of this pilot will largely be determined by our ability to recruit this hard to reach population. Research shows that engaging community members throughout the study process increases community buy-in thereby increasing participant enrollment [46]. The CAB, which is primarily comprised of AA women, support uterine cancer survivorship as a priority health need of the target population. Therefore, we will continue to engage the CAB to guide us on effective recruitment strategies and on the development of a culturally-appropriate intervention. This study will enroll patients from a large academic medical center, where the greatest number of uterine cancer survivors are seen. We anticipate that because of the trust relationship between the women and their gyn-oncologists that the physicians will be instrumental to our meeting the recruitment goal. We recognize that unlike survivors of other cancers (breast, colon) AA survivors of uterine cancer may be apprehensive about discussing their cancer experience among unfamiliar people. We hope that over time the shared experience of uterine cancer survivorship among the group of women will create a bond that reduces possible apprehension regarding study participation.

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Abbreviations

AA	African-American
ACS	American Cancer Society
AICR	American Institute on Cancer Research
AU	Augusta University
BMI	body mass index
CAB	College of Nursing Community Advisory Board
CSRA	Central Savannah River Area
HBM	Health Belief Model
HHS	U.S Department of Health and Human Services

FFQ	Food frequency questionnaire
IRB	Institutional Review Board
PA	physical activity
S-TOFHLA	Shortened Test of Functional Health Literacy in Adults
SUCCEED	Survivors of Uterine Cancer Empowered by Exercise and Healthy diet
TPB	Theory of Planned Behavior
UCSs	uterine cancer survivors
USDA	U.S. Department of Agriculture



Fig. 1.
FitBit Blaze PA monitoring device.



Fig. 2.
FitBit app and web interface.

Table 1

Summary of educational intervention.

Summary of Educational Intervention
Goal setting
Diet record
Physical activity record
Uterine cancer educational information
Time management (barriers to action)
Triggers/cues to action
Culturally tailored recipes (barriers to action)
Menu suggestions
Meal planning
Food labels
Grocery shopping
Dietary information
Portion sizes
Eating out in social situations (barriers to action)
Health messaging on importance of healthy diet/physical activity (benefits to action)
Use of Fitbit watch to monitor physical activity

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Table 2

FitBit watch, app, and web interface measures.

•	Steps
•	Distance
•	Floors
•	Heart Rate
•	Active Minutes
•	Calorie Intake
•	Sleep
•	Food Intake
•	Friends/Social
•	Group Challenges

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