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Virtual Weight Loss Program for African-American Breast Cancer Survivors

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NCI CCC
A Comprehensive Cancer Center Designated by the National Cancer Institute

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LIST OF ABBREVIATIONS

AA	African-American
BMI	Body mass index
CINJ	Cancer Institute of New Jersey
DCIS	Ductal carcinoma in-situ
DSMP	Data Safety Monitoring Plan
HbA1C	Hemoglobin A1C
HRQOL	Health Related Quality of Life
IRB	Institutional Review Board
PI	Principal Investigator
QoL	Quality of life
NCI	National Cancer Institute
NIH	National Institutes of Health
OHRS	Office of Human Research Services
OHRP	Office of Human Research Protection
RCT	Randomized controlled trial
RWJMS	Robert Wood Johnson Medical School
SCT	Social Cognitive Theory
WCHS	Women's Circle of Health Study

1. Purpose/Specific Objectives

Our long-term goal is to help African-American (AA) breast cancer survivors maintain a healthy weight, thereby decreasing their morbidity and mortality and improving their quality of life (QoL). The purpose of this proposed study is to pilot test the use of a free commercial web-based weight loss program (SparkPeople) in AA breast cancer survivors. This program is congruent with constructs of Social Cognitive Theory (SCT). Although this extremely popular online program has been freely available since 2005, there are no prospective scientific evaluations of this program, particularly among AA populations, who are especially in need of efficient weight control interventions.

1.1 Primary Objective

Determine feasibility of using a free online commercial weight loss program (SparkPeople) in AA breast cancer survivors, as measured by:

1. Accrual: % patients recruited and completing baseline assessments.
2. Study retention: % patients completing 6 month follow-up assessment
3. Intervention adherence and sustainability (measured at 3,6,9,12 months):
    a. Use of website- number of log-ins, time spent, and use of features such as food diaries, joining teams, posting on message boards (provided by SparkPeople)
    b. Use of Fitbit monitor- % patients who wore the monitor and synced data
    c. Satisfaction (e.g., ease of use of website, usefulness of content, extra training and support needed) and barriers to participation (e.g., lack of computer access, lack of skills, time, interest, etc.)

Hypothesis: Using the online weight loss program will be feasible in AA breast cancer survivors (defined as $\geq$ 75% recruitment rate and $\geq$ 80% retention rate).

1.2 Secondary Objective

Collect preliminary data on effect sizes of changes in our outcomes and potential mediators associated with the use of the online weight loss program. Change from baseline to 3 and 6 months in:

1. Weight, BMI, waist circumference (primary)
2. Caloric intake and physical activity levels
3. Cardiopulmonary fitness and cardiometabolic risk factors (blood pressure, lipids, HbA1C)
4. Quality of life
5. SCT constructs (social support, self-efficacy, outcome expectations, self-regulation)

2. Background and Significance

Approximately 70% of women diagnosed with breast cancer are overweight, and many women with pre- and postmenopausal breast cancer gain weight after diagnosis.[1] Obesity, defined as a body mass index (BMI) $\geq$ 30 kg/m^2, is associated with later stage breast cancer diagnosis, higher breast cancer recurrence and death, higher prevalence of comorbid conditions (e.g., cardiovascular disease and diabetes), and poorer health and quality of life (QoL).[2,3] The epidemic of obesity in the US presents a major pubic health challenge, particularly for African-American (AA) women, who have the highest prevalence of obesity (at 58.6%, and expected to rise to 71% by 2020).[4,5] AA women are diagnosed at later breast cancer stage, which is partially explained by their higher obesity rates.[6] They also have the highest breast cancer mortality and shortest survival of any racial/ethnic group.[7] While it is unclear whether obesity in AA women contributes to their increased breast cancer mortality,[8-10] abdominal obesity is associated with all-cause mortality in AA women,[10] who have the highest prevalence of diabetes, diabetes-related complications (e.g., visual impairment and end-stage renal disease), hypertension, and death from diabetes and heart disease.[11,12] Weight loss after breast cancer diagnosis may lower rates of recurrence,[13] and it improves fitness, fatigue, and quality of life.[14] As little as 3%-5% loss of baseline weight can reduce risk of diabetes, hypertension, and

dyslipidemia.[15] Therefore, weight management after cancer diagnosis and treatment in AA breast cancer survivors is crucial to reduce disparities in breast cancer outcomes and improve their QoL.

Losing weight is extremely difficult, and physicians are poorly trained or lack time to provide behavioral counseling for weight loss. In fact, rates of weight counseling in primary care have declined, particularly in patients with obesity.[16] Intensive lifestyle interventions have shown promise in promoting weight loss and improving lifestyle behaviors, functional status, and QoL in breast cancer survivors.[1] To date, only 3 trials (2 RCT and 1 single-arm) have recruited significant numbers of AA breast cancer survivors (mean weight loss at 6 months -2.6 kg to -5.57 kg), and all of these used face-to-face sessions and weekly telephone counseling.[17-20] However, many patients lack access, financial resources, or time to participate in face-to-face weight loss programs, and the intensive resources needed for this mode of delivery limit its practicality, reach and sustainability. Additionally, many patients sometimes avoid these comprehensive programs because of need for frequent face-to-face interactions with practitioners (including dieticians) that may express weight bias (a negative attitude toward, belief about, or behavior against people who are overweight or obese).[21,22] Studies in other populations have demonstrated successful weight loss outcomes with web-based programs as adjuncts or replacements to face-to-face or telephone-based behavioral counseling, but these programs use their own privately developed online sites, which limits reproducibility.[23-25] Meanwhile, free commercial online weight loss programs have become extremely popular, due to their convenience, accessibility, and social support tools. For example, SparkPeople.com, with over 13 million hits per month, features educational and motivational articles and videos, self-monitoring tools, incentives, and social support communities (including discussion forums, teams, challenges, and expert blogs), with options for daily/weekly content delivered to members' email. We chose this program, which has been freely available since 2005, because it follows the new obesity guidelines that recommend a comprehensive lifestyle program including reduced calorie diet, increased physical activity, and behavioral strategies (e.g, self-monitoring of weight, diet, physical activity).[15] It emphasizes safe weight loss, including setting reasonable weight loss goals, exercising safely, and receiving medical attention regularly when needed. Additionally, it offers unique opportunities for social support (includes encouragement, motivation, information, and shared experiences),[26] a component that promotes weight loss,[27] including the SparkTeams Breast Cancer Survivors (995 members) and African American Newbies (7,133 members). Members in SparkPeople value its convenience, anonymity, and non-judgmental interactions,[26] which may make this program especially appealing to AA breast cancer survivors, who may not share personal health information to family and community members.[28] The SparkPeople program is congruent with constructs of **social cognitive theory** (including **behavioral capability** [improving knowledge and skills through articles and videos]; **self-efficacy** [with strategies to increase confidence in one's ability to take action including goal setting, self-monitoring, and reinforcements]; **observational learning** [through watching videos and learning from others on message boards]; **outcome expectations** [anticipated outcomes of behavior]; and **reinforcement** [incentives such as *SparkPoints* are awarded for using the tools and features on the site]).[29]

Retrospective analyses of SparkPeople found it provided accurate information[30] and valuable social support to its members.[26] More active usage of the website was associated with greater weight loss.[31] One prospective trial, in mostly white women at increased risk for breast cancer, used telephone coaching and training to use SparkPeople's self-monitoring tools.[32] While this trial did not have direct measures of the SparkPeople website use, 64% of participants found the website helpful, and in that group, women lost mean 5.6 kg weight (SD 3.0) at 12 weeks and increased their total activity by 70 min/week (SD 40). This program used accelerometers to collect physical activity at baseline and 12 weeks, but it did not monitor activity during the trial, and the accelerometers were not web-integrated. There are no other prospective scientific evaluations of this website, particularly in AA breast cancer survivors who are especially in need of efficient weight control interventions. Thus, this study is needed,

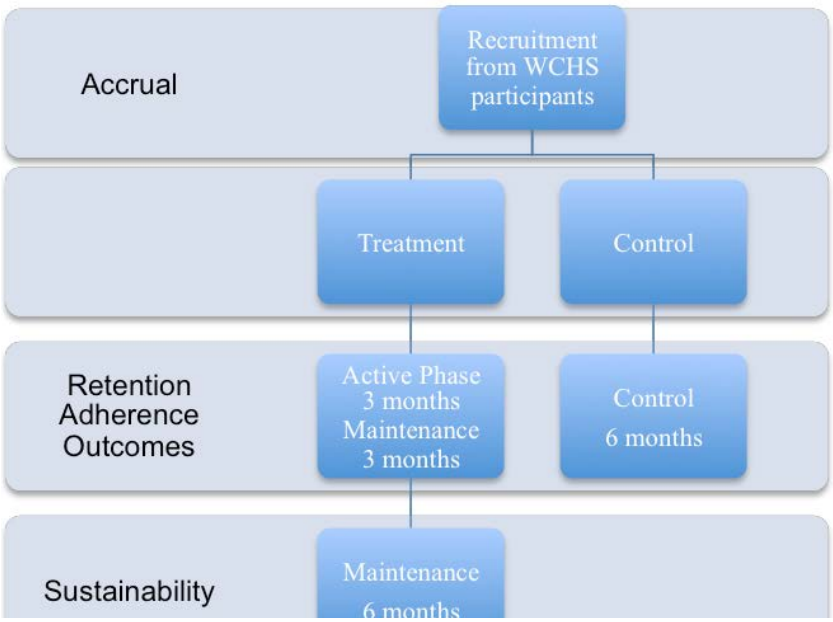
timely, and has great potential impact to improve the clinical management of long-term breast cancer survivors struggling with weight control. Programs like this one offer the option of replacing costly traditional weight loss interventions with ones that are easily disseminated, less burdensome and potentially more sustainable.

3. Participating Institutions

This study will take place at Rutgers-Robert Wood Johnson Medical School, Rutgers Cancer Institute of New Jersey, Rutgers Cancer Institute of New Jersey at University Hospital, and Rutgers-New Jersey Medical School. Additionally, Sisters Network of Central New Jersey has agreed to distribute flyers to their members.

4. Experimental Design and Methods

We will pilot-test the use of the free online SparkPeople weight loss program using a randomized controlled study in approximately 70 AA overweight or obese breast cancer survivors to test feasibility and estimate effect sizes for a future larger scale R01 RCT. This 6-month randomized controlled trial will randomize subjects 1:1 to one of the 2 treatment groups (SparkPeople or wait-list control), stratified by age (older vs. younger than 60 years), with equal allocation between intervention and control arms to ensure similar patient populations in each group. Accrual, retention and treatment outcome measures will be assessed at 0, 3 and 6 months. After 6 months, the control group will receive the intervention, while the original treatment group will be followed for sustainability (Figure 1). Having a delayed intervention will enhance recruitment and provides greater sample size to



Intervention

All subjects will receive a handout of their personalized goals for weight loss, diet, and physical activity with instructions to proceed slowly and as tolerated, starting with mild-moderate exercise 10 min/day with stepwise increase in time and intensity, as per recommended guidelines.[15] All subjects will be provided with and trained in the use of the Fitbit monitoring device, a wrist-worn activity tracker that monitors steps taken, distance travelled, stairs climbed, calories burned, and minutes spent doing intense activity and sleeping. It pairs with a website or smartphone, and wirelessly uploads activity data to provide the user visualization of daily activity patterns. Treatment group participants (N=35) will also receive one 30-minute session with the research assistant for training on how to use the SparkPeople website (described in **Significance**). They may request an additional training session if needed. They will be instructed to self-monitor their diet at least weekly (using SparkPeople) and physical activity levels daily (using the Fitbit Force monitor, which integrates with SparkPeople website).

The SCT-based intervention includes an active phase (3 months SparkPeople plus reminders) and a maintenance phase (3 months SparkPeople without reminders). Because more active usage of the website (at least weekly) is associated with greater weight loss, and low compliance and high attrition is a main limitation of web-based weight loss programs, treatment group subjects will receive weekly motivational reminders (via email, text, or phone, based on patient preference) for 3 months to log onto the web site, do their self-monitoring, and use the social support tools. After 3 months, subjects enter the maintenance phase without reminders. Follow-up meetings with the research assistant during data collection meetings will also serve as reinforcements. After 6 months, control group participants (N~35) will receive the SparkPeople treatment, while those in the original treatment group will be followed for 6 months to assess sustainability.

4.1 Duration of Study

Each participant will be on study for 12 months. We estimate two years to complete the entire study, from IRB approval to completion of analysis.

5. Patient Selection Criteria

Seventy AA long-term breast cancer survivors with BMI at least 25 kg/m^2 will be recruited via two methods: (1) among participants in an on-going population-based case-control study of breast cancer in AA women based at Rutgers Cancer Institute of New Jersey, the Women's Circle of Health Study (WCHS; Bandera, PI; IRB protocol# 2-2004-5053) and (2) via distribution of study flyers at cancer support group organizations and community clinics in New Jersey. Only WCHS cases agreeing to participate in future studies will be invited to participate in this new study and asked to signed a new informed consent specific for this protocol. In WCHS, cases are identified through the New Jersey State Cancer Registry using rapid case ascertainment. Cases are age 21-75 years, residing in ten counties in NJ, able to understand and read English, with no cognitive impairments and no previous history of cancer other than non-melanoma skin cancer, and diagnosed with primary, histologically confirmed invasive breast cancer (Stage I-III) or ductal carcinoma in situ (DCIS or Stage 0). As of 2012, there were 289 AA invasive breast cancer cases in this study (99% Stage 0 to III), of which 221 were obese (BMI $\geq$ 30). For the community recruitment method, flyers will be mailed and emailed to cancer support group organizations (e.g., Sister's Network), other community organizations (e.g., churches), community practices and clinics in New Jersey, and academic or other health care organizations (e.g., the Cancer Institute of New Jersey, Robert Wood Johnson Medical School, New Jersey Medical School). Flyers will be posted at these sites both physically at their location and digitally on their social media platforms and/or distributed to members/patients to decide if they are interested in participating. Interested patients who see the study flyer in the community may directly contact the study team by phone or email or by mailing the cut-off portion of the flyer indicating their interest and contact information. A follow-up call will be placed to these interested patients. To be eligible, participants must have home Internet access or a smartphone. While reaching 100% of the target population is not feasible, the use of smart phones and home broadband connection is exponentially increasing in all race/ethnic groups. According to recent PEW data, 80% of African-Americans (AAs) use the internet, and 72% of AAs have home broadband internet connection or a smartphone. Internet use is relatively high even among AAs with low education (63%) or household income <$30,000 (75%).[33]

5.1 Inclusion Criteria

A patient/subject is eligible for enrollment if all of the following inclusion criteria are met:

a. Patient is 21-75 years old
b. Patients must have evidence of histologically confirmed breast cancer, Stage 0 (DCIS), I, II or III, and be at least 2 years post diagnosis.
c. Patient is self-identified as African-American.
d. Patient is overweight or obese (BMI $\geq$ 25 kg/m^2).

e. Patient is able to understand and read English.
f. Patient must have home Internet or smartphone access.
g. Patient must give informed consent for this new study.

5.2 Exclusion Criteria

A patient /subject will not be eligible for this study if any of the following exclusion criteria are met:

a. Patient has a serious medical condition (e.g., stroke, liver or renal failure, congestive heart failure, myocardial infarction or cardiac surgery in past year, angina pectoris) that would compromise the safety of the patient or compromise the patient's ability to complete the study, at the discretion of the investigator.
b. Patient has serious psychiatric condition (e.g., bipolar disorder, schizophrenia or other psychosis, bulimia or anorexia nervosa, suicide attempt within 6 months or current active suicidal ideation) that would compromise the patient's ability to complete the study, at the discretion of the investigator.
c. Patient has severe disabilities limiting moderate physical activity, such as severe orthopedic conditions.
d. Patient is planning major surgery within the next 6 months.
e. Patient is taking medications or supplements for weight loss currently or within the past 3 months.
f. Patient has successfully lost 5% of body weight in the previous 6 months or has had bariatric surgery.
g. Patient is pregnant, breastfeeding, has given birth within the last 3 months or planning pregnancy within the next 12 months. If participant becomes pregnant during the course of the study, she will be removed from further participation.
h. Patient is anticipating leaving the area within the next 12 months.

5.3 Inclusion of Women and Minorities

This study's target population is African-American breast cancer survivors with obesity. Patient participants will only include women, as breast cancer occurs predominantly in women. All of the women will be African-American. We are targeting African-American women because they have the highest prevalence of obesity, breast cancer mortality, and highest rates of obesity-related comorbidities of any racial/ethnic group.

5.4 Participation of Children

Children (individuals under 21) will be excluded from the proposed research as the main research topic to be studied (obesity in breast cancer survivors) is not relevant to children.

5.5 Sources or Methods of Recruitment

Seventy AA long-term breast cancer survivors with BMI at least 25 kg/m^2 will be recruited via two methods: (1) among participants in an on-going population-based case-control study of breast cancer in AA women based at Rutgers Cancer Institute of New Jersey; and (2) via distribution of study flyers at cancer support group organizations (e.g., Sister's Network), other community organizations (e.g., churches), community practices and clinics in New Jersey, and academic or other health care organizations (e.g., the Cancer Institute of New Jersey, Robert Wood Johnson Medical School, New Jersey Medical School, Rutgers Cancer Institute of New Jersey at University Hospital). Only eligible women in the WCHS (Bandera, PI, IRB protocol# 2-2004-5053) who have expressed permission to be contacted for future studies will be sent an invitational letter with a brochure, informing them that they will receive a telephone call from research staff to confirm receipt of the letter and to further explain the study. Breast cancer survivors, who see the study flyer in the community, may directly contact the study team or mail back the cut-off portion of the flyer indicating their interest and contact

information. In the proposed study, we will recruit long-term early stage survivors (Stage 0 to Stage III) after 2 years of diagnosis, so that they have completed all primary treatment, which may cause side effects that affect nutritional, physical, and psychological well-being, and interfere with participant's motivation and success in a weight loss intervention. All patients who are interested and meet eligibility requirements will be sent a medical release form and patient informed consent form. A research assistant will make a follow up call to review the forms with the potential subjects.

5.6 Study Enrollment Procedures

A research assistant will call the potential subjects and thoroughly explain all aspects of the research study, assure confidentiality, and answer any patient questions. Subjects will sign the informed consent and release of medical information form for us to obtain medical clearance from their physician to participate in the study. It is necessary to obtain informed consent by telephone prior to commencing any research procedures because we are obtaining medical clearance (which contains PHI) from the subjects' physician prior to collecting any baseline data. They will mail the forms back to the research team in a pre-paid, addressed envelope. The research team will then fax the medical release and medical clearance form to the physician for completion. After informed consent and medical clearance are obtained, the subject will meet with a research assistant for baseline data collection and measurements (described below in Section 6). During this meeting, the research assistant will confirm understanding of the research study and answer any further questions. Subjects will also receive a Fitbit physical activity monitor, trained on its use, and instructed to perform their usual activity over the next week to obtain their baseline activity level. After all baseline data are collected, the participant will be randomized to the treatment or wait-list control group. To avoid selection and assignment bias, our biostatistician will develop 2 randomization schedules, one for each age strata, with assignment kept in separately sealed envelopes (approximately 35 subjects per treatment group split within strata). After completion of the baseline assessment, the research associate will open an envelope in designated order and assign patients. Control participants will be told they will get an internet treatment in 6 months, but they will not be told about SparkPeople. All subjects will be given a lab order for blood sample collection at Quest Laboratories unless their physician provided lab results that were taken within the past 12 months. Treatment group subjects will schedule a second meeting with the research assistant for the hands on training of SparkPeople. Control group participants will meet again with the research assistant at 3, 6, 9, and 12 months, for collection of outcome measures and completion of researcher administered surveys and interviews. Intervention group participants will meet with the research assistant again at 3, 6, and 12 months. At 9 months, the intervention group participants will receive a phone call to update their contact and clinical information, and answer selected questions from the survey (Strategies used to lose weight and satisfaction and barriers with Fitbit and SparkPeople website.)

6. Study Parameters/Measures

In addition to demographic and clinical information, the following will be collected at 0, 3, 6, 9 and 12 months from control group participants and at 0,3,6,12 months from intervention group participants:

Outcome Measures

- Weight (goal of at least 5% decrease within 6 months),[15] height, BMI, waist circumference- Anthropometric measurements will be taken using the WCHS protocol and measuring instruments (measuring tape, Tanita® BF-684W scale), as described in detail elsewhere.[34] PRIMARY OUTCOME
- Caloric intake- measured by 24-hour recall administered by research assistant using Sparkpeople.com tool. Goal is to have a reduced calorie diet to induce an energy deficit $\geq$500 kcal/day.[15]
- Physical activity levels- direct data downloads from the Fitbit server via the Fitabase research platform provide the research team an objective assessment of daily activity of participants.

Goal is for at least 150 minutes per week of moderate-high intense activity, per current guidelines.[15, 35]

- Cardiopulmonary fitness- changes in cardiopulmonary fitness will be measured by the 6-min walk test.[36]
- Cardiometabolic risk factors- Blood pressure will be measured following standardized procedures. Fasting serum lipids, glucose and HbA1C will be obtained through Quest Laboratory (no more than 30 ml blood) 3 times during the year (at 0, 6, 12 months).
- Quality of life- using Quality of Life in Adult Cancer Survivors Scale, which measures physical, psychological, social, and spiritual domains, and has good reliability (internal consistency ICC 0.98), concurrent validity, and responsiveness to change in health status.[37,38,39]
- Social Cognitive Theory variables- The Health Beliefs Survey measures nutrition and physical activity-related self-efficacy, outcome expectations, self-regulation, and social support. It has good reliability (cronbach's alpha 0.72-0.96), predictive validity, and sensitivity to change.[40,41]

Process Measures

- Accrual: % patients recruited and completing baseline assessments.
- Study retention: % patients completing follow-up assessments at 6-months.
- Intervention adherence (at 3 and 6 months in treatment group, 9 and 12 months in control group) and sustainability (at 9, 12 months in treatment group) by tracking:
  1. Use of website- number of log-ins to website, time spent on site, and use of features such as food diaries, joining teams, posting on message boards (objective data provided by SparkPeople)
  2. Use of Fitbit monitor- % patients who wore the monitor and synced data
  3. Satisfaction (e.g., ease of use of website, usefulness of content, extra training and support needed), barriers to participation (e.g., lack of computer access, lack of skills, time, interest, etc.), and any use of internet tools or other strategies outside of intervention will be measured by semi-structured interviews. If control subjects use SparkPeople on their own, their activity can also be monitored.

7. Data Collection and Records to be Kept

7.1 Research Charts

Information obtained from all subjects will include demographic, medical history, self-report questionnaire and recall responses, anthropometric measurements, cardiopulmonary fitness, blood pressure, blood measurements, physical activity data downloaded from the Fitbit server, and use of SparkPeople website provided by SparkPeople. All data for each participant will be identified with an identification number, and the key linking patient name and identification number will be kept password protected in a separate file. The key that links patient names with identification numbers will be kept only as long as specific use requires and then will be destroyed when all necessary linkages between data collection instruments have been accomplished.

All data will be entered or scanned into a relational database on a firewall-protected Rutgers-RWJMS server. Rutgers-RWJMS employs Virtual Local Area Networks (VLAN) and Virtual Private Networks (VPN), in conjunction with Intrusion Detection Systems (IDS), encryption techniques and virus protection and detection controls. Access to the server is only allowed for users with authorization and a user-specific password in order to log in the system. The data kept on this server is in a folder with the Project name. Access to this folder is restricted to the PI and system administrator. Access by anyone else to the PI's data folder has to be specifically authorized by the PI and executed by the system administrator. All subsets of the original database that are created for analyses will be

created on this server. At the request of the PI, access will be granted to the research team to download the dataset to his/her workstation. These workstations are connected to the Rutgers-RWJMS server and are password protected. As soon as analyses are completed, the results will be moved to the PI's data folder on the server and removed from the workstation.

7.2 Reports

Publications and annual reports for submission to the IRB will be written by the PI, co-investigator, or study personnel using the data captured in the study.

8. Data and Safety Monitoring

There are no adverse events anticipated from this pilot intervention that deviate from procedures ordinarily encountered in daily life or during the performance of routine physical examinations. Lifestyle interventions with diet, exercise, and behavioral therapy are already being widely used for behavior change among patients. The SparkPeople website is accessed by over 13 million members monthly, and it has been shown to provide accurate information. All unexpected and/or serious adverse events occurring during the active portion of the intervention will be reported to the Rutgers CINJ Office of Human Research Services and the Rutgers IRB in accordance with IRB policy.

All data, including scanned copies of signed consent forms, will be entered into the University secured server described above. Data will not contain personal identifiers. The PI and the biostatistician will oversee all data management. The data safety and monitoring plan will be reviewed and approved by the Rutgers Institutional Review Board prior to accrual of human subjects.

9. Statistical Considerations

9.1 Primary and Secondary Hypotheses and Endpoints

Aim 1: Is the intervention trial feasible?

Hypothesis: Using the online SparkPeople program will be feasible in AA breast cancer survivors (defined as $\geq$ 75% recruitment rate and $\geq$ 80% retention rate).

Other web-based obesity interventions found a recruitment rate of 50%,[42] however, we expect our rate to be higher as the study sample is an activated population who have already participated in a previous study, met eligibility criteria, and have expressed interest in future studies.

AIM 2: **What is the potential effect size of changes in our outcomes (at 3 and 6 months)?**

The purpose is to calculate effect sizes for a larger randomized trial, as this feasibility study is not powered to detect an intervention effect. However, with 35 participants per treatment arm and standard deviations equal to those observed in Longin et al's 2012 on-line weight loss program (SD=6.3 kg),[43] we have 80% power to detect an effect of intervention on weight loss such that the intervention arm participants' weights decrease, on average, 4.3 kgs more than the wait list participants' weight decrease. With respect to percent weight loss from baseline (Longin et al., SD=5.9%), we have 80% power to detect a decrease at least 4.0% more among the intervention arm. With only 25 subjects, these effect sizes would become 5.0 kg and 4.7%, respectively. Longin et al.'s one-armed trial resulted in an average weight loss of 5.0 kg or 4.9% from baseline among obese participants, similar to our detectable level with only 25 subjects. In fact, we expect a dropout rate much closer to 18% (average attrition rates of other web-based lifestyle interventions),[24] rather than this much higher dropout rate of 28.6 percent. Thus, we should have sufficient power to detect an intervention effect unless the control group sees significant weight loss.

9.2 Sample Size Justification

We plan to recruit a maximum of 70 eligible women. If 70 women are enrolled and complete baseline surveys by the time 107 possible participants are approached and at least 50 of these participants

complete follow-up surveys, then we will declare the study feasible. We chose the sample size and decision rules so that the probability of declaring feasibility would be approximately 5% under unacceptable rates of acceptance and retention and exceed 95% under acceptable rates of acceptance and retention. If the true recruitment and retention rates are 57% and 60%, respectively, which we consider to be too low to warrant further research, then the probability of declaring feasibility would be 5%. If the true recruitment and retention rates are 75% and 80%, respectively, which we consider large enough to warrant further research, then the probability of declaring feasibility would be over 95% (Table 2). The planned sample size provides sufficient power to declare feasibility.

Table 2. Probability of declaring feasibility under various assumptions

Feasibility Component	Unacceptable Rate	Acceptable Rate	Decision rule for claiming feasibility per outcome	Prob. Declare Feasible under Unacceptable Rates	Prob. Declare Feasible under Acceptable Rates
Accrual Rate	57%	75%	If 70 women have completed baseline surveys by the 107th (inclusive) reached	5%	99%
Retention Rate	60%	80%	If 50/70 participants complete follow-up surveys at 6 months	3%	97%

9.3 Statistical Analysis

In order to plan for a larger randomized clinical trial, we will characterize changes in outcomes using standard methods (percentages, means, medians) stratified by study arm. In exploratory analyses, we will utilize mixed linear models to assess differences between treatment arms in changes in weight, caloric intake, physical activity, cardiopulmonary fitness, cardiometabolic risk factors, quality of life, and SCT constructs. We will also assess correlations among outcomes, examine potential moderators and mediators of outcomes (e.g., patient demographics, baseline BMI, QoL, SCT constructs), and characterize the patterns of missing data. The percent variation explained and the significance of potential mediators will be examined by combining effects from component regression models.[44,45] In particular, the product of the two regression coefficients governing the mediating path (from intervention group to mediating variable and mediating variable to outcome) will be multiplied together and compared to the overall effect of intervention group. Bootstrap procedures will be utilized to formally test for significance of the mediating pathway.

9.4 Compliance and Missing Data

We will measure intervention adherence (at 3 and 6 months in treatment group, 9 and12 months in control group) and sustainability (at 9,12 months in treatment group) by tracking:

1. Use of website (number of log-ins to website, time spent on site, and use of features such as food diaries, joining teams, posting on message boards (objective data provided by SparkPeople);
2. Use of Fitbit monitor (% subjects who wore the monitor and synced data).
3. Satisfaction (e.g., ease of use of website, usefulness of content, extra training and support needed), barriers to participation (e.g., lack of computer access, lack of skills, time, interest, etc.), and any use of internet tools or other strategies outside of intervention will be measured by semi-structured interviews.

Weekly motivational messages will be sent and additional training with use of the SparkPeople site will be provided as needed. Information about barriers and reasons for drop out will be collected, making us well-positioned to comment on the support needed to maintain adherence with a free

commercial online program. To minimize loss to follow up, multiple contact information of participants (cell/home phone numbers and email addresses) as well as contact information for up to 3 close relatives/friends and patient's primary care doctor and oncologist will be obtained at baseline and verified at follow-up time points. If participants cannot complete a follow-up visit, they will be asked to complete the questionnaires by phone or online. They may also be given the option to meet at their physician's office to complete the anthropometric measurements.

10. Human Subjects

This human subject research meets the definition of a clinical trial, as it is a randomized controlled trial comparing an online program (SparkPeople) to a control group in decreasing weight among 70 African-American breast cancer survivors with obesity. This research is not an NIH-defined Phase III clinical trial as the SparkPeople program with its lifestyle recommendations is already being widely used for weight loss and behavior change among the general public. However, this program has never been scientifically evaluated.

10.1 Subject Population

The proposed study subject population (N~ 70) will be recruited among participants in an on-going population-based case-control study of breast cancer in AA women based at Rutgers Cancer Institute of New Jersey, the Women's Circle of Health Study (Bandera, PI), or recruited from the community, as described above under section 5. To be eligible, participants must be 21-75 years old, black race, overweight or obese (BMI $\geq$ 25), long-term early stage breast cancer survivors (Stage 0 to Stage III) after 2 years of diagnosis, so that they have completed all initial therapies and have returned to their usual life. They must speak and understand English, and have home internet access or a smartphone. We will exclude individuals with serious medical (e.g., stroke, liver or renal failure, congestive heart failure, myocardial infarction or cardiac surgery in past year, angina pectoris) or psychiatric conditions (e.g., bipolar disorder, schizophrenia or other psychosis, bulimia or anorexia nervosa, suicide attempt within 6 months or current active suicidal ideation), and severe disabilities limiting moderate physical activity and basic functional exercises, such as severe orthopedic conditions. Other persons excluded include: those planning major surgery, taking medications or supplements for weight loss within the past 3 months, those who have successfully lost 5% of body weight in the previous 6 months or have had bariatric surgery, are pregnant, breastfeeding, given birth within the last 3 months or planning pregnancy within the next 2 years, or are anticipating leaving the area within the next 1 year.

All subjects will receive a handout of their goals for weight loss, diet, and physical activity based on current American Heart Association recommended management of obesity guidelines. Additionally all subjects will receive a Fitbit activity monitor to measure their activity levels. Treatment group participants (N=35) will receive in-person training on use of the SparkPeople website and instructed to self-monitor their diet (using SparkPeople) and physical activity levels, using a Fitbit monitor, which integrates with the SparkPeople website. At baseline, 3, 6, 9 (control participants only) and 12 months, all subjects will answer questions on a survey and undergo measurements of weight, % body fat, waist circumference, cardiopulmonary fitness, and blood pressure. The intervention group participants will receive a phone call at 9 months to update their contact and clinical information, and answer selected questions from the survey (Strategies used to lose weight and satisfaction and barriers with Fitbit and SparkPeople website.) Additionally, blood will be collected at Quest Laboratories for lipids, glucose and hemoglobin A1C.

10.2 Potential Risks

This is a minimal risk study, which engenders little deviation from procedures ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. There are no test articles (investigational new drugs, devices, or biologics) to be used in this study.

Lifestyle interventions with diet, exercise, and behavioral therapy are already being widely used for behavior change among patients. The SparkPeople website is accessed by over 13 million members monthly, and it has been shown to provide accurate information.

There may be potential risks due to exertion of exercises recommended at SparkPeople. Though uncommon, these include such things as shortness of breath, abnormal blood pressure responses, fainting, nausea/vomiting, irregularities in heartbeat, or injury. The SparkPeople program emphasizes safe weight loss, including setting reasonable weight loss goals, exercising safely, and receiving medical attention regularly when needed. In addition, all subjects will be given handouts with goals for exercise and instructed to proceed slowly and as tolerated, starting with mild-moderate exercise 10 min/day with stepwise increase in time and intensity, as per recommended guidelines. Any subjects that experience adverse events from exercise will be advised to contact their primary care physician. There may also be skin discoloration, discomfort or soreness at the venipuncture site, which typically resolves on its own.

Breach of confidentiality of participants is another potential risk. In order to ensure the protection of personal health information for each subject of the study, there will be no personal identifiers on any of the data collection instruments. Each subject will be assigned a unique subject identification number and this unique identifying number will serve as a link and will be secured separately. A master file which links the subject identification number with personal identifiers (name, date of birth, address, phone number) will be maintained separately in a password protected file on the University secured server. These data will be kept only as long as specific use requires and then will be destroyed when all necessary linkages between data collection instruments have been accomplished. The protocol poses no other physical, psychological, financial, legal or other risk to patients.

10.3 Consent Procedures

The PI will send eligible patients from the WCHS a written letter and brochure about the study, informing them that they will receive a telephone call from research staff to confirm receipt of the letter and to further explain the study. Additionally breast cancer survivors, who see the study flyer in the community, may directly contact the study team or mail back the cut-off portion of the flyer indicating their interest and contact information. All patients who are interested and meet eligibility requirements will be sent informed consent and medical release authorization documents by mail. The research assistant will follow up with a phone call to thoroughly explain all aspects of the research study, assure confidentiality, and answer any patient questions. The signed, informed consent along with the medical release authorization will be mailed back to the research team in a prepaid addressed envelope. The research team will then fax the medical release authorization and medical clearance form to the subject's physician for completion. After informed consent and medical clearance are obtained, the subject will meet with a research assistant for baseline data collection and measurements. During this first face-to-face meeting, the research assistant will confirm understanding of the research study and answer any further questions. Signed, informed consent will be obtained before obtaining any baseline data or measurements.

10.4 Potential Benefits

This intervention, if found feasible and successful, may help breast cancer survivors with obesity lose weight, improve cardiac risk factors and increase their quality of life. For these patients, they may gain greater knowledge regarding nutrition and exercise, and improved self-efficacy in following healthy diet and exercise recommendations. If effective, this program offers promise as a convenient and efficient weight loss program that can be easily and widely disseminated to other breast cancer survivors.

10.5 Risk-Benefit Ratio

The minimal risk involved in this study is reasonable in relation to the anticipated benefits of the research. Alternatives to participating are not participating; choosing not to participate does not affect patients' medical care. Results of the proposed research will inform the feasibility and preliminary effectiveness of a free web-based program to decrease weight in AA breast cancer survivors with obesity. Data from this study will be used to generate sample size estimates and refine research procedures for a future R01 application that will evaluate the efficacy of the SparkPeople program in decreasing weight among AA breast cancer survivors. Results of the study may provide important tools to help reduce their comorbidities, improve quality and length of survival, and decrease health disparities. In relation to the importance of the knowledge that reasonably may be expected to result, the risks to subjects are very low.

10.6 Gender and Minorities

All participants will be female and African-American. We are targeting African-American women because they have the highest prevalence of obesity, breast cancer mortality, and highest rates of obesity-related comorbidities of any racial/ethnic group.

10.7 Compensation

Participants will be provided with a free Fitbit physical activity monitor. In addition to receiving the Fitbit monitoring device as incentive, all patients will receive $25 after each completed in-person visit. They will also be reimbursed for parking, if needed. Additionally, participants will be rewarded with another $10 gift card to complete blood draws at Quest labs.

11. Economic/Financial Considerations

This study is financed through a grant from the National Cancer Institute R21CA191431.

12. Publication of Research Findings

The policies and procedures of the Rutgers University legal department (see: Investigator's Handbook) will govern publication of the trial. It is expected that the results of this study will be submitted for publication in a timely manner following the conclusion. The PI and all co-authors will review any abstract or manuscript prior to submission or use.

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