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Protocol and Recruitment Results from a Randomized Controlled Trial Comparing Group Phone-Based versus Newsletter Interventions for Weight Loss Maintenance among Rural Breast Cancer Survivors

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Abstract

Obesity is a risk factor for breast cancer recurrence and death. Women who reside in rural areas have higher obesity prevalence and suffer from breast cancer treatment-related disparities compared to urban women. The objective of this 5-year randomized controlled trial is to compare methods for delivering extended care for weight loss maintenance among rural breast cancer survivors. Group phone-based counseling via conference calls addresses access barriers, is more cost-effective than individual phone counseling, and provides group support which may be ideal for rural breast cancer survivors who are more likely to have unmet support needs. Women (n = 210) diagnosed with Stage 0 to III breast cancer in the past 10 years who are ≥ 3 months out from initial cancer treatments, have a BMI 27–45 kg/m^2, and have physician clearance were enrolled from multiple cancer centers. During Phase I (months 0 to 6), all women receive a behavioral weight loss intervention delivered through group phone sessions. Women who successfully lose 5% of weight enter Phase II (months 6 to 18) and are randomized to one of two extended care arms: continued group phone-based treatment or a mail-based newsletter. During Phase III, no contact is made (months 18 to 24). The primary outcome is weight loss maintenance from 6 to 18 months. Secondary outcomes include quality of life, serum biomarkers, and cost-effectiveness. This study will provide essential information in how to reach rural survivors in future efforts to establish weight loss support for breast cancer survivors as a standard of care.

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Keywords

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1. Introduction

Body weight has a negative impact on breast cancer outcome, with women who are obese at diagnosis having higher risk of recurrence and death compared to their normal weight counterparts [1–4]. In addition, weight gain is common after diagnosis particularly in women who receive systemic therapy and become post-menopausal [5, 6] with some [7] but not all [8] studies showing increased risk of recurrence with clinically significant weight gain. Biochemical mediators of obesity-associated risk are thought to be hormones, insulin, and adipocytokines [9, 10]. Obesity-related comorbid conditions such as heart disease and type 2 diabetes are also a common concern in the long-term care of breast cancer survivors [11, 12].

Given the strong observational evidence linking obesity and physical inactivity [13–15] with poor breast cancer prognosis, large-scale randomized clinical trials are needed to test the effect of intentional weight loss on breast cancer recurrence and mortality. In the meantime, intermediate trials are needed to demonstrate ability to produce long-term weight loss maintenance and associated biomarker modulation in a cost-efficient way that can also be extended to underserved and hard-to-reach survivors.

Nearly 20% of women in the U.S. reside in a rural area [16] representing one of the largest medically underserved populations in the nation [17] and one of the most understudied groups of breast cancer survivors [18]. Rural women are more likely to be obese [19] and have lower physical activity levels [20–22]. Delivering evidence-based behavioral weight control treatment to rural areas remains a challenge. The standard treatment schedule typically includes face-to-face weekly sessions for 16 to 26 weeks [23] followed by extended maintenance care for 1 to 2 years [23, 24]. Barriers in rural areas to this traditional high intensity approach include transportation distance and limited availability of trained health counselors. Among web- and phone-based alternatives, phone-based treatment has the greatest reach for rural areas where televideo capacity is limited to sparsely located clinics and only 55% of residents have home broadband internet access [25]. Moreover, studies have demonstrated greater weight loss maintenance with individual phone counseling compared to mail [26], email, and web-based interventions [27, 28].

Compared to individual phone counseling, group phone counseling via conference calls has the benefit of diminishing costs and capitalizing on the mechanisms of in-person groups by allowing participants to interact with each other in real time [29]. Group treatment has been shown to outperform individual treatment for weight loss [30, 31] presumably due to group support, problem-solving, and accountability [29, 32]. Group phone counseling may be especially ideal for rural breast cancer survivors who often report unmet support needs and no contact with other survivors [18, 33, 34].

This study is a 5-year randomized controlled trial in rural breast cancer survivors designed to examine two alternatives for delivering extended care for weight loss maintenance after a 6-month group phone-based weight loss phase. Subsequent to the weight loss phase, participants are randomized into one of two weight loss maintenance strategies: continued group phone counseling or a mailed newsletter comparison arm. The primary endpoint is weight loss maintenance from 6 to 18 months. Secondary endpoints include quality of life, serum biomarkers, and cost-effectiveness across the two arms. The main hypothesis is that continued group phone counseling is more effective as a weight loss maintenance strategy than switching to a lower-cost newsletter approach. The cost-effectiveness endpoint will explicitly value the benefit gained from the more expensive group phone counseling.

2. Methods

2.1 Overview

The overarching objective of the study is to test a delivery strategy that produces meaningful long-term weight loss maintenance, improved quality of life, and breast cancer biomarker modulation, with far-reaching potential for dissemination to rural and otherwise hard-to-reach populations of breast cancer survivors. The study involves 3 phases: 1) a 6-month weight loss phase (0 to 6 months) where all participants receive group phone sessions, 2) a 12-month weight loss maintenance phase (6 to 18 months) where participants are randomized to continued group phone sessions or the newsletter comparison condition, and 3) a 6-month no contact follow-up phase (18 to 24 months) to evaluate sustained effects of the intervention after the two types of extended care ends. The primary endpoint is weight change from 6 to 18 months. Participants are recruited in 8 cohorts, with one phone group and one newsletter group in each cohort.

2.2. Eligibility criteria

Eligible participants are post-menopausal female breast cancer survivors with a body mass index (BMI) of 27–45 kg/m^2, age ≤ 75 years old, who have been diagnosed with Stage 0-IIIc disease within the past 10 years (except stage 0 with mastectomy only), have completed all local and systemic therapy (including herceptin) at least 3 months prior to entry, and have clearance from their oncologist or current medical provider to participate in a weight control study. Women can be on or off anti-hormone therapy. Participants must reside in a rural area according to the Rural-Urban Commuting Area (RUCA) Codes, Urban Influence Codes, amount of agricultural income, and/or individual commuting patterns [35]. Participants must be able to walk briskly unassisted and without serious medical risk, and all participants complete a 6 minute walk test as a screening tool to confirm self-report ability to walk. Women with pending joint replacements, serious cardiac or pulmonary conditions (e.g., congestive heart failure, chronic obstructive pulmonary disease), and insulin-dependent diabetes are excluded. Participants must have access to a telephone and be weight stable within ten pounds three months prior to entry with no ongoing participation in another formal weight loss program, current use of pharmacotherapy for weight loss, or a history of bariatric surgery. Participants who have serious food allergies or are on a special diet preventing consumption of recommended diet are excluded. Participants who screen positive for current substance abuse [36], major depression [37], binge eating disorder [38], or

serious psychiatric conditions are also excluded as they are not deemed good candidates for a behavioral weight loss program.

2.3. Participant Recruitment

Recruitment occurred between October 2011 and September 2013 in collaboration with eleven regional cancer centers, hospitals, or clinics in the states of Kansas, Nebraska, and Iowa. Local cancer center partners include members of the Midwest Cancer Alliance, a network based out of the University of Kansas Cancer Center with the goal to foster cancer clinical trials and supportive care throughout the region, and NCI Community Cancer Centers in Nebraska and Iowa. Institutional Review Board (IRB) approval and a HIPPA waiver was granted by the University of Kansas Medical Center and approved at each site. Each collaborating cancer center or clinic provided names and addresses of patients treated for breast cancer in the past 10 years and a cover letter signed by a treating physician introducing the study to accompany the mailing of the study brochure. Brochures were mailed to patients living in rural zip codes only, which ranged from 24% to 99% of all patients seen at each sites. Screening continued until a minimum of 24 women were scheduled for the orientation and baseline visit, with an enrollment goal of 20 to 30 participants per cohort to form two intervention groups ranging in size from 10 to 15 participants. Potential participants responded to the study brochure either by calling the study recruitment phone number or returning an opt-in card by mail with their contact information. Additional recruitment methods included paid newspaper advertisements in 3 of the 11 locations, community presentations, direct physician referrals, local and state-wide media coverage of the investigative team's related research, and a mailing of the brochure by the Mid-Kansas Susan G. Komen Foundation.

2.4. Participant Screening

Potential participants who contacted the study line or returned an opt-in card were screened for eligibility by phone or through a secure online survey sent via e-mail invitation. Women who completed the online survey received a follow-up phone call to complete the initial screening. Women who were eligible after the phone screening were sent a depression screener [37] and medical release form allowing the study team to obtain a chart review confirming their breast cancer diagnosis and treatment history and to speak with the approving physician when necessary. Participants who were eligible and who received written approval by their physician to participate were invited to a study orientation visit held the evening before the baseline assessment visit at the local collaborating cancer centers. At this visit, study staff obtained signed informed consent, confirmed BMI, and conducted the 6 minute walk test. These visits were conducted in two groups for each of the 8 cohorts with a study team of 10–12 staff who traveled to the site.

Figure 1 shows participant flow throughout the screening process and reasons for exclusion. A total of 721 women were screened by phone, of which 688 (95%) had responded to the mailed brochure. After phone screening and chart review of breast cancer history, 257 were eligible. The most common reasons for exclusion were BMI < 27 kg/m^2, inability to exercise (e.g., joint pain, pending knee replacements), and > 10 years since diagnosis. Characteristics of the 210 enrolled participants are shown in Table 1.

2.5. Randomization

Participants were randomized 1:1 to each of the two study arms. Randomization was stratified by cohort and by whether or not the participant was on any medication containing metformin as this could influence change in weight and insulin, one of the main biomarker endpoints. To maintain the same conference call groups from Phase I to Phase II, participants were randomized to groups within study arms at baseline, however, randomization was blinded from both participants and the investigative staff until the beginning of maintenance at 6 months so as not to influence initial treatment response. Participants must return for the 6-month assessment and lose ≥ 5% of baseline weight to be included in Phase II and the primary analysis.

2.6. Intervention Description

2.6.1. Phase I: Weight Loss (0 to 6 months)—The intervention is guided by a social-cognitive framework [39] and incorporates key behavioral strategies including self-monitoring, goal setting, stimulus control, social support and reinforcement, cognitive reframing of unrealistic and negative thoughts, and developing positive expectancies for long-term weight control. The primary objective is to decrease caloric intake and increase physical activity to produce weight loss of approximately 0.4 to 0.9 kg per week, with a study goal of 10% reduction from baseline, followed by maintenance of diet and physical behaviors to sustain a 5 to 10% body weight reduction for 18 months. The intervention is tailored to the special needs of rural women and breast cancer survivors. Within degrees of rurality, there is a continuum of rural culture that is influenced by access difficulties, lack of privacy, isolation, greater poverty, and older populations [40]. These aspects of rural life influence rural values which have been described as conservatism, self-reliance, and orientation toward work, family, and religion [41]. However, traditions and customs vary from town to town and from farm to town. Thus, the intervention highlights the shared identity among rural breast cancer survivors while at the same time attending to differences in culture and values that may exist. Specific breast cancer topics are incorporated addressing special dietary and physical activity topics related to breast cancer risk, body image and reconstruction, and managing late side effects including lymphedema and arthralgia.

Diet: During weight loss, participants are instructed to follow a diet that is reduced to 1200–1500 kcal/day and includes ≥ 5 fruit and vegetable (FV) servings per day, < 25% kcal from fat, and 20–30 g of fiber. To facilitate adherence, participants are instructed to purchase and consume approved prepackaged frozen entrees available in their local grocery stores (< 350 kcal each and < 9 g of fat) or their equivalent (e.g. canned soup), and to add fresh or frozen FVs and calorie-free beverages. In addition, participants are provided with meal replacement shakes to aid weight loss for the first 6 months, after which they were encouraged to purchase and consume a combination of two shakes and/or entrees per day. Prepackaged meals and shakes are affordable at $1 to $4 each, have consistently shown greater weight loss and weight loss maintenance compared to traditional diets that rely completely on individuals preparing all their own meals [42], and result in greater increases in FVs and decreases in fat intake [43, 44].

Physical activity: Physical activity is gradually increased through a guided home-based program. Home-based programs have been shown to produce greater long-term adherence compared to on-site programs [45], and a survey on exercise preferences among rural breast cancer survivors indicated that the majority prefer home-based physical activity, predominantly walking [46]. Moderate intensity physical activity (MVPA) is increased from 15 min/day, 3 days/week to 225 min/week by week 12, consistent with national guidelines for weight control [47]. Using this program, our previous participants have achieved 190 min/week of MVPA at 6 months as measured by accelerometry [48]. Participants are instructed in types of activities (any MVPA lasting 10 min or longer) and strategies to monitor and increase intensity, plan for weather, and increase enjoyment. Symptoms related to lymphedema, arthralgia, and neuropathy are monitored and addressed as is general safety. To enhance functional fitness, the intervention also includes an optional resistance training component using lightweight dumbbells with visual guidance provided by a module-based DVD for breast cancer rehabilitation titled “Strength and Courage ” [49]. The resistance component is light to maintain safety and is not expected to provide benefits for weight loss. Participants receive a Physical Activity Tool Kit including two DVDs, a pedometer, and self-monitoring charts.

Self-monitoring: Throughout the intervention, self-monitoring is emphasized as a key behavioral strategy. Each week, participants send a self-monitoring report to their group leader by voice message, email, or fax including their weight and daily fruit and vegetable servings, prepackaged meals, unplanned snacks, meals out, physical activity minutes, and pedometer steps. One week per month, participants keep a complete food log and count calories using a calorie counter book provided, and return food logs by mail in pre-stamped envelopes. To enhance self-monitoring feedback, participants are sent quarterly reports with charts of their weekly weight and weekly physical activity minutes.

2.6.2. Phase II: Weight Loss Maintenance (6 to 18 months)—Phase II is designed to assist participants in maintaining the diet and physical activity behaviors adopted in Phase I. Participants are given a new calorie goal calculated from the Harris-Benedict equation to sustain their reduced body weight [50], and the physical activity goal stays at 225 min/week for the duration of maintenance. Self-monitoring continues to be a focus of the intervention, and participants send food logs and self-monitoring forms to their group leader weekly. The maintenance phase is less didactic than the weight loss phase and incorporates social support and a social cognitive approach to relapse prevention using the problem-solving model developed by Perri et al for enhancing long-term coping skills for maintaining new habits [32]. Maintenance sessions begin with review of self-monitoring data, followed by a check-in from all group members regarding eating or exercise difficulties experienced since the last meeting. One of these problem situations then became the target for the session, and the leader guided the participants through a 5-step problem-solving approach to generate a solution plan. During the last 10–15 minutes, brief didactic materials are reviewed, however, the majority of the session is dedicated to the group problem-solving exercise and discussion. This allows for extensive attention to participants' immediate concerns and opportunities for peers to provide emotional support and practical solutions to relevant problems.

2.6.3. Format of group phone sessions—During Phase I, all participants receive weekly group phone counseling sessions with 12 to 16 women via conference call for 26 consecutive weeks. Sessions last 60 minutes and begin with an open-ended check-in question, followed by review of weekly self-monitoring data, question and answer time, and end with a new didactic topic of the week addressing diet, physical activity, or behavioral change topics. The group counselor facilitates direct participant interaction and calls on participants by name if necessary. Group cohesiveness is enhanced by reflecting commonalities and facilitating interpersonal learning. Participants are invited to share a biographical page with the group including a picture and brief description of family and interests. During Phase II, participants who are randomized to continued group phone counseling receive 26 bi-weekly phone sessions from 6 to 18 months. Throughout the program, participants are expected to treat sessions as a standing appointment, to call in on-time and stay on the call for the duration of the session, be in a location free of distractions and background noise, and to attend at least 75% of sessions. Participants cover their own costs for cell phone or long distance charges.

2.6.4. Newsletter comparison arm—We chose a mail-based comparison condition as a traditional method for delivering written materials and a less costly alternative to bi-weekly phone sessions with expected benefits beyond a no treatment control [26]. Previous lifestyle interventions with cancer survivors have included mail-based intervention with modest improvement in diet and PA behaviors [51]. The newsletters are mailed bi-weekly at the same frequency as the sessions in the group phone arm and cover the same content as the didactic component of the phone arm with an emphasis on the problem-solving model. Newsletter content also includes recipes, goal-setting tips, and group updates. Participants in the newsletter arm are instructed to continue to send their self-monitoring logs to their group leader by voice message, email, or fax; however no individual contact is made other than acknowledging receipt of logs for those who email them.

2.6.5. Phase III: Transition to Self-Reliance (18 to 24 months)—During Phase III, no sessions or newsletters are provided. Participants are encouraged to continue to self-monitor throughout this period and to send their self-monitoring logs to their group leader. However, no individual contact is made with participants other than briefly responding to questions.

2.6.6. Group leader training and quality assurance—All group leaders have a masters or doctorate in nutrition, exercise science, or psychology and at least 1 year experience with weight management counseling. Initial training includes shadowing an experienced group leader, reviewing recorded sessions, and reading relevant articles and texts as outlined in a standardized group leader manual. Ongoing supervision includes weekly staff meetings with the PI where recorded sessions are listened to, self-monitoring and attendance data are reviewed, and upcoming lessons and problems regarding participant adherence are discussed. Group leaders who are registered dietitians work closely with other group leaders to tailor diet recommendations for participants who are otherwise non-adherent. An independent third party completes session fidelity checklists for at least 25% of recorded sessions with additional review if a counselor falls below threshold. Each group

counselor leads two groups per cohort, one in each arm, to account for any group leader effect in Phase I on outcomes in Phase II.

2.7. Measures

2.7.1 Assessment visit procedures—Study personnel conduct individual in-person assessment visits at the study site for each cohort at 5 time points: baseline, 6, 12, 18, and 24 months. All participants within a cohort are scheduled for the same morning, and weight and serum are obtained after a 10 hour fast.

2.7.2. Medical history and medications—Breast cancer diagnosis and treatment history are confirmed by chart review, with signed consent from participants to release medical information. A complete self-reported medical history and list of medications is collected at baseline and updated at each subsequent visit along with any previously unreported adverse events. Participants bring all their pill bottles to each visit, and research staff query regarding actual amounts taken. All new breast cancer events are reviewed by the study oncologist.

2.7.3. Anthropomorphics—At each visit, participants are weighed in light clothing (shorts and t-shirt) in a fasting state using a calibrated digital scale accurate to 0.1 kg (Befour PS5700). Height is measured at baseline with a stadiometer to calculate BMI. To estimate central adiposity, waist circumference is obtained with 2 measurements per site within 2 cm using standardized procedures [52].

2.7.4. Diet—At baseline, 6-, 12-, and 18-month visits, trained dietitians collect two 24-hour dietary recalls on 2 non-consecutive days of the week including one weekend day using the USDA multiple-pass approach [53]. The first recall occurs during the in-person assessment visit and uses food models, containers, and charts to assist participants with estimating portion size. Participants receive a copy of the charts to take home, and the second recall occurs by phone [54]. Trained dietitians enter the dietary recalls into the Nutrition Data System for Research (NDS-R) 2011 software. Outcome variables include daily energy, % kcal from fat, and fruit and vegetable servings (excluding fried potatoes and fruit juice).

2.7.5. Physical activity—At baseline, 6-, and 18-month visits, both self-report and objective measures of physical activity are collected. The *Paffenbarger Physical Activity Questionnaire* [55] includes questions on stairs climbed, blocks walked, and other sports, leisure, and recreational activities on a typical day or week in the past month. The total number of calories expended per week is derived by summing the kcal expended for each activity using metabolic equivalents from the compendium of physical activities [56]. Participants also wear *GT3X+ Actigraph Accelerometers* (Fort Walton Beach, FL) for 7 consecutive days. The ActiGraph has been shown to provide valid assessments of activity intensity during both walking/running [57] and daily living activities [58]. The device does not have a display screen, and the lack of feedback minimizes any participant reactivity. Participants receive verbal and written instructions accompanied by a wear time log. The data collection interval is set at 10 seconds with a minimum of 10 hours constituting a valid monitored day and 4 days for a valid wear time. Data in counts per minute are downloaded

and number of minutes per day in sedentary (< 100 counts/min), light intensity (100–1951 counts/min) and moderate-to-vigorous intensity (≥ 1952 counts/min) activity are calculated using the cut-points suggested by Matthews et al. [59].

2.7.6. Quality of life and exploratory treatment mediators—Participants complete the following questionnaires at baseline, 6-, and 18-month visits.

The Medical Outcomes Study Short-Form 12 (SF-12): The SF-12 is a general quality of life measure that is highly correlated with the longer SF-36 [60]. It includes two subscales assessing general mental and physical functioning and has demonstrated adequate psychometric properties in a breast cancer population [61].

Breast Cancer Prevention Trial (BCPT) Symptom Scales: The BCPT assesses the severity of 8 physical symptoms with reliable subscales that are clinically relevant to breast cancer treatment, particularly anti-hormone therapy [62]. We included 3 subscales that are potentially modified by physical activity and weight loss, including cognitive (difficulty concentrating), musculoskeletal (joint pain), and vasomotor (hot flashes) symptoms. Items are scored from 0 to 4 based on symptom bother (“not at all” to “extremely”).

Body Image and Relationships Scale (BIRS): *T*he 32-ittem BIRS assesses body image and sexuality specifically for breast cancer survivors [63]. Items are on a 5-point Likert scale (“strongly disagree” to “strongly agree”) and form three reliable subscales: Strength and Health (e.g., “I felt confident I could make myself stronger”), Social Barriers (e.g., “I was uncomfortable with or embarrassed by physical symptoms that I attribute to my breast cancer treatment”), and Appearance and Sexuality (e.g., “I was comfortable with the appearance of my body,” “I have felt sexually attractive.”) The BIRS domains have been shown to improve after a 12-month strength training program for breast cancer survivors [64].

Social Problem-Solving Inventory (SPSI): The 25-item SPSI will be used to explore whether problem solving skills are mediators for the success of the continued group phone-based weight loss maintenance strategy compared to the newsletter strategy. It assesses problem orientation (positive versus negative) and problem-solving style (rational, impulsive, avoidant) [65] and has been shown to predict response to behavioral weight control treatment [66, 67].

2.7.7. Serum—Fasting state is confirmed by asking participants when they arrive at their testing appointment the last time they had something to eat or drink. Blood (15 ml) is collected by a licensed phlebotomist at site laboratories, processed into aliquots of serum, transported back to the University of Kansas Medical Center on dry ice, and stored at −80 degree C following standardized procedures until Clia-approved assays are run. Assays will be conducted in ancillary studies for sex hormones (limited to women who have completed anti-hormone therapy for at least 6 months), fasting insulin, adipokines (leptin, adiponectin), and inflammatory markers (IL-6 and CRP). Pre- and post-study samples will be run together to avoid batch variation and all samples will be run in duplicate.

2.7.8. Costs—Both fixed and variable costs of the interventions are collected. Fixed costs include personnel costs incurred in administration of the program, facility costs, and office supplies and equipment. Fixed personnel costs are tracked using weekly time logs for staff and facility costs are estimated using space allocations and local market rates inclusive of overhead costs. Program costs that vary by participant include counselor time, phone charges, and written materials. Counselor time for conducting sessions is tracked in real time using digital recordings of each conference call. For the mail-based condition, the project manager tracks time to package and mail the written materials. Counselor training and ongoing quality assurance time is documented through weekly logs and allocated to each treatment arm using a relative time ratio. All personnel time is valued at wage rates including benefits. Teleconference charges are tracked based upon billing documents. Costs to produce educational materials are tracked as they are printed and distributed by treatment arm. Participant costs are also a key feature distinguishing treatment arms and include time spent in session, reviewing written materials, self-monitoring/record-keeping, engaging in planned physical activity, and preparing meals. Participants complete a mailed survey quarterly assessing average time in these activities over the past month. Participants' time is valued as their self-reported hourly wage, or if not reported, estimated from their occupation, age, and gender using data from the Bureau of Labor Statistics.

2.8. Strategies to Promote Adherence and Retention

Group leaders contact non-adherent participants following a standardized schedule to promote attendance, adherence, and retention. Within one day of an unexplained session absence, group leaders attempt to contact participants. After two unexplained absences, the group leader sends a standardized letter expressing concern, providing encouragement, and asking for a return phone call. After four unexplained absences, a letter is sent from the project director and primary investigator. This letter acknowledges the difficulty of lifestyle change, how personal situations and time commitments change over time, encourages the participant to re-join the meetings at any time, and emphasizes the importance of returning for the next data collection visit. In addition, group leaders track adherence to self-monitoring and categorize it as complete, partially complete, or none. Group leaders contact participants who fail to report any self-monitoring data two weeks in a row. After 6 consecutive weeks, the project director calls the participant, and after 8 consecutive weeks, a letter is sent that encourages the participant to return to self-monitoring basics and to start by weighing once per week at a minimum. Additional retention strategies include sending participants holiday cards and scheduling data collection visits 6 weeks out. Participants receive a $30 gift card at baseline, 6, and 12 month visits, a $75 gift card at 18 and 24 month visits, and mileage reimbursement for all visits.

2.9. Data Management and Statistical Analyses

2.9.1. Data management—The collected data are stored in the Comprehensive Research Information System (CRIS), a secure web-based Clinical Information Management System that follows a standardized format compliant with NIH and other reporting standards. Data are entered by study personnel according to the protocol and to the U.S. Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.

2.9.2. Sample size justification—Our primary endpoint is weight regain during phase II, that is, the difference between weight at the end of the 18th month and weight at the end of the 6th month of the study. Our primary comparison is continued group phone based versus mail weight maintenance strategies. Based upon results found by Perri et al. [26] we expect to see a 1.2 kg regain in the phone based arm and a 3.7 kg regain in the mail based arm with a common standard deviation of 5.6 kg. Thus, 80 subjects in each arm will provide 80% power to detect a difference between regains with a type I error rate of 0.05 using a two-sample t-test. Our history indicates that during the first 6 months 90% of participants will be retained and 78% will be retained *and* meet a minimum 5% weight loss goal [48]. We also expect 1% attrition due to breast cancer recurrence per 6 months. Women with invasive breast cancer have a risk of recurrence of 2%/year within 3–5 years post diagnosis, despite anti-hormonal therapy and/or chemotherapy, and a late relapse rate of 1.5–2%/year for years 5–10 [68, 69]. Data from participants who recur will not be included in analysis. To account for this potential 23% attrition during the weight loss phase our target enrollment was 208 women into the initial phase. During Phase II, we expect similar retention rates across arms based on our prior trial among rural women showing no differences in attrition at 18 months across phone counseling, face-to-face counseling, and a newsletter only control condition [26].

2.9.3. Primary analysis—A participant's weight regain will be computed as the difference between her weight at the end of the 18^{th} month and her weight at the end of the 6^{th} month. The weight regain variable is a continuous variable that may take on negative or positive numbers. This variable will be positive if the participant gains weight and negative if the participant continues to lose weight from month 6 to month 18. Our research hypothesis is that participants who continue in group phone counseling will have on average lower values in their weight regain variable than participants who switch to the newsletter condition.

A linear regression model of weight regain will be built. Participants who do not reach weight loss of 5% or greater in Phase I will not be included in the primary analysis. Weight regain will be the dependent variable of the model. A dichotomous variable representing maintenance strategy (1= continued phone contact, 0=mail contact) will be created and used as independent variable of the regression model. We hypothesize that the regression coefficient of this variable will be significantly lower than 0. To control for potential confounders, the following variables will also be included as independent variables: baseline weight, amount of weight lost during Phase I, current anti-hormone therapy, education, degree of rurality, and quality of life. In an additional analysis that simultaneously will include weight regains at the ends of the 12^{th}, 18^{th} and 24^{th} months of the study (measured from the end of the 6^{th} month of the study), a random intercept linear model will be built. The dependent variable of this model will be the weight regains. Two dummy variables representing the three time points at which weight regains were measured will be created and used as independent variables. Interaction terms between these dummies and the maintenance strategy variable will also be included in the model and will allow examining whether time is a modifier of the effect of maintenance strategy. Potential confounders will also be controlled for in these analyses.

An advantage of complementing the analysis using random intercept linear models is that these models utilize the information provided by participants with incomplete data, not only information from participants with complete data. These models are robust to the presence of missing values under a missing-at-random assumption. To explore the sensitivity of the model to the presence of possible noningnorable missing data, such as missing data caused by informative drop-out, a joint random intercept linear model that will simultaneously model the weigh-regain variable and the missingness process will be fitted [70].

2.9.4. Secondary analyses—Regression models analogous to those used in the primary analysis will be used to examine the effects of weight maintenance strategy on changes in quality of life, diet and physical activity from the end of 6th to 18th months. Freedman's validation ratio[71] will be used to measure the extent to which possible differences in weight regain during Phase II between weight maintenance strategies might be mediated by changes in psychosocial domains targeted by the weight loss maintenance program (problem-solving skills, vigilance in the self-regulatory process, i.e., self-monitoring). The rationale of this analysis is that we hypothesize that differences in maintenance strategies will occur mainly as a result of different effects on problem-solving skills, and self-monitoring vigilance during Phase II, since the group phone strategy addresses these skills more in-depth than the newsletter strategy. To compute the validation ratio, two linear regression models with weight regain as the dependent variable will be fitted. The first model will include only the maintenance strategy variable as independent variable, and the second model will include both the maintenance strategy and the change in the total SPSI score during Phase II as independent variables. The validation ratio will compare the regression coefficients of the maintenance strategy variable from the two models. The significance of the ratio will be tested through the Fieller's method [71]. The significance of the validation ratio, which implies a significant difference between the regression coefficients, will suggest that changes in psychosocial domains mediate our hypothesized differences between maintenance strategies. Five additional validation ratios will be computed and examined analogously using the five SPSI scales. Similar analyses will be conducted for vigilance with self-monitoring as measured by the proportion of weekly self-monitoring records completed. Incremental cost-effectiveness ratios will be computed from a societal perspective to compare the additional cost needed to increase the primary endpoint. If the primary endpoint does not differ between treatment arms, a cost-minimization analysis will be reported.

3. Discussion

The proposed study has several unique features that will help inform future attempts to disseminate lifestyle interventions to geographically dispersed breast cancer survivors. The group phone-based intervention is intensive with weekly and then bi-weekly sessions and can be delivered to any location. Only a few small studies have targeted weight loss among breast cancer survivors, and most of them have used in-person interventions delivered in groups [72–74] or individually [75] with reported weight losses ranging from 6 kg at 6 months to 9 kg at 12 months. The ongoing ENERGY trial is the largest weight control trial to date among breast cancer survivors in the U.S. with 693 women enrolled. This 2-year

intervention consists of in-person weekly group meetings for 4 months, followed by bi-weekly in-person meetings for 2 months, and monthly in-person meetings thereafter, plus 24–38 individual counseling calls or emails throughout the 2 years [76]. Weight loss results from this trial are pending. The DIANA-5 trial in Italy has enrolled 1208 early stage breast cancer survivors into a Mediterranean diet and physical activity intervention, with monthly group exercise classes, cooking classes, and shared meals, versus a control group [77]. The primary endpoint is breast cancer recurrence and will be assessed through 2015. The German SUCCESS study enrolled 3,547 breast cancer survivors into a 2 × 2 factorial trial comparing the impact of a weight loss intervention versus a control condition subsequent to a randomized chemotherapy phase on disease-free survival [78]. The weight loss intervention is delivered through individual calls with a personal lifestyle coach. Results of this large trial are also pending. Ligibel et al. examined a distance-based weight loss program among 338 breast cancer survivors delivered through 19 individual phone sessions and mailings. Although the trial was stopped early due to loss of funding, preliminary results showed 6% weight loss compared to 0.6% in a control arm [76]. Other previous distance-based lifestyle interventions for cancer survivors have been relatively lower intensity, have combined multiple cancer types, and have not targeted weight loss specifically. The FRESH START trial included a 10-month program of tailored mailed print materials targeting fruit and vegetable consumption, reduced fat intake, and physical activity compared to non-tailored mailed materials among breast and prostate cancer survivors. Results showed improvements in diet and physical activity and modest improvements in BMI (−0.3 vs. 0.1 kg/m^2) [51]. The RENEW trial targeted functional improvements among 641 overweight breast, prostate, and colon cancer survivors age 65 and older with an intervention consisting of a personally tailored workbook, quarterly newsletters, and 15 individual phone sessions over 12 months. The RENEW intervention imposed a slow rate of weight loss due to concerns about sarcopenia in an older population. Functional, diet, and physical activity improvements were observed along with modest weight loss (2.1 in the intervention arm vs. 0.9 kg in the wait-list control arm) [79].

Our distance-based intervention is unique in that it capitalizes on the benefits of real-time group support using simple phone technology that is universally available from anywhere. The weight loss intervention is also designed to produce a high level of weight loss facilitated by intensive self-monitoring and the use of prepackaged meals. In our pilot study we found 14% weight loss (12.5 kg) during the 6 month weight loss phase [48]. Although it is not clear the exact amount of weight loss needed to reduce risk of recurrence or new primary breast cancer in overweight and obese women, preliminary studies suggest a sustained weight loss of 10% [80, 81]. The goal of our maintenance intervention is to sustain weight losses of 10% or more by 18 months. In addition, only women who lose at least 5% of baseline weight enter the randomized phase of the intervention. Thus, the study design is focused on determining the most optimal way of delivering extended maintenance care to prevent weight regain. Without extended contact, weight regain is the norm with approximately 50% of lost weight regained within the first year [82].

We chose two maintenance interventions that require no in-person visits but have a high frequency of bi-weekly contact for the duration of the maintenance phase. Recognizing that weight regain remains a substantial risk beyond the first year and that extended care at some

level may be needed indefinitely, controlling costs of care is crucial for eventual dissemination. Our intervention maximizes the potential for cost-savings from both phone delivery and treating 12–15 women simultaneously. We have explicitly included analysis of costs associated with the two extended care interventions as a step toward translation to clinical practice.

Our study is one of few studies targeting weight control in underserved populations of breast cancer survivors with other trials targeting African Americans [83]. Barriers faced by rural women include limited access to fitness facilities and lower-cost large chain grocery stores, sociocultural dietary norms such as high fat and potluck meals, norms against exercising during leisure time, and in the Midwest plains weather constraints for outdoor exercise with extreme temperatures, high winds, and little shelter [84, 85]. These barriers are in addition to barriers common to lower socioeconomic groups such as job- and family-related stress, lower education and literacy, and poorer access to healthcare [86]. In addition to having higher obesity rates, rural breast cancer survivors appear to have more difficulty adjusting to breast cancer diagnosis. They report lower physical well-being, worse breast cancer-specific quality of life, and higher levels of anxiety and depression compared to their urban counterparts [87, 88]. Many report unmet support needs, decreasing social support over time, and needing assistance with meeting other survivors to help normalize their experiences [34]. At the same time they may also feel isolated due to privacy concerns from living in a small community where a `fish bowl' phenomenon occurs, i.e., people all know one another and are aware that others are interested in knowing and talking about their lives [40]. Group phone counseling provides the opportunity to address lifestyle change with survivors across distant rural communities. Participants in our study live is areas with varying degrees of rurality from large towns to isolated farms, but they share a common identity by being breast cancer survivors in the rural Midwest. By including survivorship topics in the weight control program, shared identity is highlighted and survivorship needs are addressed at the same time participants strive toward common health behavior goals aimed at improving quality of life and longevity.

In summary, this trial will examine the effects of two distance-based strategies for delivering a behavioral weight loss maintenance intervention subsequent to successful weight loss among obese rural breast cancer survivors. It has many unique features including randomization after successful weight loss, the rural survivor target group, the high accessibility and support benefits of the group phone-based delivery strategy, and the collection of cost data. This trial targets a large and often overlooked underserved group of breast cancer survivors who are in high need of this type of intervention due to higher obesity rates, poorer quality of life, and less access to evidence-based weight control programs [89]. The study has potential to demonstrate how to effectively deliver behavioral weight control intervention with clinically meaningful and sustained weight loss, improvements in quality of life, and modulation of important biomarkers among breast cancer survivors who live in small or isolated communities far from academic cancer centers.

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References

[1]. Chlebowski RT, Aiello E, McTiernan A. Weight loss in breast cancer patient management. J Clin Oncol. 2002; 20:1128–43. [PubMed: 11844838]

[2]. Cleveland RJ, Eng SM, Abrahamson PE, Britton JA, Teitelbaum SL, Neugut AI, et al. Weight gain prior to diagnosis and survival from breast cancer. Cancer Epidemiol Biomarkers Prev. 2007; 16:1803–11. [PubMed: 17855698]

[3]. Protani M, Coory M, Martin JH. Effect of obesity on survival of women with breast cancer: systematic review and meta-analysis. Breast Cancer Res Treat. 2010; 123:627–35. [PubMed: 20571870]

[4]. Majed B, Moreau T, Senouci K, Salmon RJ, Fourquet A, Asselain B. Is obesity an independent prognosis factor in woman breast cancer? Breast Cancer Res Treat. 2008; 111:329–42. [PubMed: 17939036]

[5]. Demark-Wahnefried W, Peterson BL, Winer EP, Marks L, Aziz N, Marcom PK, et al. Changes in weight, body composition, and factors influencing energy balance among premenopausal breast cancer patients receiving adjuvant chemotherapy. J Clin Oncol. 2001; 19:2381–9. [PubMed: 11331316]

[6]. Goodwin PJ, Ennis M, Pritchard KI, McCready D, Koo J, Sidlofsky S, et al. Adjuvant treatment and onset of menopause predict weight gain after breast cancer diagnosis. J Clin Oncol. 1999; 17:120–9. [PubMed: 10458225]

[7]. Kroenke CH, Chen WY, Rosner B, Holmes MD. Weight, weight gain, and survival after breast cancer diagnosis. J Clin Oncol. 2005; 23:1370–8. [PubMed: 15684320]

[8]. Caan BJ, Kwan ML, Hartzell G, Castillo A, Slattery ML, Sternfeld B, et al. Pre-diagnosis body mass index, post-diagnosis weight change, and prognosis among women with early stage breast cancer. Cancer Causes Control. 2008; 19:1319–28. [PubMed: 18752034]

[9]. Hursting SD, Lashinger LM, Wheatley KW, Rogers CJ, Colbert LH, Nunez NP, et al. Reducing the weight of cancer: mechanistic targets for breaking the obesity-carcinogenesis link. Best Pract Res Clin Endocrinol Metab. 2008; 22:659–69. [PubMed: 18971125]

[10]. Renehan AG, Roberts DL, Dive C. Obesity and cancer: pathophysiological and biological mechanisms. Arch Physiol Biochem. 2008; 114:71–83. [PubMed: 18465361]

[11]. Bardia A, Arieas ET, Zhang Z, Defilippis A, Tarpinian K, Jeter S, et al. Comparison of breast cancer recurrence risk and cardiovascular disease incidence risk among postmenopausal women with breast cancer. Breast Cancer Res Treat. 2012; 131:907–14. [PubMed: 22042368]

[12]. De Bruijn KM, Arends LR, Hansen BE, Leeflang S, Ruiter R, van Eijck CH. Systematic review and meta-analysis of the association between diabetes mellitus and incidence and mortality in breast and colorectal cancer. Br J Surg. 2013; 100:1421–9. [PubMed: 24037561]

[13]. Irwin ML, McTiernan A, Manson JE, Thomson CA, Sternfeld B, Stefanick ML, et al. Physical activity and survival in postmenopausal women with breast cancer: results from the women's health initiative. Cancer Prev Res (Phila). 2011; 4:522–9. [PubMed: 21464032]

[14]. Holmes MD, Chen WY, Feskanich D, Kroenke CH, Colditz GA. Physical activity and survival after breast cancer diagnosis. JAMA. 2005; 293:2479–86. [PubMed: 15914748]

[15]. Irwin ML, Smith AW, McTiernan A, Ballard-Barbash R, Cronin K, Gilliland FD, et al. Influence of pre- and postdiagnosis physical activity on mortality in breast cancer survivors: the health, eating, activity, and lifestyle study. J Clin Oncol. 2008; 26:3958–64. [PubMed: 18711185]

[16]. U.S. Census Bureau. Federal Register Notice documenting Qualifying Urban Areas for Census. 2000. Available at http://www.access.gpo.gov/su_docs/fedreg/a020501c.html.67

[17]. Eberhardt, MS.; Ingram, DD.; Makuc, DM. Health, United States, 2001. National Center for Health Statistics; Hyattsville, Maryland: 2001. Urban and Rural Health Chartbook.

[18]. Bettencourt BA, Schlegel RJ, Talley AE, Molix LA. The breast cancer experience of rural women: a literature review. Psychooncology. 2007; 16:875–87. [PubMed: 17611958]

[19]. Befort C, Nazir N, Perri MG. Prevalence of obesity among adults from rural and urban areas of the United States: Findings from NHANES (2005–2008). J Rural Health. 2012 On-line first:DOI: 10.1111/j.748-0361.2012.00411.x.

[20]. Patterson PD, Moore CG, Probst JC, Shinogle JA. Obesity and physical inactivity in rural America. J Rural Health. 2004; 20:151–9. [PubMed: 15085629]

[21]. Wilcox S, Castro C, King AC, Housemann R, Brownson RC. Determinants of leisure time physical activity in rural compared with urban older and ethnically diverse women in the United States. J Epidemiol Community Health. 2000; 54:667–72. [PubMed: 10942445]

[22]. Parks SE, Housemann RA, Brownson RC. Differential correlates of physical activity in urban and rural adults of various socioeconomic backgrounds in the United States. J Epidemiol Community Health. 2003; 57:29–35. [PubMed: 12490645]

[23]. Wadden TA, West DS, Neiberg RH, Wing RR, Ryan DH, Johnson KC, et al. One-year weight losses in the Look AHEAD study: factors associated with success. Obesity (Silver Spring). 2009; 17:713–22. [PubMed: 19180071]

[24]. Perri, MG.; Corsica, JA. Improving the maintenance of weight lost in behavioral treatment of obesity. In: Wadden, TA.; Stunkard, A., editors. Handbook of Obesity Treatment. Guilford Press; New York: 2002.

[25]. Broadband Adoption. 2011. Pew Internet and American Life Project.

[26]. Perri MG, Limacher MC, Durning PE, Janicke DM, Lutes LD, Bobroff LB, et al. Extended-care programs for weight management in rural communities: the treatment of obesity in underserved rural settings (TOURS) randomized trial. Arch Intern Med. 2008; 168:2347–54. [PubMed: 19029500]

[27]. van Wier MF, Ariens GA, Dekkers JC, Hendriksen IJ, Smid T, van Mechelen W. Phone and e-mail counselling are effective for weight management in an overweight working population: a randomized controlled trial. BMC public health. 2009; 9:6. [PubMed: 19134171]

[28]. Svetkey LP, Stevens VJ, Brantley PJ, Appel LJ, Hollis JF, Loria CM, et al. Comparison of strategies for sustaining weight loss: the weight loss maintenance randomized controlled trial. JAMA. 2008; 299:1139–48. [PubMed: 18334689]

[29]. Donnelly JE, Smith BK, Dunn L, Mayo MM, Jacobsen DJ, Stewart EE, et al. Comparison of a phone vs clinic approach to achieve 10% weight loss. International journal of obesity (2005). 2007; 31:1270–6. [PubMed: 17325684]

[30]. Befort CA, Donnelly JE, Sullivan DK, Ellerbeck EF, Perri MG. Group versus individual phone-based obesity treatment for rural women. Eating behaviors. 2010; 11:11–7. [PubMed: 19962115]

[31]. Renjilian DA, Perri MG, Nezu AM, McKelvey WF, Shermer RL, Anton SD. Individual versus group therapy for obesity: effects of matching participants to their treatment preferences. J Consult Clin Psychol. 2001; 69:717–21. [PubMed: 11550739]

[32]. Perri MG, Nezu AM, McKelvey WF, Shermer RL, Renjilian DA, Viegener BJ. Relapse prevention training and problem-solving therapy in the long-term management of obesity. J Consult Clin Psychol. 2001; 69:722–6. [PubMed: 11550740]

[33]. Gray RE, James P, Manthorne J, Gould J, Fitch MI. A consultation with Canadian rural women with breast cancer. Health Expectations. 2003; 7:40–50. [PubMed: 14982498]

[34]. Wilson SE, Andersen MR, Meischke H. Meeting the needs of rural breast cancer survivors: what still needs to be done? J Womens Health Gend Based Med. 2000; 9:667–77. [PubMed: 10957755]

[35]. Rural-Urban Commuting Area Codes (RUCAs). Health Resources and Service Administration, Federal Office of Rural Health Policy (ORHP) and U.S. Department of Agriculture, Economic Research Service. Available at http://depts.washington.edu/uwruca/index.php

[36]. Brown RL, Leonard T, Saunders LA, Papasouliotis O. A two-item conjoint screen for alcohol and other drug problems. J Am Board Fam Pract. 2001; 14:95–106. [PubMed: 11314930]

[37]. Hann D, Winter K, Jacobsen P. Measurement of depressive symptoms in cancer patients: evaluation of the Center for Epidemiological Studies Depression Scale (CES-D). J Psychosom Res. 1999; 46:437–43. [PubMed: 10404478]

[38]. Gormally J, Black S, Daston S, Rardin D. The assessment of binge eating severity among obese persons. Addict Behav. 1982; 7:47–55. [PubMed: 7080884]

[39]. Bandura, A. Social Foundation of Thought and Action: A Social Cognitive Theory. Prentice Hall; Englewood Cliffs, NJ: 1986.

[40]. Slama, K. Minnesota Psychologist. 2004. Rural culture is a diversity issue; p. 9-11.

[41]. Wagonfeld, MO. A snapshot of rural and frontier America. In: Stamm, BH., editor. Rural Behavioral Health Care: An Interdisciplinary Guide. American Psychological Association; Washington D.C.: 2003.

[42]. Heymsfield SB, van Mierlo CA, van der Knaap HC, Heo M, Frier HI. Weight management using a meal replacement strategy: meta and pooling analysis from six studies. Int J Obes Relat Metab Disord. 2003; 27:537–49. [PubMed: 12704397]

[43]. Pi-Sunyer FX, Maggio CA, McCarron DA, Reusser ME, Stern JS, Haynes RB, et al. Multicenter randomized trial of a comprehensive prepared meal program in type 2 diabetes. Diabetes Care. 1999; 22:191–7. [PubMed: 10333932]

[44]. Metz JA, Stern JS, Kris-Etherton P, Reusser ME, Morris CD, Hatton DC, et al. A randomized trial of improved weight loss with a prepared meal plan in overweight and obese patients: impact on cardiovascular risk reduction. Arch Intern Med. 2000; 160:2150–8. [PubMed: 10904458]

[45]. Perri MG, Martin AD, Leermakers EA, Sears SF, Notelovitz M. Effects of group- versus home-based exercise in the treatment of obesity. J Consult Clin Psychol. 1997; 65:278–85. [PubMed: 9086691]

[46]. Rogers LQ, Markwell SJ, Verhulst S, McAuley E, Courneya KS. Rural breast cancer survivors: exercise preferences and their determinants. Psychooncology. 2009; 18:412–21. [PubMed: 19241491]

[47]. Haskell WL, Lee IM, Pate RR, Powell KE, Blair SN, Franklin BA, et al. Physical activity and public health: updated recommendation for adults from the American College of Sports Medicine and the American Heart Association. Med Sci Sports Exerc. 2007; 39:1423–34. [PubMed: 17762377]

[48]. Befort CA, Klemp JR, Austin HL, Perri MG, Schmitz KH, Sullivan DK, et al. Outcomes of a weight loss intervention among rural breast cancer survivors. Breast Cancer Res Treat. 2012; 132:631–9. [PubMed: 22198470]

[49]. Poppenberg, J.; Cowden, S. Trifocal Media. 2007. Strength and Courage: Exercises for Breast Cancer Survivors.

[50]. Frankenfield DC, Rowe WA, Smith JS, Cooney RN. Validation of several established equations for resting metabolic rate in obese and nonobese people. J Am Diet Assoc. 2003; 103:1152–9. [PubMed: 12963943]

[51]. Demark-Wahnefried W, Clipp EC, Lipkus IM, Lobach D, Snyder DC, Sloane R, et al. Main outcomes of the FRESH START trial: a sequentially tailored, diet and exercise mailed print intervention among breast and prostate cancer survivors. J Clin Oncol. 2007; 25:2709–18. [PubMed: 17602076]

[52]. Lohman, TG.; Roche, AF.; Martorell, R. Anthropometric standardization reference manual. Human Kinetics Books; Champaign, IL: 1988.

[53]. Conway JM, Ingwersen LA, Vinyard BT, Moshfegh AJ. Effectiveness of the US Department of Agriculture 5-step multiple-pass method in assessing food intake in obese and nonobese women. Am J Clin Nutr. 2003; 77:1171–8. [PubMed: 12716668]

[54]. Tran KM, Johnson RK, Soultanakis RP, Matthews DE. In-person vs telephone-administered multiple-pass 24-hour recalls in women: validation with doubly labeled water. J Am Diet Assoc. 2000; 100:777–83. [PubMed: 10916515]

[55]. Paffenbarger RS Jr. Blair SN, Lee IM, Hyde RT. Measurement of physical activity to assess health effects in free-living populations. Med Sci Sports Exerc. 1993; 25:60–70. [PubMed: 8423758]

[56]. Ainsworth BE, Haskell WL, Herrmann SD, Meckes N, Bassett DR Jr. Tudor-Locke C, et al. 2011 Compendium of Physical Activities: a second update of codes and MET values. Med Sci Sports Exerc. 2011; 43:1575–81. [PubMed: 21681120]

[57]. Brage S, Wedderkopp N, Franks PW, Andersen LB, Froberg K. Reexamination of validity and reliability of the CSA monitor in walking and running. Med Sci Sports Exerc. 2003; 35:1447–54. [PubMed: 12900703]

[58]. Bassett DR Jr. Ainsworth BE, Swartz AM, Strath SJ, O'Brien WL, King GA. Validity of four motion sensors in measuring moderate intensity physical activity. Med Sci Sports Exerc. 2000; 32:S471–80. [PubMed: 10993417]

[59]. Matthews CE, Ainsworth BE, Thompson RW, Bassett DR Jr. Sources of variance in daily physical activity levels as measured by an accelerometer. Med Sci Sports Exerc. 2002; 34:1376–81. [PubMed: 12165695]

[60]. Ware J Jr. Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. Med Care. 1996; 34:220–33. [PubMed: 8628042]

[61]. Carpenter JS, Andrykowski MA. Menopausal symptoms in breast cancer survivors. Oncol Nurs Forum. 1999; 26:1311–7. [PubMed: 10497770]

[62]. Cella D, Land SR, Chang CH, Day R, Costantino JP, Wolmark N, et al. Symptom measurement in the Breast Cancer Prevention Trial (BCPT) (P-1): psychometric properties of a new measure of symptoms for midlife women. Breast Cancer Res Treat. 2008; 109:515–26. [PubMed: 17851765]

[63]. Hormes JM, Lytle LA, Gross CR, Ahmed RL, Troxel AB, Schmitz KH. The body image and relationships scale: development and validation of a measure of body image in female breast cancer survivors. J Clin Oncol. 2008; 26:1269–74. [PubMed: 18323550]

[64]. Speck RM, Gross CR, Hormes JM, Ahmed RL, Lytle LA, Hwang WT, et al. Changes in the Body Image and Relationship Scale following a one-year strength training trial for breast cancer survivors with or at risk for lymphedema. Breast Cancer Res Treat. 2010; 121:421–30. [PubMed: 19771507]

[65]. D'Zurilla, TJ.; Nezu, AM.; Maydeu-Olivares, A. Social Problem-Solving Inventory--Revised: Technical Manual. Multi-Health Systems; North Tonawanda, NY: 2002.

[66]. Befort C, Austin H, Krigel S, Bannit A, Nollen N. Social Problem Solving Inventory predicts success in behavioral weight control. Ann Behav Med. 2010; 39:S145.

[67]. Murawski ME, Milsom VA, Ross KM, Rickel KA, DeBraganza N, Gibbons LM, et al. Problem solving, treatment adherence, and weight-loss outcome among women participating in lifestyle treatment for obesity. Eating behaviors. 2009; 10:146–51. [PubMed: 19665096]

[68]. Bosco JL, Lash TL, Prout MN, Buist DS, Geiger AM, Haque R, et al. Breast cancer recurrence in older women five to ten years after diagnosis. Cancer Epidemiol Biomarkers Prev. 2009; 18:2979–83. [PubMed: 19843686]

[69]. Brewster AM, Hortobagyi GN, Broglio KR, Kau SW, Santa-Maria CA, Arun B, et al. Residual risk of breast cancer recurrence 5 years after adjuvant therapy. J Natl Cancer Inst. 2008; 100:1179–83. [PubMed: 18695137]

[70]. Pantazis N, Touloumi G. Analyzing longitudinal data in the presence of informative drop-out: the jmre1 command. The Strata Journal. 2010; 10:226–51.

[71]. Freedman LS. Confidence intervals and statistical power of the “validation” ratio for surrogate or intermediate endpoints. J Stat Plan Infer. 2001; 96:143–53.

[72]. Campbell KL, Van Patten CL, Neil SE, Kirkham AA, Gotay CC, Gelmon KA, et al. Feasibility of a lifestyle intervention on body weight and serum biomarkers in breast cancer survivors with overweight and obesity. Journal of the Academy of Nutrition and Dietetics. 2012; 112:559–67. [PubMed: 22709706]

[73]. Jen KL, Djuric Z, DiLaura NM, Buison A, Redd JN, Maranci V, et al. Improvement of metabolism among obese breast cancer survivors in differing weight loss regimens. Obes Res. 2004; 12:306–12. [PubMed: 14981223]

[74]. Greenlee HA, Crew KD, Mata JM, McKinley PS, Rundle AG, Zhang W, et al. A pilot randomized controlled trial of a commercial diet and exercise weight loss program in minority breast cancer survivors. Obesity (Silver Spring). 2013; 21:65–76. [PubMed: 23505170]

[75]. Thomson CA, Stopeck AT, Bea JW, Cussler E, Nardi E, Frey G, et al. Changes in body weight and metabolic indexes in overweight breast cancer survivors enrolled in a randomized trial of low-fat vs. reduced carbohydrate diets. Nutr Cancer. 2010; 62:1142–52. [PubMed: 21058203]

[76]. Rock CL, Byers TE, Colditz GA, Demark-Wahnefried W, Ganz PA, Wolin KY, et al. Reducing breast cancer recurrence with weight loss, a vanguard trial: the Exercise and Nutrition to Enhance Recovery and Good Health for You (ENERGY) Trial. Contemporary clinical trials. 2013; 34:282–95. [PubMed: 23266440]

[77]. Villarini A, Pasanisi P, Traina A, Mano MP, Bonanni B, Panico S, et al. Lifestyle and breast cancer recurrences: the DIANA-5 trial. Tumori. 2012; 98:1–18. [PubMed: 22495696]

[78]. Rack B, Andergassen U, Neugebauer J, Salmen J, Hepp P, Sommer H, et al. The German SUCCESS C Study - The First European Lifestyle Study on Breast Cancer. Breast care. 2010; 5:395–400. [PubMed: 21494405]

[79]. Morey MC, Snyder DC, Sloane R, Cohen HJ, Peterson B, Hartman TJ, et al. Effects of home-based diet and exercise on functional outcomes among older, overweight long-term cancer survivors: RENEW: a randomized controlled trial. JAMA. 2009; 301:1883–91. [PubMed: 19436015]

[80]. Eliassen AH, Colditz GA, Rosner B, Willett WC, Hankinson SE. Adult weight change and risk of postmenopausal breast cancer. JAMA. 2006; 296:193–201. [PubMed: 16835425]

[81]. Teras LR, Goodman M, Patel AV, Diver WR, Flanders WD, Feigelson HS. Weight loss and postmenopausal breast cancer in a prospective cohort of overweight and obese US women. Cancer Causes Control. 2011; 22:573–9. [PubMed: 21327461]

[82]. Wadden TA, Butryn ML, Byrne KJ. Efficacy of lifestyle modification for long-term weight control. Obes Res. 2004; 12(Suppl):151S–62S. [PubMed: 15687411]

[83]. Stolley MR, Sharp LK, Oh A, Schiffer L. A weight loss intervention for African American breast cancer survivors, 2006. Preventing chronic disease. 2009; 6:A22. [PubMed: 19080028]

[84]. Ely AC, Befort C, Banitt A, Gibson C, Sullivan D. A qualitative assessment of weight control among rural Kansas women. J Nutr Educ Behav. 2009; 41:207–11. [PubMed: 19411055]

[85]. McIntosh, WA.; Sobal, J. Rural eating, diet, nutrition, and body weight. In: Glasgow, N.; Morton, LW.; Johnson, NE., editors. Critical Issues in Rural Health. Blackwell; Ames, IA: 2004.

[86]. Adler NE, Ostrove JM. Socioeconomic status and health: what we know and what we don't. Ann N Y Acad Sci. 1999; 896:3–15. [PubMed: 10681884]

[87]. Burris JL, Andrykowski M. Disparities in mental health between rural and nonrural cancer survivors: a preliminary study. Psychooncology. 2010; 19:637–45. [PubMed: 19582800]

[88]. DiSipio T, Hayes SC, Newman B, Aitken J, Janda M. Does quality of life among breast cancer survivors one year after diagnosis differ depending on urban and non-urban residence? A comparative study. Health Qual Life Outcomes. 2010; 8:3. [PubMed: 20059768]

[89]. Befort CA, Austin H, Klemp JR. Weight control needs and experiences among rural breast cancer survivors. Psychooncology. 2011; 20:1069–75. [PubMed: 20734339]

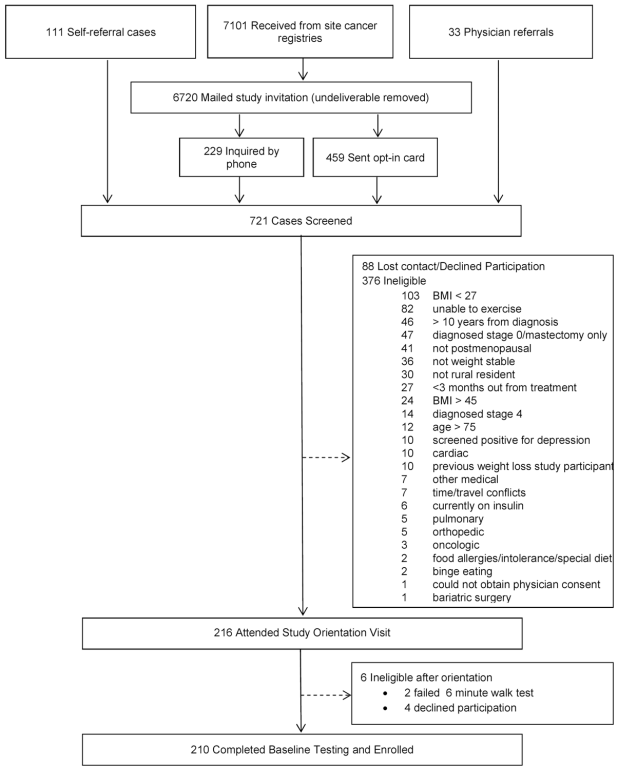

Figure 1.
Participant flow during screening and enrollment

Table 1

Participant Baseline Characteristics (n = 210)

	M (SD) or n (%)
Age	58.1 (9.9)
BMI	33.9 (4.4)
Rurality[a]	
Large rural	98 (46.7%)
Small/Isolated rural	112 (53.3%)
Time since treatment (years)	3.5 (2.4)
Stage	
0	18 (8.6%)
I	85 (40.5%)
II	76 (36.2%)
III	31 (14.8%)
Education	
High School/GED	45 (21.4%)
Some college	90 (42.9%)
Bachelor's Degree	41 (19.5%)
Masters/Doctorate	34 (16.2%)
Race/Ethnicity (Caucasian)	204 (97.1%)
Marital Status	
Married/Cohabitating	182 (86.7%)
Single/Divorced	18 (8.5)
Widowed	10 (4.8%)
Employment	
Full-Time	102 (48.6%)
Part Time	49 (23.3%)
Retired/Not employed	59 (28.1%)

BMI = body mass index;

[a]Rural Urban Commuting Area Codes; Large rural core = areas in which primary flow is within an urban cluster of 10,000 to 49,999; Small rural core = the primary flow is within an urban cluster of 2,500 to 9,999; Isolated rural = the primary flow is to a tract outside any urban area or cluster.