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Better exercise adherence after treatment for cancer (BEAT Cancer) study: Rationale, design, and methods

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Abstract

Most breast cancer survivors do not engage in regular physical activity. Our physical activity behavior change intervention for breast cancer survivors significantly improved physical activity and health outcomes post-intervention during a pilot, feasibility study. Testing in additional sites with a larger sample and longer follow-up is warranted to confirm program effectiveness short and longer term. Importantly, the pilot intervention resulted in changes in physical activity and social cognitive theory constructs, enhancing our potential for testing mechanisms mediating physical activity behavior change. Here, we report the rationale, design, and methods for a two-site, randomized controlled trial comparing the effects of the BEAT Cancer physical activity behavior change intervention to usual care on short and longer term physical activity adherence among breast cancer survivors. Secondary aims include examining social cognitive theory mechanisms of physical activity behavior change and health benefits of the intervention. Study recruitment goal is 256 breast cancer survivors with a history of ductal carcinoma in situ or Stage I, II, or IIIA disease who have completed primary cancer treatment. Outcome measures are obtained at baseline, 3 months (i.e., immediately post-intervention), 6 months, and 12 months and include physical activity, psychosocial factors, fatigue, sleep quality, lower extremity joint dysfunction, cardiorespiratory fitness, muscle strength, and waist-to-hip ratio. Confirming behavior change effectiveness, health effects, and underlying mechanisms of physical activity behavior change interventions will facilitate translation to community settings for improving the health and well-being of breast cancer survivors.

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Keywords

oncology; exercise; survivorship; predictors; adherence

1. Introduction

Physical activity after breast cancer diagnosis improves quality of life, reduces fatigue, and may reduce the risk of cancer recurrence and mortality [1-3]. Unfortunately, physical activity participation declines during treatment and often does not return to pre-treatment levels [4]. Also, the majority of breast cancer survivors are either sedentary or exercise below recommended levels [5], with as many as 62% reporting reductions in physical activity level after diagnosis ($p < 0.05$) [6]. This pattern supports the need for effective interventions to increase physical activity behavior after breast cancer treatment. Given that physical activity barriers, correlates, and preferences vary by cancer type, interventions specifically designed for breast cancer survivors are warranted [4, 7-12].

Testing such interventions is optimally done with randomized, controlled physical activity behavior change trials with a primary outcome of physical activity behavior rather than a health outcome which is typically used in exercise efficacy or effectiveness trials [13]. Of the available randomized trials of physical activity behavior change interventions in cancer survivors, seven have focused on breast cancer, one on prostate cancer, one on endometrial cancer, and four on mixed cancer types [14-25]. It is encouraging that eight of these studies have demonstrated significant improvements in physical activity and two of the four without activity increases reported improvements in exercise stage of change. However, only one (i.e., our pilot testing of the BEAT Cancer intervention) has demonstrated statistically significant increases in objectively measured adherence three months after intervention completion [26].

Pilot testing of the BEAT Cancer intervention successfully demonstrated feasibility and participant acceptability. Importantly, preliminary testing also demonstrated promising and sustained improvements in objective physical activity, waist-to-hip ratio, and lower extremity joint dysfunction three months after intervention completion [26]. This intervention addressed physical activity preferences and correlates by combining group and individual components that gradually tapered participants from a supervised to an off-site, self-directed exercise program [15]. Although feasibility testing of this intervention yielded promising results, testing in additional sites with a larger sample size and longer follow-up is warranted. Specifically, a more definitive, Phase III trial is needed to determine program effectiveness and longer term physical activity and health benefits when implemented on a larger scale. Importantly, the pilot intervention resulted in changes in physical activity and social cognitive theory constructs, suggesting a need to and potential for determining mechanisms mediating physical activity behavior change. This information is critical to advancing our theoretical and pragmatic understanding of interventions that effectively change physical activity behavior and improve health both short and longer term for breast cancer survivors. Therefore, the on-going 2-site, randomized controlled behavior change trial designed to address these issues is described in this report.

2. Research goals (specific aims and hypotheses)

The primary study aim is to compare the effects of the BEAT Cancer physical activity behavior change intervention to usual care on short and longer term physical activity adherence among breast cancer survivors. Physical activity adherence will be assessed by accelerometer and self-report at baseline, 3 months (i.e., immediately post-intervention), 6

months, and 12 months. We hypothesize that, when compared with usual care, the intervention will result in significant increases in physical activity adherence immediately post-intervention that will be maintained at 6 and 12 months.

A secondary study aim is to compare the BEAT Cancer physical activity behavior change intervention to usual care on social cognitive factors and examine the extent to which such changes mediate physical activity behavior change. We hypothesize that, when compared with usual care, the intervention will result in significant improvement in social cognitive theory factors specifically targeted by the intervention {self-efficacy, self-efficacy sources [i.e., mastery experiences (e.g., prior physical activity), observational learning (e.g., role models), social persuasion (e.g., social support), and interpretation of affective and physiologic states (e.g., enjoyment, emotional coping)], outcome expectations and expectancies (values), self-control (goal setting), and perceived barriers}. We also hypothesize the following mediating relationships: 1) social cognitive theory factors targeted by the intervention will mediate the effect of the intervention on physical activity adherence, 2) efficacy sources will mediate the effect of the intervention on self-efficacy, and 3) outcome expectations and expectancies (values), goals, and perceived barriers will mediate the effect of self-efficacy on physical activity (Figure 1).

Another secondary study aim is to compare the short and longer term effects of the BEAT Cancer physical activity behavior change intervention to usual care on changes in health outcomes. We hypothesize that, when compared with usual care, the intervention will result in significant improvements in cardiorespiratory fitness, muscle strength, waist-to-hip ratio, quality of life, fatigue, sleep quality, and joint dysfunction.

3. Study design

3.1. Rationale for use of the social cognitive theory

Social cognitive theory is based on a dynamic and reciprocal model of interactions among behavior, personal factors, and environmental influences [27] and is recognized as a useful framework for the design of physical activity interventions [27-29]. Social cognitive theory constructs have been consistently identified as physical activity correlates in breast cancer survivors based on cross-sectional studies [10, 30-32], but prospective examinations of the social cognitive theory in breast cancer survivors are limited. Indeed, most applications of social cognitive theory to health behaviors in any population have failed to fully examine the multiple constructs underlying the theory. The most frequently examined construct is self-efficacy, in many ways the “active agent” of social cognitive theory. Although Bandura suggests that mastery experiences, social modeling (observational learning), social persuasion, and the interpretation of affective and physiologic states are the most potent sources of efficacy information [33] and that self-efficacy directly influences behavior, he has also articulated the indirect relationships of self-efficacy with behavior [27]. Specifically, self-efficacy is theorized to have an indirect effect on behavior through outcome expectations, impediments (barriers) and facilitators, and goals. Outcome expectations have demonstrated positive associations and perceived barriers have demonstrated negative associations with physical activity and self-efficacy among breast cancer survivors and other populations [31, 32, 34-36]. Goal setting enhances self-control and resultant behavior adherence [28]. Therefore, our intervention includes these constructs as targets and the BEAT Cancer study will test the mediation of expectations, goals, and barriers on the influence of self-efficacy on physical activity as noted in Figure 1.

3.2. Study population

A total of 256 breast cancer survivors who have completed primary cancer treatment will be randomized to receive the 3-month BEAT Cancer physical activity behavior change

intervention or usual care. Participants are being enrolled at the Southern Illinois University (SIU) School of Medicine (Springfield, IL) and University of Illinois Urbana-Champaign (Urbana, IL) with the coordinating center being the SIU School of Medicine in Springfield, IL. The goal is for both recruiting sites to enroll an equal number of participants (i.e., 128 per site). Institutional review board approval has been obtained at both recruiting study sites and informed consent is being obtained prior to carrying out any study-related procedures. Assessments are occurring at baseline, 3 months, 6 months, and 12 months.

3.3. Eligibility criteria

The following eligibility criteria are designed to identify breast cancer survivors who do not exercise regularly but would be capable of participating in our physical activity intervention. Inclusion criteria are as follows: 1) Female breast cancer patients between the ages of 18 and 70 years of age with a diagnosis of ductal carcinoma in situ (DCIS) or Stage I, II, or IIIA breast cancer and who are not currently receiving (and do not plan to receive during the duration of study enrollment) chemotherapy or radiation therapy (participant may be undergoing longer term therapies such as aromatase inhibitors, estrogen receptor modulators, etc), 2) ≥ 8 weeks post-surgical procedure, 3) English speaking, 4) Medical clearance for participation provided by primary care physician or oncologist, and 5) Participating, on average, in no more than 30 minutes of vigorous physical activity or 60 minutes of moderate activity per week during the past six months. Exclusion criteria are as follows: 1) Dementia or organic brain syndrome, 2) Medical, psychological, or social characteristic that would interfere with ability to fully participate in program activities and assessments (e.g., psychosis, schizophrenia, etc.), 3) Contraindication to participation in a regular physical activity program, 4) Metastatic or recurrent disease, 5) Inability to ambulate, 6) Elective surgery planned during the duration of the intervention which would interfere with intervention participation (e.g., breast reconstructive surgery), and 7) Planned travel that interferes with the scheduled study sessions (i.e., no travel in the first 4 weeks and no travel ≥ 1 week in the last 8 weeks of the intervention).

3.4. Recruitment and screening

Participants are recruited through direct and indirect methods including newspaper advertising, relevant newsletters (e.g., local cancer centers), cancer support groups, institutional websites, relevant websites (e.g., Army of Women), and flyers in patient waiting areas [e.g., hospitals, physician offices, local cancer centers/clinics, and retail or service outlets of interest to women (e.g., beauty salons)]. Although not the primary focus of recruitment, local oncologists are encouraged to refer patients as a way to expand recruitment efforts into multiple arenas. Other recruitment strategies include attending breast cancer tumor board meetings to screen the patient list for eligible participants and giving presentations at cancer clinic research meetings.

Potential participants for telephone screening are identified by physician referral or by self-disclosing contact information in response to advertising or flyer. All potential participants are provided a description of the study and screened for eligibility based on a pre-determined scripted telephone interview. The fact that the intervention is primarily a walking intervention is emphasized to minimize inaccurate expectations about intervention activities.

3.5. Enrollment and randomization

Interested and potentially eligible participants identified from screening are given an appointment for orientation and enrollment. Participants are enrolled in cohorts or “waves” to facilitate the social support provided by the group meetings (see intervention description below). A packet of information (including the informed consent) is mailed to the potential

participants prior to orientation to facilitate sufficient time to read and understand the informed consent. During orientation, the informed consent and HIPAA (Health Insurance Portability and Accountability Act) authorization are signed and participants are given instructions for completion of the study assessments (e.g., diet record instructions, use of the accelerometer and record sheet, etc.). Participants are then sent home with assessment materials which are returned one week later when they come for the fitness, muscle strength, and anthropometric assessments. All baseline testing must be complete (including documentation of the required number of valid days based on the accelerometer) before the participant is randomized.

Randomization, based on computer generated numbers, is performed in blocks of 4 within each site to facilitate an equal distribution between the two study groups at each site. The coordinating center performed the computer generation of numbers for each site, placed the numbers in sealed, opaque envelopes, and delivered the envelopes to the collaborating site with written protocol for use. Assignments are made in the order in which participants complete the baseline testing and are kept in sealed envelopes until all baseline testing is complete. Participants are contacted monthly during enrollment to determine any changes in their contact information that may have occurred.

3.6. Assessments

3.6.1. Schedule—Assessments occur at baseline (pre-intervention), 3 months (M3; immediately post-intervention), 6 months (M6; 3 months post-intervention), and 12 months (M12; 9 months post-intervention). For each assessment, the study staff of the local study site provides the accelerometer, survey, and diet record to the participant along with instructions. The participant is instructed to complete the assessments at home and return them one week later. Whenever possible, the assessment tools are administered one week prior to the physical assessment session (i.e., cardiorespiratory fitness testing, muscle strength testing, and anthropometric measurements) which is performed by an exercise specialist (blinded to the participant's study group allocation) in the exercise laboratory of the local study site. This facilitates return of the accelerometer, survey, and diet record in a timely fashion. Assessment results are available to the participant, upon request, after she completes (or withdraws from) the study.

3.6.2. Physical activity measures (primary study aim outcome)—Physical activity is objectively measured by seven day accelerometer monitoring (MTI/ActiGraph; model numbers GT1M and GT3X). Accelerometers are numbered and tracked so that each participant uses the same accelerometer for all assessments. Participants are given the accelerometer, record sheet including exercise log, telephone number to access help, reminder sheets, and instructions (oral and written) for wearing the instrument. Participants are asked to wear the motion sensor during waking hours for seven consecutive days, perform their normal or usual activity, and remove the motion sensor while bathing, showering, or swimming. Accelerometer data is downloaded and reviewed for the required number of valid days immediately upon return by the participant. Monitoring is repeated if less than four valid days are recorded. Based on published protocol [37], the following guidelines for accelerometer data cleaning and management are used: 1) time is not considered monitored time if there are ≥ 20 minutes of consecutive zeros or if there are ≥ 10 minutes of constant counts > 0 ; 2) total possible monitoring time is determined by reconciling the record sheet with when the monitor starts/stops recording counts; waking time is determined from the record sheet; 3) total actual monitoring time is calculated by subtracting the time with consecutive zeros or constant numbers from the total possible time; 4) if the actual monitoring time is ≥ 10 hours or $> 60\%$ of waking time, then the day is valid [37]; and 5) four valid days are required for a valid measure and daily means are calculated

[37]. Activity counts are used to ascertain activity durations (minutes/day) in specific intensity levels (inactive [0-499 counts/min], light [500-1951 counts/min], moderate [1952-5724 counts/min], and vigorous [5725+ counts/min]) [38, 39]. Total weekly minutes of moderate + vigorous activity is the primary outcome measure because of the intervention goal. Also, activity logs obtained during accelerometer monitoring identify the rare participant who engages in activities not detectable by accelerometer (e.g., swimming) [15] for the purpose of estimating these physical activity minutes for inclusion in the activity minutes analyzed.

Participants are asked to report the average weekly duration and frequency of light, moderate, and vigorous activity over the past month using the Godin Leisure Time Exercise Questionnaire. [40-42]. Reported duration is multiplied by frequency to determine minutes per week spent in each of the three activity levels (light, moderate, or vigorous). Although the objective measurement of physical activity is our primary measure, we are using the self-report information to measure leisure time physical activity because the accelerometer does not differentiate between leisure and other types of physical activity such as occupational. We plan to use the continuous variable of moderate + vigorous minutes per week.

3.6.3. Measures of social cognitive constructs and efficacy sources

(secondary study aim #1)—The social cognitive theory constructs are measured by self-administered survey. Barriers self-efficacy (i.e., confidence in ability to overcome barriers) is measured utilizing a 9-item scale specifically designed for breast cancer patients [43]. The scale utilizes frequently reported barriers among breast cancer patients (e.g., “How confident are you that you can exercise when you are tired?”). Walking task self-efficacy scale is assessed with a 6-item scale asking participants to rate confidence in their ability to walk at a moderately fast pace for 5, 10, 15, 20, 25, and 30 minute [44]. Analyses for barriers and walking task self-efficacy is using the mean score for the Likert scale (0% = not at all confident to 100% = extremely confident).

For sources of self-efficacy, constructs related to mastery experiences, social modeling (observational learning), social persuasion, and interpretation of affective and physiologic states are being obtained. Past-performance mastery is assessed with temporally preceding (prior) physical activity behavior as measured by self-report (Godin Leisure Time Exercise Questionnaire; described above) and accelerometer (described above) at each assessment time point. When analyzed as a potential mediator of change in self-efficacy rather than the outcome mediated by self-efficacy (Figure 1), the physical activity measure obtained prior to the change in self-efficacy will be used. For example, physical activity immediately post-intervention (M3) may mediate the effect of the intervention on self-efficacy 3 months post-intervention (M6). Because we will test the three aspects of the theoretical framework separately (Figure 1), physical activity measures may be used as a source of self-efficacy or an intervention outcome mediated by self-efficacy depending on the aspect of the pathway being examined. However, the time point for the physical activity measure used will vary based on whether mediation of self-efficacy by sources or mediation of the intervention on physical activity by self-efficacy is being tested so that the temporal relationship required for cause and effect conclusions is maintained. Observational learning (i.e., role models) is measured by three yes/no questions asking about breast cancer exercise role models with the responses summed for a role model score [32]. For social persuasion, social support is measured by asking for the frequency with which friends (two items) or family (two items) encourage or offer to exercise with the participant. Items are summed for a friends, family, and total social support score [45, 46]. Several methods assess physiologic or affective state. Physical activity enjoyment is measured with a single question (5-point Likert scale) [32]. Fatigue is measured as described for secondary aim #2 outcomes that follow. Emotional coping is measured with the Functional Assessment of Cancer Therapy-Breast (FACT-B)

emotional well-being subscale (also described in the secondary aim #2 outcomes section that follows) [47]. This subscale estimates emotional coping because the item responses reflect how well the participant is coping with their cancer from an emotional standpoint (i.e., items address sadness, coping, hope, nervousness, fear of dying, fear that condition may worsen). Affective state will also be measured with the SF-36 mental health subscale [48] and the 14-item Hospital Anxiety and Depression Scale (HADS) [49].

For outcome expectations, participants are asked to rate their agreement on a 5-point Likert scale (1 = strongly disagree to 5 = strongly agree) with the statement that exercise would result in 17 potential benefits or risks. Fourteen positive benefits (e.g., feel less depressed) and 3 negative outcomes (e.g., increased joint pain) are included. Responses are summed for positive outcome expectations and negative outcome expectations [32]. For outcome expectancies (values) (i.e., importance), participants are asked to rate the importance of achieving each of the 14 benefits or avoiding each of the three risks on a 5-point Likert scale (1 = not important at all to 5 = extremely important). Responses are summed for positive outcome values (expectancies) and negative outcome values (expectancies) [32]. The multiplicative functions for each expectation and its value are not calculated because these have been reported to be inferior to examining associations for expectations and values separately [32].

For goal setting, participants are asked to indicate their exercise plans for the past month, next 3 months, and next 6 months (i.e., 1 = plan to exercise less, 2 = about the same, or 3 = more) [50]. Participants are also asked about their exercise goal for the past month, next 3 months, and next 6 months (i.e., 5-point Likert type scale; 1 = not planning to exercise at all to 5 = exercising 7 days per week for ≥ 30 minutes a day). In addition to Likert scale analyses (i.e., for each time period and summed across time periods), responses are dichotomized into having or not having an exercise goal. Perceived barriers (or barriers interference) is measured by asking participants to rate on a 5-point Likert scale (1 = never to 5 = very often) how often 21 different barriers interfere with exercise. The items are summed for a perceived barriers score [31, 32, 51].

3.6.4. Health outcome measures (i.e., secondary study aim #2)—

Cardiorespiratory fitness is assessed using a submaximal treadmill test following the guidelines of the American College of Sports Medicine (ACSM) [52]. The fitness test gradually increases speed and elevation using the Naughton protocol until the participant achieves 85 percent of predicted maximal heart rate [53]. The oxygen cost of walking at the treadmill grade and speed achieved at 85% of predicted maximal heart rate is estimated using published regression equations and expressed in ml/kg/minute [54]. The Naughton protocol is preferred when testing sedentary, older participants who may be fatigued or suffer balance difficulties related to breast cancer treatment because of its slower starting speed and progression. Also, maximal oxygen consumption testing is uncomfortable for participants and may increase study drop-outs [55, 56]. If the participant is taking a medication that blunts the heart rate response (e.g., beta blocker), the participant's rating of perceived exertion (RPE) will be used as a proxy for the target heart rate (i.e., RPE of "hard" as indicated by 15 on a RPE scale of 6 to 20 or 7 on a RPE scale of 1 to 10 [54]) [52].

Muscle strength testing utilizes a back and leg dynamometer. The participant stands on a platform with trunk erect and knee flexion of 130° (verified with a goniometer). With elbows straight and a pronated grip, the hand-bar is held in both hands across the thighs and the chain length adjusted for the participant's height. The participant slowly attempts to extend her knees while pulling on the hand-bar with maximal effort without using her back. The participant completes three trials with a one-minute rest between trials. The maximum reading (best of the three efforts) provides the absolute strength measure in kilograms force.

Body mass index (BMI) is calculated from the height and weight [weight (kg)/ height (m²)] obtained from a scale and stadiometer [SIU is using the Continental Health-O-Meter #400 DML medical scale (precision to nearest 8th of a pound) and University of Illinois is using a Seca 763 Digital Column Scale (precision to nearest .1 pounds)]. Waist and hip circumferences are measured using a non-stretching tape measure with a 4 ounce tension indicator device that standardizes tension across repeated measurements. The participant stands with abdomen relaxed and arms at sides with no clothing at the waist and only undergarments at the hip. The waist circumference is measured at the smallest circumference of the torso and at the end of exhalation. Hip circumference is measured at the level of the maximum extension of the buttocks [57]. At each testing, three measurements are obtained and the results averaged before calculation of the waist-to-hip ratio.

Two health-related quality of life measures are obtained. The SF-36 is a self-administered 36-item survey that is scored according to published protocol for overall scores (physical and mental) and 8 subscores (i.e., physical functioning, social functioning, role-physical, role-emotional, mental health, vitality, pain, and general health) [48]. The SF-36 does not target a specific demographic or chronic disease population [48], facilitating comparison of our results to cancer (other than breast) and non-cancer populations. The health status assessed by the SF-36 provides information related to global quality of life. The Functional Assessment of Cancer Therapy-Breast (FACT-B) is included as an alternative measure of quality of life because of its relevance for breast cancer populations [47] and frequency of use in prior studies (i.e., enhances comparison of study results with other published breast cancer reports). Using the sum of 5-point Likert scales, the 37-item FACT-B instrument includes the subscales of physical well-being (PWB), social well-being (SWB), emotional well-being (EWB), functional well-being (FWB), and additional concerns (AC) [47].

In addition to health-related quality of life, global quality of life is measured with the Satisfaction With Life Scale (SWLS) which allows the participant to provide a global assessment of their quality of life based on their chosen criteria [58]. The 5-item SWLS uses a 7-point Likert response (1 = strongly disagree to 7 = strongly agree) with items summed for analysis. Due to the fact that subscales may overlap with other health-related and social cognitive proposal outcomes [e.g., fatigue overlapping with vitality (SF-36) and physical well-being (FACT-B); joint pain with bodily pain (SF-36) and physical/functional well-being (FACT-B)], the data analysis plan will avoid using constructs that overlap when examining mediators of intervention effect.

Fatigue is measured with the 13-item multi-dimensional fatigue scale (i.e., Fatigue Symptom Inventory) [59]. Sleep dysfunction is measured subjectively using the Pittsburgh Sleep Quality Index (PSQI) with scoring according to published protocol [60]. Sleep quality is objectively assessed with the same accelerometer used for measuring physical activity by transferring the accelerometer from the waist to the wrist while the participant is in bed to sleep [61]. The participant records her time in bed and time out of bed on the accelerometer record sheet, the accelerometer is set for one minute epochs, and a minimum of three valid nights of monitoring are required. Joint pain, stiffness, and physical function is measured with the 5-point Likert scale (i.e., 1 = none to 5 = extreme) version of the 24-item Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [62]. Five items assess amount of joint pain with two assessing joint stiffness and 17 assessing degree of interference with physical functioning due to joint symptoms. Items are summed for the 3 subscores and the overall score.

3.6.5. Potential covariates—Self-administered survey measures age, race/ethnicity, marital status, smoking history, alcohol consumption, medical factors (i.e., breast cancer

stage, hormone receptor status, cancer treatment types, time since diagnosis, time since treatment, comorbid conditions, and current medications). If a participant is not able to recall medical-related information, a medical release form is completed allowing study staff to request this information from the participant's physician. Due to the fact that diet changes (e.g., caloric intake) unrelated to our intervention may influence body composition, a 3-day diet record (i.e., one weekend day and two week days) is obtained. Also, exercise preferences may influence the effect of exercise on health outcomes (e.g., quality of life) and are assessed with several multiple-choice and yes/no questions adapted from that used in prior studies by the investigators [10, 63-65].

3.7. Process evaluation

At each assessment period, participants are asked to provide a written evaluation of the study staff and procedures with the intervention group also providing an evaluation of the BEAT Cancer intervention. All participants are asked to report their agreement (Likert scale; 1 = strongly agree to 5 = strongly disagree) with each of the following: study objectives and responsibilities were made clear, study staff were helpful and easy to contact, would recommend participation in the research study to others, and their exercise habits changed during the study. Three open-ended items ask participants to report suggestions for changes to improve the study, what they found particularly beneficial about the study or study staff, and ways the study could be made more convenient for them. Participants are asked to provide an overall rating of the study and its staff (Likert scale; 1 = poor to 5 = excellent) and to indicate if they participated in an exercise program other than the BEAT Cancer study (yes/no response with request to specify program if answer is "yes"). The evaluation form for the intervention group participants includes 25 additional items. Specifically, participants are asked to report their agreement (Likert scale; 1 = strongly agree to 5 = strongly disagree) with each of the following: exercise specialists were knowledgeable, exercise sessions were tailored sufficiently to their needs, exercise specialists were respectful and sensitive, would recommend the BEAT Cancer exercise study to others, group meeting times were convenient, group meetings were helpful and meaningful, number of group meetings was appropriate, and the behavioral modification plan (i.e., ABC Blueprint described in intervention section that follows) was helpful. Two open-ended items ask what the participant found most helpful about the intervention and what they would change to improve the intervention. Twelve open-ended items ask about the following four aspects of the supervised exercise sessions, group sessions, and update sessions: what they found particularly helpful, what they would change to improve the activity, did they miss any sessions, and reasons for missed sessions. Intervention participants are also asked to provide an overall rating of the BEAT Cancer intervention (Likert scale; 1 = poor to 5 = excellent), their preference for exercising alone or with others with or without cancer (multiple choice), and preferred group meeting time (multiple choice). Items included on the participant evaluation form relate to the BEAT Cancer study staff and program specifically, which is a different focus from that of the survey measuring the study outcomes. However, the potential for selected items to confound or moderate the intervention effect on physical activity behavior will be explored (e.g., participation in another exercise study, how well they liked the intervention).

3.8. Interventions

3.8.1. Overview—The BEAT Cancer (Better Exercise Adherence after Treatment for Cancer) intervention is a 3-month physical activity behavior change intervention for breast cancer survivors. The intervention goal is to gradually increase participants to ≥ 150 weekly minutes of moderate intensity physical activity. This pilot tested intervention was designed based on needs assessments and the social cognitive theory [15, 26]. Table 1 provides the timeline and social cognitive theory targets for each activity [i.e., six discussion group

sessions (once a week for three weeks then every other week for six weeks), 12 supervised exercise sessions (three per week for two weeks then two per week for two weeks then one per week for two weeks), multiple home-based exercise sessions beginning in the third week (off-site, unsupervised), and three face-to-face update counseling sessions (once every other week during the final six weeks)]. Figure 1 provides a schematic of the theorized mechanisms of behavior change hypothesized to occur with the intervention. In addition to the constructs related to that listed in Figure 1, behavioral capability (addresses mastery experiences) and environment (factors external to the individual that influence behavior as a barrier or facilitator) are also targeted [28]. Finally, Bandura has theorized that behavior results from an ongoing, interaction among the behavior, the individual, and their environment [66]. Therefore, the intervention integrates time for personal reflection on goals, progress, and experiences in an effort to facilitate this process.

3.8.2. Discussion group session content—The content and schedule of the discussion group sessions are provided in Table 1. Sessions usually occur in the early evening, during the week and last 1.5 hours. Participants are notified of the exact times and dates for the group sessions at the time of study enrollment. The group sessions are led by a group leader trained and monitored for quality control by a licensed clinical professional counselor with experience in physical activity behavior change interventions for cancer survivors. The intervention and related materials is designed in such a way that group leaders are not limited to psychology professionals but can include research staff with differing educational backgrounds and excellent interpersonal communication skills. This approach is allowing us to develop and streamline training materials and approaches that can be maximally disseminated to future group facilitators drawn from the community (e.g., exercise facility staff, community center staff, motivated volunteers, etc.).

Patient education materials are provided as part of the group sessions. Each intervention participant is provided a notebook which contains the following: 1) welcome and role of the BEAT Cancer discussion groups, 2) general information such as personnel contact list, locations, and schedules for intervention sessions, 3) instructions for completing quality control feedback at the end of each group session, 4) exercise-specific information related to intervention goals, exercise safety, healthy nutrition for optimal physical energy, restarting exercise after relapse, stretching guide (photos and instructions), and exercise log sheets, 5) quality control feedback sheet for each group session, 6) instructional materials for each group session, 7) supplemental literature and educational materials, 8) citations, 9) decorative blank pages for journaling, and 10) blank ABC Blueprint forms. The ABC Blueprint is a personal, written behavioral modification plan that is reviewed and updated by each participant throughout the intervention. It contains three elements: 1) Preparing for Action (i.e., antecedents planned by the participant as a way to facilitate exercise adherence), 2) Behavior (i.e., more specific exercise information such as duration and type), and 3) Consequences (i.e., reinforcements for continued exercise adherence) [67]. The 3-ring notebooks with section tabs allow participants to insert the instructional materials for each group session which are provided at the end of the group session. Due to the importance of group interaction, holding materials specific to each session until the end of the session is used to reduce the chance of participants using having the materials ahead of time as an excuse not to attend the group sessions.

3.8.3. Supervised exercise session content—The schedule of the supervised exercise sessions is provided in Table 1. Each supervised exercise session is implemented by an exercise specialist who is certified by the American College of Sports Medicine (ACSM) (or is certification eligible), uses a structured encounter form, and lasts about one hour. Sessions include warm-up, aerobic walking on the treadmill according to protocol, cool-down, and stretching. A checklist documents correct stretching techniques (week 1 and

week 2) and correct use of the heart rate monitor (week 1). A brief discussion of healthy nutrition for optimal physical energy is included during one of the sessions in week 1. Walking is the required exercise type during the first six weeks of the intervention due to the use of a treadmill during the supervised exercise sessions. After week 6, the participant may choose other exercise types based on preference as long as the target intensity and duration are achieved. Since this is a physical activity behavior change intervention, some participants may have a preference for exercise duration and/or frequency. Therefore, variability in the exercise duration and frequency may occur due to individual adaptation to preferences and physical condition (e.g., baseline fitness). Table 2 provides a summary of the exercise prescription with possible range of variability.

3.8.4. Face-to-face update counseling session content—The face-to-face update counseling sessions occur according to the schedule provided in Table 1, are carried out by an exercise specialist, use a structured encounter form, and last about 30 minutes. These sessions provide exercise prescription updates and additional behavioral support for the participants during the weeks they are performing all exercise sessions at home (off-site, unsupervised). Each update session includes the following: 1) discuss progress, 2) review activity log sheets, 3) assess adherence and barriers, 4) assess heart rate monitor use, and 4) set goals by providing exercise prescription for the next two weeks. The final session in the 12th week also includes discussion of relapse prevention and the safe return to exercise after a period of relapse.

3.8.5. Staff protocol manuals—Due to the individual and group components of the intervention, two separate protocol manuals were created (one for the exercise specialists and one for the discussion group leaders). The exercise specialists' manual describes correct implementation of the intervention (i.e., supervised exercise sessions and update counseling sessions) and completion of the physical assessment (i.e., treadmill fitness test, dynamometer, waist-to-hip ratio, height, and weight). Scripts for use during supervised exercise sessions and the physical assessments, as well as, general information about breast cancer treatment, exercise precautions, and exercise barriers are included. In addition to a copy of study forms used by the exercise specialist, the manual includes instructions for cleaning equipment, using the heart rate monitor, correct measurement of blood pressure, emergency procedures, and maintenance of participant confidentiality and strict adherence to study protocol.

The group leader manual contains the following items: 1) overview of the BEAT Cancer study and its intervention, 2) motivational group dynamics, 3) general information (e.g., personnel contact list), 4) instructions for completing self-evaluation of group process at the end of each session, and 5) exercise-specific information and supplemental literature and educational materials similar to that provided in the participant notebook (and described in the preceding patient education materials section). The group leader manual also includes the following items for each group session: 1) self-evaluation quality control sheet, 2) group leader instructions, 3) copy of participant notebook content, and 4) hard copy of PowerPoint slides with notes suggesting discussion questions and transition statements.

3.8.6. Missed sessions—If a supervised exercise or update counseling session is missed, a make-up session is scheduled as soon as possible with no more than three supervised sessions allowed per week. All supervised sessions and update sessions must be made up by the end of week 12 of the intervention. If a group session is missed, the participant is given the handout materials but a make-up discussion group is not possible.

3.8.7. Usual care intervention—The “usual care” group receives written materials obtained from the American Cancer Society describing physical activity recommendations

for cancer survivors. These materials are felt to be “usual care” because they are readily accessible to most cancer survivors and are based on current evidence-based knowledge related to exercise recommendations in cancer survivors. To ensure consistent exposure to “usual care” materials, all participants in both study groups are given these written materials. Finally, participants randomized to the usual care (i.e., written materials only group) are given the opportunity to receive tailored exercise recommendations and three individual sessions with an exercise specialist at no additional cost to the participant within three months of completing the 12 month follow-up.

3.9. Staff training and quality control

Study staff members are trained at both study sites before implementing study procedures. Booster sessions occur annually to facilitate continued adherence to the protocol. Training for the group leaders begins with a six-hour session lead by a clinical psychologist (Dr. Vicari) in which they review and discuss the group leader manual (didactic, group discussion) and videos of group session examples (demonstrations). The group leaders are made aware of the individual exercise specialist session activities in an effort to improve the consistency of messaging between the individual exercise sessions and the discussion group sessions. The Group leaders are encouraged to practice group session presentations on their own and contact the clinical psychologist as questions arise after the training session. Group leaders also participate in a one-on-one session with the clinical psychologist after each group session (telephone or face-to-face) for approximately 30 to 40 minutes to obtain feedback (including self-assessment and attendee evaluations), ask questions, problem solve, and refine skills. These one-on-one group sessions occur less frequently as the group leader gains confidence and experience (i.e., primarily occurs during the first two waves of group sessions). Ongoing monitoring of competency and quality control is performed for the discussion group leaders (by Dr. Anton) using group participant feedback forms and group leader self-evaluation forms completed after each session. Forms are summarized and reviewed with the group leaders. Also, a videotape of each group session is reviewed by Dr. Anton and written feedback provided to the group leaders until consistent and adequate group leader performance is confirmed (e.g., $\geq$ two waves of group sessions completed by the leader).

The initial exercise specialists’ training session lead by exercise physiologists (Dr. Hopkins-Price and Dr. Anton) lasts six hours and includes a review of the exercise specialist manual (didactic), procedure demonstrations (in-person observation), and skills practice on another staff member or a volunteer with feedback provided by the exercise physiologists. Although the exercise specialists completing assessments differ from those implementing the intervention, review of all procedures are done initially to facilitate a consistent understanding of the study across the study sites. Once the majority of exercise specialists have been trained, newly hired exercise specialists are trained in 2 hour, face-to-face training sessions focusing on either the assessment or the intervention (depending on which study aspect the staff will be performing). These sessions review the protocol manual (didactic), demonstrate procedures, and provide feedback as the staff practice the skills on another staff member or volunteer. Also, exercise specialists implementing the intervention are made aware of the group session activities in an effort to facilitate consistent messaging between the individual and group sessions. Competency and quality control for the exercise specialists are monitored by direct observation (i.e., physical assessments, supervised exercise sessions, update counseling sessions). A co-investigator (i.e., Dr. Anton) uses observational checklists and provides feedback (written and verbal) to the exercise specialists to ensure consistent and correct implementation of the study protocol.

3.10. Participant safety

Participant safety is a priority during all study activities and emergency response protocols are posted at both study sites. Physician supervision is provided during fitness testing when deemed appropriate based on ACSM guidelines [68]. Adverse events are identified spontaneously or non-spontaneously. The most likely way an adverse event is spontaneously identified is when the participant reports an event to the intervention or assessment staff during contact time. Non-spontaneous adverse events are identified during regularly scheduled telephone interviews by research staff blinded to the treatment condition of the participant. These phone interviews take place once every three months during study enrollment. Adverse events are reported to the institutional review boards according to site-specific policies and procedures with a description provided to the Data and Safety Monitoring Board (DSMB) at each DSMB meeting (i.e., two times per year).

3.11. Sample size and power considerations

Sample size is based on recruitment feasibility and estimated study power. With regard to feasibility, four participants per month per site is a feasible recruitment goal allowing enrollment of 256 participants over the 32 month recruitment period. Based on pilot testing, 7% of participants may drop out before the 3 month follow-up and 12% may drop out before the 6 month follow-up [26]. Because the expected drop-out rate before the 12 month follow-up is unknown, 194 participants (or 97 per study group after an estimated 24% drop out rate) are used to calculate a conservative study power estimate [i.e., able to detect a small to medium effect size = 0.40 ($p < .05$, power of .80)] [69]. This study power is sufficient for detecting a between group difference of 40 ± 98.7 weekly minutes of $\geq$ moderate intensity physical activity. Given the between group difference of 100 weekly minutes noted in the pilot study [26], we anticipate that this study power will be adequate for detecting a significant difference in the primary study outcome. Moreover, this sample size is sufficient for detecting several of the secondary outcomes with effect sizes expected to be greater than or approaching that of 0.40 (e.g., effect sizes collected during pilot testing were 0.64 for fitness, 0.81 for muscle strength, -.77 for waist-to-hip ratio, -0.30 for sleep latency, 0.70 for joint stiffness, 0.67 for perceived barriers interference, 0.33 for family social support, 0.61 for enjoyment, and -0.38 for negative outcome values [15, 70]). Also relevant, the Freedman and Schatzkin difference-in-coefficients test provides a more statistically powerful methodology allowing detection of statistically significant mediation in randomized trials with sample sizes smaller than that of the BEAT Cancer study [70-72].

3.12. Data management and analysis considerations

Data entry is occurring at the coordinating center and is performed by individuals blinded to the participant's group allocation. An intent-to-treat analysis will be used. Missing data will be handled with maximum likelihood methods for those analyses involving the mixed-model ANOVA. The remaining analyses (e.g., mediation) will handle missing data by carrying the last available value forward. If disproportionate numbers of participants are lost to follow-up between the two study groups, data will be analyzed with and without the imputed missing data with results compared for discrepancies suggesting potential bias. For the primary study aim, the difference in physical activity change over time between the two study conditions (i.e., intervention and usual care) will be assessed with mixed-model ANOVA with group (i.e., condition) allocation being the between-groups factor and time (i.e., pre/post intervention) being the within-subjects factor. The primary outcome is weekly minutes of $\geq$ moderate intensity physical activity (based on accelerometer). Although our primary time point of M6 will confirm the longer term adherence reported in our feasibility study [26], inclusion of the M12 assessment allows us to determine if adherence is maintained until M12. The relationships between potential covariates and change in physical activity will be determined with inclusion of covariates in adjusted mixed-model ANOVA if indicated. If

the group by time interaction is significant, follow-up analyses will be performed to determine the pattern of differences for each follow-up period (i.e., M3, M6, and M12). Also, mixed-model ANOVA will be performed with and without covarying for baseline physical activity to determine discrepancies in the intervention effects. A similar approach will be used to determine the magnitude of change in social cognitive factors and the health outcomes (i.e., secondary study aims). Mediation analyses will assess the usefulness of our a priori theoretical framework for physical activity adherence (Figure 1). The analysis will be organized around three aspects of the theoretical framework (i.e., mediation of the intervention on physical activity adherence by all social cognitive theory constructs, mediation of the intervention on self-efficacy by efficacy sources, and the mediation of self-efficacy on physical activity by selected social cognitive theory constructs). Mediation related to physical activity at M3, M6, and M12 will be assessed using the Freedman-Schatzkin difference-in-coefficients test [71, 72].

4. Discussion

The BEAT Cancer physical activity behavior change intervention is the first to utilize an interdisciplinary approach to address specific physical activity correlates and preferences of breast cancer survivors. No prior behavioral change intervention study among cancer survivors has reported the use of both individual sessions with an exercise specialist and group counseling sessions in a format that gradually tapers the participant onto a self-directed program in an effort to optimize change in specific physical activity correlates which may respond better to one modality rather than another. The significance of our BEAT Cancer behavior change study is further supported by its assessment of objective physical activity and longer term adherence along with examination of social cognitive mediation of activity change in a comprehensive manner during both adoption and maintenance. Our attention to preparing the intervention for translation to other sites improves potential dissemination after trial completion. Finally, the study sites are adjacent to non-metropolitan, more rural populations which provide the unique opportunity to enroll an underserved population not adequately examined in survivorship studies of any cancer type.

The significance of our secondary study aim to examine mechanisms of behavior change warrants particular attention. Cross-sectional studies examining predictors of physical activity behavior may overestimate associations between correlates and behavior and preclude testing of causality between a correlate and behavior change [73, 74]. Therefore, prospective, randomized intervention studies testing causality between behavioral interventions and behavior change and determining which theoretical mechanisms mediate such change are needed [73]. Of the previously reported randomized controlled physical activity behavior change studies in cancer survivors, the predictive nature of activity correlates have been reported by five. Specifically, higher perceived behavioral control-mediated increased activity in breast cancer survivors who received an oncologist recommendation to exercise [75]; intention and planning mediated the increase in activity among breast cancer survivors receiving a pedometer and/or printed materials based on the theory of planned behavior [76]; baseline self-efficacy predicted post-intervention activity in a mixed cancer group [18], and reduced barriers interference mediated the increase in activity among breast cancer survivors during pilot testing of the BEAT Cancer intervention [70]. In contrast, self-efficacy was associated with exercise but did not mediate a mail-delivered intervention in breast and prostate cancer survivors due to lack of association between the intervention and self-efficacy [77]. Very few behavior change studies have tested comprehensive theoretical models which consider an individual's behavior as a result of the complex interplay of personal attributes within the biological, social, and environmental context in which the individual must make lifestyle choices [78, 79]. Our

cross-sectional study [31] among a population-based sample of 192 breast cancer survivors suggests that such a complex interplay of social cognitive theory constructs is tenable and examination of the extent to which these constructs mediate behavioral change is warranted. Establishing such mechanisms will have important translational value for designing physical activity programs which maximize adherence and potentially reduce disease recurrence and mortality in breast cancer survivors.

Given the wide variety of possible health outcomes that could have been measured, we selected health outcomes to be examined in the BEAT Cancer study based on improvement during pilot testing [15, 26], published reports of improvement after a walking intervention, and/or clinical significance. To clarify, it is not our objective to determine the effect of a specific “walking dose” on these outcomes but to determine if the activity increase noted with the behavior change intervention is sufficient for various health benefits. Cardiorespiratory fitness is clinically important because of its association with reduced all-cause mortality [80] and improved quality of life [81, 82]. Similarly, lower extremity muscle strength improves after participation in a walking program [83] and may be associated with improvements in physical functioning, quality of life, and body composition [84, 85]. With regard to body composition, our intervention is not a weight loss program and large changes in body weight and body composition were not achieved during pilot testing; however, waist-to-hip ratio improvement which persisted 3 months post-intervention was noted [26]. Waist-to-hip ratio has been associated with increased physical activity and reduced breast cancer risk, suggesting its usefulness as a biomarker for estimating the long-term benefits of the program on cancer recurrence and mortality [86, 87]. Quality of life has improved with walking interventions in cancer and non-cancer populations [24, 83, 88] with our preliminary results suggesting promising improvements in social well-being immediately post-intervention and total quality of life 3 months after intervention completion [15, 26]. The BEAT Cancer study described in this report will allow more definitive testing of the different patterns of change that may occur with overall quality of life and its various aspects (e.g., social well-being, physical well-being, etc.) in response to the intervention.

We have also chosen to include three symptom-related outcomes: fatigue, sleep, and joint pain. Fatigue is a frequent and persistent long-term side effect of cancer treatment which may improve with exercise [1, 89, 90]. Sleep dysfunction is often “clustered” with fatigue [91] but is less often assessed in physical activity behavior change studies. Finally, joint pain and stiffness are frequent symptoms of hormonal therapy [92] and increase with age regardless of cancer treatment [93]; however, little is known about the effect of exercise on joint symptoms in breast cancer survivors and no prior physical activity behavior change study (with the exception of our pilot testing of the BEAT Cancer intervention) has reported this outcome. Our preliminary results suggest a transient increase in joint stiffness immediately post-intervention which is replaced by significant improvement in lower extremity joint dysfunction 3 months after intervention completion [26]. The improvement in joint symptoms is of clinical importance because of the current lack of effective therapies for arthralgias related to breast cancer therapy [94] and additional research to confirm our findings is warranted.

We acknowledge that the study is limited by the fact that budgetary constraints preclude cost-effectiveness analysis. In addition, census data in the study recruitment region [95] suggests that a feasible minority enrollment target is $\leq 25\%$ which may limit generalizability and reduce study power if post hoc data analysis stratified by race is deemed to be appropriate. With regard to the health outcomes, other important biomarkers of reduced cancer risk could have been included (e.g., metabolic or sex steroid hormones, markers of inflammation, and assessment of immune function) [96]; however, such measures would require marked increase in study cost and complexity related to sample collection, transport,

storage, and analysis. Moreover, our preliminary experience suggested that potential participants may be hesitant to enroll in a study which requires phlebotomy. Considering the study aim priorities (i.e., health related outcomes are a secondary study aim), number of follow-up measures, cost of the assays, and impact on participant recruitment, we chose not to include these outcomes in the BEAT Cancer study. Similarly, adding other symptom and/or psychosocial measures (e.g., body image, cognitive function) would increase participant burden due to survey length. The BEAT Cancer study aims to validate the health benefits of our behavior change intervention but does not aim to provide an exhaustive assessment of potential health outcomes.

5. Conclusions

The BEAT Cancer study is a physical activity behavior change study addressing the important clinical and public health problem of physical inactivity among breast cancer survivors. Physical activity programs should be offered to all breast cancer survivors without a medical contraindication given the association between physical activity and a reduction in risk for breast cancer recurrence and mortality of 35% and 46%, respectively [97]. If the BEAT Cancer intervention success is confirmed in this larger trial, the intervention can be disseminated for broader use at cancer centers and institutes. Given this increased attention to survivorship care [98], such a program would likely be well-received. Moreover, our study will allow us to determine if an increase in physical activity is sufficient for improvement in health and psychosocial outcomes while also facilitating the testing of behavior change mechanisms. Experience gained by testing effectiveness of the promising BEAT Cancer intervention will improve the translation potential when the intervention is more broadly disseminated.

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Figure 1.
Theoretical framework for understanding mechanisms of physical activity behavior change in breast cancer survivors

BEAT Cancer intervention activity timeline and social cognitive theory (SCT) construct targets

Table 1

Discussion group sessions		Intervention activity and corresponding SCT construct targets					
		Supervised exercise sessions		Home exercise sessions		Face-to-face update counseling sessions	
Week	Topic ^a	SCT target	#	SCT target	#	SCT target	#
0	1	Introduction to intervention, ABC Blueprint ^b , goal setting, and journaling; exercise benefits					
1	1	Time and stress management; ABC Blueprint, journaling, and activity logs reviewed	3	Self-efficacy (barriers and task); expectations; behavioral capability; goal setting with self-monitoring			
2	1	Barriers; benefits; safety; ABC Blueprint, journaling, and activity logs reviewed	3	(same as above)			
3			2	(same as above)	≥ 2	Self-efficacy (barriers and task); behavioral capability; goal setting with self-monitoring	
4	1	Role model speaker	2	(same as above)	≥ 2	(same as above)	
5			1	(same as above)	≥ 3	(same as above)	
6	1	ABC Blueprint; thinking as the basis for change; barriers; relapse; journaling and activity logs reviewed	1	(same as above)	≥ 3	(same as above)	
7					≥ 3	(same as above)	
8	1	Progress; relapse; wrap-up discussion; ABC Blueprint, journaling, and activity logs reviewed		Goal setting; self-control and performance; behavioral capability	≥ 3	(same as above)	1
9					≥ 3	(same as above)	
10					≥ 3	(same as above)	1
11					≥ 3	(same as above)	
12					≥ 3	(same as above)	1

^a Table lists primary topic but topic overlap and review occurs throughout all group sessions.

^b ABC Blueprint is a personal, written behavioral modification plan.

BEAT Cancer intervention exercise prescription: aerobic exercise duration, frequency, and intensity with possible ranges^a

Table 2

Intervention week	Frequency of supervised exercise sessions	Frequency of exercise sessions at home	Duration of each exercise session in minutes: preferred target (range allowed)	Total exercise minutes per week	Intensity: rating of perceived exertion (on scale of 1 to 10)	Intensity: percent of heart rate reserve
1	3	0	20 (15 to 25)	45 to 75	1.5 to 3	40 to 59%
2	3	0	25 (20 to 30)	60 to 90	1.5 to 3	40 to 59%
3	2	≥ 2	30 (25 to 35)	100 to 140	1.5 to 3	40 to 59%
4	2	≥ 2	30 (30 to 40)	120 to 160	1.5 to 3	40 to 59%
5	1	≥ 3	30 (30 to 50)	120 to 200	2.5 to 4	40 to 59%
6	1	≥ 3	30 (30 to 50)	150 to 200	2.5 to 4	40 to 59%
7	0	≥ 3	30 (30 to 50)	≥ 150	2.5 to 4	40 to 59%
8	0	≥ 3	30 (30 to 50)	≥ 150	2.5 to 4	40 to 59%
9	0	≥ 3	30 (30 to 50)	≥ 150	3.5 to 5.5	40 to 59%
10	0	≥ 3	30 (30 to 50)	≥ 150	3.5 to 5.5	40 to 59%
11	0	≥ 3	30 (30 to 50)	≥ 150	3.5 to 5.5	40 to 59%
12	0	≥ 3	30 (30 to 50)	≥ 150	3.5 to 5.5	40 to 59%

^aPossible ranges allow adaptation based on participant preference and physical condition. For example, participants may vary with regard to the preferred number of sessions per week (three 50-minute sessions rather than five 30-minute sessions per week). Also, because participants vary with regard to age, baseline fitness, etc., exercise specialists adapt the exercise prescription (within the allowed range) depending on the participant's physical ability. Participants are instructed not to exercise beyond the upper limit of the allowed range to improve safety because participants may occasionally try to exercise excessively.