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The Exercising Together Project: Design and recruitment for a randomized, controlled trial to determine the benefits of partnered strength training for couples coping with prostate cancer

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Abstract

Prostate cancer can threaten quality of life for the patient and his spouse and the quality of his marital relationship. The purpose of our study is to evaluate the effects of “Exercising Together” – a partnered strength training program for married couples coping with prostate cancer – on the physical and emotional health of prostate cancer survivors (PCS) and their spouses and on marital quality. We are conducting a 6-month randomized controlled trial with two groups: 1) Exercising Together - a progressive, supervised strength training program and 2) a usual care control condition. The primary aims of this exploratory study are to: 1) Determine the effect of partnered strength training on physical and emotional health (muscle strength, physical function, body composition and self-report physical and mental health) in PCS, 2) Determine the effect of partnered strength training on physical and emotional health in spouses and 3) Explore the effect of partnered strength training on marital quality (incongruence, communication, relationship quality, intimacy) of the PCS and spouse. Target accrual has been met in this study with 64 couples enrolled and randomized to exercise (n=32) or usual care (n=32) groups. This study is the first to examine the feasibility of this exercise format in both the chronically ill patient and spouse and explore benefits at the individual and couple level.

Keywords

resistance exercise; physical fitness; survivors; caregivers; marital relationship

INTRODUCTION

Prognosis after diagnosis of prostate cancer is favorable, with over 2 million prostate cancer survivors (PCS) presently living in the US [1]. PCS can experience treatment-related side effects and symptoms that can decrease physical function and quality of life (QOL) [2-4].

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Most PCS are older and the combined effects of aging, cancer and cancer treatment could make older PCS more likely to exhibit worse physical function than younger PCS [5, 6]. Inactivity may further contribute to reduced QOL with over 75% of PCS reporting insufficient physical activity [7-9]. PCS are prone to developing unhealthy body composition (i.e., sarcopenic obesity and osteoporosis) that is exacerbated by androgen deprivation therapy (ADT) [10, 11]. Inactivity, functional decline, unhealthy body composition and older age predispose PCS to chronic illness, increased risk of disability and falls, and disease progression [12, 13].

The impact of chronic illness extends beyond the patient to affect his family. Most men diagnosed with prostate cancer are married [14] and prostate cancer has been called the “relationship disease” because of the strain it places on the spouse and marriage. Spouses of PCS report increased anxiety, distress and depression and reduced QOL, often more than that experienced by their ill husbands [15, 16]. Spouses provide most of the support and care during the course of a chronic illness, particularly for older patients. Spouse caregivers experience significant health declines, are at greater risk for mortality than other family caregivers [17, 18], and are less likely to engage in health promoting behaviors, such as physical activity [19].

Prostate cancer also threatens marital quality, which can in turn reduce each partner’s QOL. Marital relationships can be complicated by an illness experience. These relationship changes may result in poor communication [20, 21] and in turn, poorer outcomes [22]. In contrast, couples who maintain high relationship quality have better psychological adjustment [23], increased survival from debilitating illness [24] and better illness management and adherence to treatment [25] than those couples with poor relationship quality.

Engaging in shared activities may protect the couple’s marital relationship, and if the activity is exercise, the individual’s physical and emotional health may also be improved. Exercise can reduce side-effects and symptoms from cancer treatment [26], slow age-related declines in physical function [27], and improve emotional well-being [28]. Strength training is a particularly suitable type of exercise for the older PCS because it can restore muscle strength, balance and mobility that are worsened by cancer treatment and age [29-31]. Strength training may also be an ideal shared activity because it requires verbal and non-verbal interactions between partners that may improve relationship quality outside of the exercise setting and because it improves physical function and emotional well-being [32]. However, no study has applied partnered exercise training in a couple coping with chronic illness and examined potential benefits at both the individual and couple level. This paper describes the rationale, design and baseline descriptive data on participants in a preliminary study to evaluate the benefits of “Exercising Together” – a partnered strength training program for married couples coping with prostate cancer.

The study addresses the following specific aims: 1) Determine the effect of partnered strength training on physical and emotional health in PCS, 2) Determine the effect of partnered strength training on physical and emotional health in spouses, 3) Explore the effect of partnered strength training on marital quality of the PCS and spouse.

METHODS

Study Design and Setting

The study is a randomized controlled trial with two parallel groups comparing the effects of “Exercising Together” (ET) – a program of partnered strength training versus usual care (UC). The intervention period is 6 months, with outcomes measured at baseline, 3 and 6

months. The study is being conducted at Oregon Health & Science University (OHSU) in Portland, Oregon, including all exercise training. The OHSU IRB approved the study protocol and all participants provided signed informed consent. The trial is registered with ClinicalTrials.gov (NCT00954044). The trial started in September 2009 and is expected to complete in early 2012.

Sample

Participants in this study are PCS who have completed primary cancer treatment and their spouses. The eligibility criteria are inclusive to demonstrate the feasibility of the intervention in a broad range of PCS and to enhance the generalizability of the findings. Men and women with chronic conditions and health problems are eligible unless the problems are serious enough to preclude participation in strength training. PCS are eligible if they received treatment for histologically confirmed prostate cancer of any stage, are not currently undergoing radiation therapy or chemotherapy for prostate cancer, are aged 60 or over and are currently residing with an identifiable spouse (or co-residing partner) willing to participate. Same sex couples are eligible to participate. Spouses are eligible if they are currently residing with the PCS and are willing to participate in the study. Both PCS and spouse must meet the following additional eligibility criteria: 1) not currently participating in moderate-vigorous intensity strength training ≥ 2 hrs/wk, 2) cognitively able to answer the survey questions, participate in the performance tests, and give informed consent, 3) free of medical conditions, movement or neurological disorders, or medications that are contraindications to participation in strength training and, 4) willing to be randomized.

Sample size was estimated to provide sufficient power to detect differences in physical function and body composition outcomes of the first and second aims with a power of .80 for a two-tailed repeated measures analysis of variance with $\alpha < 0.05$. Using these criteria, 25 men and 25 women (25 couples) would be needed in each group at the end of the intervention period to detect a post-intervention difference of 2% in % body fat and 4 seconds in chair stand time between groups [28, 33]. The third aim, evaluating couple-level outcomes, has not been examined in prior studies in PCS so data from this study will be used to calculate an effect size for these outcomes for future studies. With a planned attrition of 20% during the intervention period, we aimed to recruit 31 couples per group (62 total couples), with equal numbers of men and women in each group. Attrition estimates are based on our previous studies using an exercise program similar to that in the ET intervention [33, 34], including men with prostate cancer [29].

Recruitment

The primary recruitment strategy for the study was a mailing to potentially eligible participants identified through the Oregon State Cancer Registry (OSCaR) program. OSCaR is a population-based reporting system, run by the Oregon Department of Human Services, which collects and analyzes information about cancer cases in Oregon. The registry sent an information letter to all men with a prostate cancer diagnosis within a 60-mile radius of the intervention site describing the study and asking them to return a pre-paid response form indicating their willingness to be contacted. Additional recruitment strategies included recruitment through the OHSU prostate cancer clinic, prostate cancer support groups and patient conferences, and internet-based media. Recruitment occurred in 3 “waves”, recruited about 3-4 months apart, so that participants could be tested close to the start of the intervention.

Procedures

Interested couples are screened and, if eligible sign an informed consent form to be enrolled in the study. Next, an initial testing session is scheduled and requests for medical clearance

to exercise are sent to participant's physicians. Those who receive medical clearance undergo initial testing in the following order: questionnaires, DXA scan, and tests of balance, gait, and strength. Tests follow standard operating procedures, are administered by a single trained technician blinded to group assignment, and are repeated at 3 and 6 months. Following the completion of baseline testing, couples learn their group assignment by receiving a sealed, sequentially numbered envelope from the project director and opening the envelope which contains the group assignment randomly assigned to their sequence number. The sequence number was generated by a statistician using MS Excel.

Study Interventions

Exercising Together—Participants assigned to this group are expected to attend 2 exercise sessions per week for 6 months and are accompanied by their partners. Classes last approximately 1 hour, including warm-up and cool-down periods. Participants attend classes along with other couples from the same recruitment wave in order to enhance the socialization among participants and to insure that progression of exercise is consistent among participants within each recruitment wave. We recognize that the socialization from group exercise may confound interpretation of psychosocial outcomes, but we accept this tradeoff given the need to insure participant safety and intervention fidelity. To ensure consistency of instruction and intervention fidelity across recruitment waves, all study classes are instructed by the same exercise physiologist, who is certified in strength training instruction and has experience training older adults.

Recommendations for improving muscle strength in older adults support the use of both multiple- and single-joint exercises with slow to moderate lifting velocity, for 1-3 sets per exercise at a weight that can be done for 8–12 repetitions (approximately 60-80% of 1-repetition max) with 1–2 min of rest in between sets [35]. Exercising Together (ET) is a partnered strength training program based on our prior studies in community-dwelling women [34, 36] and our previous study in PCS on ADT [29, 37]. We have shown that these progressive resistance exercise programs improved bone mass, body composition (↑muscle, ↓ fat), strength, gait, and balance. Participants wear a weighted vest while performing lower body resistance exercises (chair rises, 90° squats, lunges). By wearing weighted vests, men and women can perform functional exercises, such as lunges and squats, without encountering balance-related safety risks associated with handheld barbells and dumbbells. Participants use hand weights to provide overload for upper body exercises (1-arm row, bench press, push ups, triceps extension, shoulder raise).

Volume of resistance exercise, determined by intensity (weight, tailored to each individual) and duration (number of repetitions and sets), is gradually increased from low weight and high repetitions to more weight and fewer repetitions over the training period for continuous overload. Once a participant can reach the higher end of the target set and repetition range, weight is increased and the number of sets and number of repetitions are lowered. The progression for intensity of lower body resistance exercise, expressed as a % of body weight loaded into the vest, increases from 1% to 15% of body weight at a rate of ~2%-4% per month for the first 4 months. Intensity of upper body resistance exercise, expressed as repetition maximum (RM), progresses from 15 RM to 8-10 RM, at a rate of ~1-2 RM per month for the first 4 months.

Unique features of our strength training program make it particularly suitable to be performed as a partnered exercise, even among training partners who differ in their exercise capacity. We prescribe resistance exercise as a relative intensity so that it can be tailored for each individual. Specifically, the amount of weight placed in vests for lower body exercise is prescribed as a % of body weight, so that untrained individuals with greater body mass, reflective of absolute lean mass, begin with a higher weight than smaller individuals. For

upper body exercises, the individually determined amount of weight that a participant can lift the prescribed number of times (repetition maximum) will be used to set the resistance. In contrast, other paired activities, such as dance, require that both partners exercise at the same absolute intensity. This is likely to demand different levels of effort from each individual and can create safety concerns for the partner who is expending greater effort. Prescribing exercise relative to an individual's starting capacity, as described above, rather than as an absolute intensity ensures safety and allows individuals with different exercise capacity to exercise in a group or partnered setting. For example, with lower body exercise both training partners will be performing squats but the PCS and his spouse will have different weight in his/her vest according to his/her body weight and initial capacity; with upper body exercise the PCS and his spouse will likely use different hand weights in order to lift the prescribed number of repetitions.

Unlike group exercise where individuals perform the same exercise in synchronized fashion led by an exercise instructor, partnered strength training requires training partners to interact with one another, verbally and physically, during training. We hypothesize that the communications and observations used when training may persist outside of the exercise setting and enhance the overall relationship of the couple. In ET, the PCS and his spouse are training partners whose role it is to assist one another when performing exercises, help each other maintain proper form and provide motivation. Partners assist one another to get into proper exercise form, monitor to ensure form is maintained, correct form as needed and verbally encourage completion of the set. We have identified what we feel are the key characteristics of a successful training team (Table 1) and use this to guide training of couples to maximize their teamwork during each exercise session.

As with any form of exercise, there is a slight risk of injury. Previous studies indicate that supervised, high-intensity resistance exercise can be performed in older populations [38], including PCS [39]. We have taken several steps to reduce the risk of injury associated with the ET program. The types of exercises that we have selected have been performed in PCS on ADT, otherwise healthy men, and women aged 30-85 years without any reported injuries [40-45]. Following initial testing and prior to the beginning of exercise training, each participant's oncologist or primary care provider must provide clearance to exercise. Participants report to the study team any injury that results from the study program or prevents participation. Men or women with injuries and/or adverse symptoms are asked to refrain from exercise until they can consult with their physician about rejoining training. As necessary, adjustments in the training program are made on an individual basis and if given, are in conjunction with medical treatment guidelines and detailed in participant records.

Usual Care (UC)—Participants randomly assigned to the UC group serve as controls. Participants in UC are tested at the same time points as the ET group and receive two telephone calls at months 2 and 5 to set up an appointment time for the 3 and 6-month measurement sessions. At the end of the study, control group participants receive a home-based instructional video of the strength training program used in ET, and are offered a half-day workshop where they can learn the program.

Outcome Measures

Primary endpoints will compare the effects of ET vs. UC on the physical and emotional health of both the PCS and spouse and include the following:

Physical function is measured by the Physical Performance Battery (PPB), developed for the Established Populations for Epidemiologic Studies of the Elderly (EPESE) study [46]. The PPB consists of three timed performance tests: 5 repeated chair stands, standing balance, and gait speed over 4 meters. Each test is scored 0 (unable) to 4, based on quartiles of

performance [47], then scores are summed. Validity of the PPB in older adults has been demonstrated by significant associations between low scores on the PPB and subsequent mobility disability, ADL disability, hospitalization, admission to a nursing home, and mortality [46-49]. A 0.5 point change in PPB score is considered meaningful [50].

Maximal muscle strength of the upper and lower body (kg) is determined with the one-repetition maximum test (1-RM) for leg and bench press conducted according to standard protocols [51]. The 1-RM test has a low potential for injury and to be an effective means of evaluating strength, even in geriatric populations that have never lifted weights before [52, 53] and in cancer survivors [54].

Body composition, defined as the total amount of muscle and fat mass (kg) and the ratio of fat to total body mass (% body fat), is determined from a whole body Dual-Energy X-ray Absorptiometry (DXA) scan performed by trained and licensed personnel.

Fatigue is measured by the revised Piper Fatigue Scale [55] that has established reliability and validity [56-58]. Total and four subscales of fatigue (behavioral/severity, affective meaning, sensory and cognitive/mood) are determined from the 22-item survey [55]. The scale has detected reductions in fatigue in cancer patients undergoing behavioral interventions to reduce fatigue, including exercise [59, 60].

Symptoms. Symptom presence is measured with a 16-item checklist (yes/no), with severity of each item rated with a 5-level Likert-type scale and total scores are then summed. Test-retest reliability for symptom/side effect severity is 0.8 [61] and the pattern of results obtained across multiple longitudinal studies of people undergoing cancer treatment has demonstrated the clinical validity of the checklist [62]. In addition to completion of the checklist by each partner, the spouse completes the checklist based on her observations of her husband's symptoms. The spouse and PCS ratings of his symptoms will be compared to determine the level of incongruence in symptom assessment for marital quality outcomes.

Self-report physical health and mental health is measured by the Short-Form 36 (SF-36) physical and mental component summaries. The SF-36 was designed as a generic measure of health-related quality of life for use in general population surveys [63], and it has been used frequently to measure health in studies of cancer survivors [59, 64-66]. The physical component summary includes scales of physical functioning, role-physical, pain, general health while the mental component summary includes scales of vitality, social functioning, role-emotional, and mental health. Normative scores for each scale range from 0-100, with higher scores indicating better function. A 5-point change in the PCS or MCS is considered meaningful [67].

Depression is evaluated by the Center for Epidemiological Studies-Depression (CES-D) [68]. The CES-D scale has been widely used, demonstrating good internal consistency, sensitivity, specificity and validity [69]. Scores range from 0-60, with a 5-point change considered clinically relevant [70].

Strain incurred by a spouse is measured using the role overload scale [71]. Role overload assesses the extent to which spouse's time and energy are exhausted by the demands of caring for their partner. The scale has exhibited high reliability in studies of family care [71-75], and evidence of construct validity with patient physical function and family member depression [71, 72]. Strain will be assessed in both the spouse and PCS. Since the study focuses on older couples and comorbidities increase with age, it is possible that the PCS may also engage in caregiving activities for his wife.

Secondary endpoints evaluate marital quality for the couple (symptom incongruence, couple communication, relationship quality & intimacy). Incongruence is determined by comparing PCS symptom rating to spouse ratings of her husband's symptoms as described previously. Both the PCS and spouse complete each of the following instruments for other outcomes, unless when noted:

Couple Communication is measured in two ways:

Communication problems are evaluated using the Cancer-Related Communication Problems scale (CRCP) [76]. This 15-item measure was specifically developed for cancer patients and their spouses and assesses common communication difficulties associated with a threatening disease. The scale has demonstrated high reliability and evidence of validity with cancer patients and spouses and marital quality [76]. Scores range from 0-15 with higher scores indicating a higher number of communication problems.

Concealment of symptoms is measured using the Emotional-Intimacy Disruptive Behavior Scale [20]. Patients report the extent to which they engage in 8 behaviors using a scale from 1 (rarely or none of the time) to 4 (most or all of the time). High scores indicate greater concealment. Only the PCS completes this survey.

Relationship quality is measured using the 15-item Mutuality scale [77]. Mutuality is defined as positive quality of the relationship and includes love and affection, shared pleasurable activities, shared values, and reciprocity. Participants respond to items using a Likert-type scale from 0 (*not at all*) to 4 (*a great deal*). Summary scores are averaged across the 15 items and range from 0-4 where high scores indicate high levels of mutuality, characterized by a great deal of reciprocity, love, pleasurable activities and shared values.

Physical intimacy behavior of patient and spouse is measured using the Physical Intimacy Behavior scale [20]. Respondents are asked to report, on a scale of 1-4, the frequency with which they engage in, initiate and avoid each of four affectionate and two sexual behaviors. Three scales assess the frequency, initiation and avoidance of affectionate and sexual behaviors. Higher scores indicate greater engagement in intimate behaviors.

Descriptive variables are measured to evaluate the similarity of randomized groups and to account for potential confounders to the interventions.

Demographic and clinical variables, including age, education, income, other common demographic variables, length of relationship and cancer specific information (diagnosis, type and dates of cancer treatments) are measured at baseline by a questionnaire developed for this study.

Presence of chronic medical conditions is measured by the Charlson Comorbidity Index [78], a weighted index originally developed to predict mortality. We have added two additional questions about thyroid function and osteoarthritis because these conditions affect physical functioning [79].

Exercise outside the exercise intervention is tracked to account for potential confounding of primary outcomes by exercise outside the intervention. Activity outside the intervention is measured by the CHAMPS Physical Activity Questionnaire for Older Adults, which asks 41 questions about sedentary, low, moderate, and vigorous activities during the last 4 weeks [80, 81] that are summed into energy expended in all activities (kcal/week). By separating items into activity categories, types of physical activity that participants engage in (i.e., aerobic, strength, flexibility) can also be inspected. If energy expenditure significantly differs between groups at baseline and/or physical activity outside the intervention

significantly changes over the 6-month study period, baseline values and/or mean difference scores will be considered as covariates in analyses.

Adherence (% of prescribed sessions completed) is tracked by attendance logs recorded by the exercise instructor. Adherence is determined for both the individual and couple since it is expected that men and/or women will occasionally miss classes due to travel, illness or other reasons.

Data Analysis

With the exception of demographic characteristics and clinical history, all self-report measures will be scored using published scoring procedures. The univariate distribution of each variable will be examined to check for excessive skewness and outliers [82]. When data are missing we will examine patterns of missing data for non-randomness by comparing characteristics between participants with missing versus complete data, identifying variables with a high degree of missing data, and comparing missing data over time. For randomly missing data we will perform analyses using mean substitution to retain sample size. Non-random missing data will be evaluated to determine the reason for non-randomness and a strategy developed, such as eliminating cases. We will test for differences 1) between ET and UC and 2) between the completers and dropouts on initial values and demographics using t-tests and chi-squares. For Aims 1 and 2 and the Aim 3 outcomes of couple communication, relationship quality, and physical intimacy, separate 2×3 mixed-design analysis of covariance will be conducted on each outcome with group (ET versus UC) as the between subjects factor and time (0, 3, 6 months) as the within subjects factor. Age and use of ADT (for Aim 1) will be included in the model as covariates as will initial values on demographics and study outcomes if different at baseline. Of interest are significant group $\times$ time interactions that indicate that the means over time for the groups change with differing patterns. Bonferonni correction will be applied to the alpha level to control the experiment-wise error rate within each Aim. All analyses will be done as an intent-to-treat analysis carrying baseline values forward for non-completers. Finally, to explore the effect of the intervention on incongruence regarding PCS symptoms (Aim 3), two incongruence scores will be created at each time point to represent each couple's level of incongruence on PCS presence of symptoms and their symptom severity. Incongruence scores will be created using the Hierarchical Linear Modeling (HLM) program, which estimates a latent incongruence score for each couple while controlling for the correlation in the paired scores associated with each couple (i.e., one for the patient and one for the spouse). Latent scores are stored in a HLM residual file and can be output into SPSS for analyses in MD-ANCOVA, as described above. Statistical advantages of HLM to create incongruence scores is well-documented [83-86].

RESULTS

Recruitment

Recruitment of participants began in December 2008 and concluded in October 2010. A variety of approaches were used to recruit potential participants, resulting in N=290 initial contacts (Fig 1). The most fruitful strategies were mailings through the state cancer registry (n=142) and contacting persons from prior recruitment efforts by the Principal Investigator (PI) who were willing to be notified of future research opportunities (n=102). Of potential participants, 64 couples were eligible and willing to participate (22%) resulting in a study sample that exceeded our target of N=62. Out of the remaining contacts, 45% were not interested in participating, 17% were deemed ineligible and, 16% were unavailable for follow-up contact. Practical constraints, e.g., lack of time and the need to travel to the exercise site, were the primary reasons cited by couples unwilling to participate. Most cases

of ineligibility were from PCS who did not have a spouse/partner or when one or both members of the couple were already strength trained. All 64 couples that were eligible and willing to participate completed a baseline assessment and were randomized to either ET (n=32) or UC (n=32).

DISCUSSION

Prostate cancer threatens QOL of the patient and his spouse and the quality of his marital relationship. Though each is affected by prostate cancer in distinct ways, the physical and emotional health of the patient and his spouse can simultaneously decline. In addition to the impact on each individual, struggles with communication and intimacy can compromise marital quality, which may further jeopardize well-being of each patient and spouse. Exercise is an activity that could be done together by the PCS and his spouse and as a shared activity could confer relationship benefits. Strength training may be a particularly effective type of shared activity because when it is done in partnership each training partner provides assistance, encouragement and feedback to the other and this maximizes training benefits and assures safety. If these teamwork strategies persist outside of the training room, the relationship quality of the couple may improve. The current study provides the first opportunity to explore the effects of an innovative partnered application of exercise to examine effects on both physical and emotional health outcomes at the level of the individual patient and spouse and at the level of the couple. Specifically, we expect that physical functioning will improve (increased PPB score, muscle strength, decreased fatigue), % body fat will decrease, relationship quality will increase (increased intimacy, better communication, reduced strain) and patient-spouse agreement about PCS symptoms will improve as a result of the ET intervention while we expect these outcomes to remain stable or decline in UC.

Any first-time study in a clinical population comes with challenges that must be considered in the research plan. PCS may experience a cancer recurrence or cancer progression over the course of the study. We will allow any PCS that experiences a recurrence or progression of his cancer to continue in the study exercise classes, if medical clearance is obtained from his oncologist. We will, however, consider the patient and couple data separate from planned analyses because disease recurrence can alter the physical capacity of the patient to exercise and will likely alter the emotional health of each member of the couple and their relationship. Similarly, if one partner of a couple in ET is unable or unwilling to continue exercise training, the other partner will be allowed to continue in the exercise program and we will adapt their program so that it can be performed independently. The remaining partner's data will be considered for individual outcomes but the couple's data will not be used in analysis on dyads. While we expect participants to tolerate and enjoy the training program, if an individual or the group shows signs that the program is too rigorous or progressing too quickly we will adjust the program accordingly and document these modifications.

We recognize that adherence to structured interventions require a substantial time commitment on behalf of participants, particularly those who continue to work. In our previous studies using the ET intervention, over 80% of our sample completed the 9-month [33] or 12-month exercise program [34] and retention rates in our recent study in PCS on ADT, the frailest of the three study groups, is 93% at 6 months (unpublished data). Exercise adherence is greater among married couples who attend exercise facilities compared to singles, thus it is possible that retention and adherence could be greater than our estimates. Based on retention and adherence rates in our previous work in older men and women, including PCS, we expect strong retention and adherence in the proposed study as well.

We recognize that couples who volunteer to participate may already engage in shared activities and/or may engage in more shared activities, outside of the interventions, after enrollment in the program. We expect that few shared activities will be those where participants are interacting on the level they would be in ET or in such a way that discussion of symptoms occurs. Nor do we expect many couples to engage in interactive types of exercise. We will track physical activity outside of the interventions and also collect information on shared activities other than the ET program (investigator-developed questionnaire) and consider these variables when interpreting outcomes.

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Figure 1.

Table 1

Role of each training team member (Trainer and Exerciser) during an exercise session with accompanying description and examples

Team Role	Description	Examples
<i>Trainer</i>		
Assess	<ul style="list-style-type: none"> • Determine partner's ability to do the day's exercise • Set intensity and goal reps 	<ul style="list-style-type: none"> • Ask partner about energy level and specific symptoms. • Find out how they felt after their last exercise session. Was the move too easy or too difficult?
Assist	<ul style="list-style-type: none"> • Help partner with position and use of proper technique. • Count repetitions. 	<ul style="list-style-type: none"> • As necessary help partner into and out of position (i.e., lying on bench for chest press) and hand weights to them. • Give verbal and physical reminders about proper form and breathing throughout the movement. • Count repetitions looking for signs of failure.
Applaud	<ul style="list-style-type: none"> • Verbal encouragement during and after exercise 	<ul style="list-style-type: none"> • Encouragement during exercise (i.e., good work, keep going, you can do it, just one more) • Praise for good effort and proper technique
Advise	<ul style="list-style-type: none"> • Discuss how exercise felt and form • Determine goal for next session 	<ul style="list-style-type: none"> • Ask partner how the exercise felt (any pain, difficulty, or too easy) • Depending on response determine intensity and rep goal for next exercise session or consult with instructor for modifications • Give feedback on form and any adjustments for next session
<i>Exerciser</i>		
Receive	<ul style="list-style-type: none"> • Listen to instruction, feedback and praise from trainer 	<ul style="list-style-type: none"> • Demonstrate active listening by verbal or non-verbal acknowledgement.
Respond	<ul style="list-style-type: none"> • Change performance in response to feedback • Discuss accomplishments of the day and goals for next session 	<ul style="list-style-type: none"> • Adjust form and/or effort in response to trainer's feedback during the exercise • Incorporate trainer's feedback on performance into goal setting for next session