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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.

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1. 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]. 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

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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 recruitment of 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.

2. Methods

2.1. 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.

2.2. 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 $\geq$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].

2.3. Recruitment

The primary recruitment strategy for the study is 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 sends an information letter to all men with a prostate cancer diagnosis within a 60-mile radius of the intervention site describing the study and asks them to return a pre-paid response form indicating their willingness to be contacted. Additional recruitment strategies include recruitment through the OHSU prostate cancer clinic, prostate cancer support groups and patient conferences, and internet-based media. Recruitment occurs in 3 "waves", recruited about 3–4 months apart, so that participants could be tested close to the start of the intervention.

2.4. Procedures

Interested couples are screened and, if eligible sign an informed consent form to be enrolled in the study. Next, an

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