

Effects of Resistance Training Frequency on Physical Functioning and Quality of Life in
Prostate Cancer Survivors: A Pilot Randomized Controlled Trial

by

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ABSTRACT

Background: Resistance training (RT) improves physical functioning and quality of life in prostate cancer survivors but the optimal frequency of RT is unknown. **Methods:** A pilot randomized controlled trial was conducted to estimate the potential effects of 12 weeks of supervised RT for 3 days/week (n=16) versus 2 days/week (n=14) in recently diagnosed prostate cancer survivors. The primary outcome was muscular strength assessed by a multiple repetition maximum test at baseline and post-intervention. Secondary outcomes were objective physical functioning assessed by the Senior's Fitness Test, health-related quality of life assessed by the Medical Outcomes Survey-Short Form (SF)-36 scale, and several psychosocial functioning scales. **Results:** A statistical trend ($p < 0.10$) and/or potentially meaningful effect (standardized effect size $d \geq 0.20$) was found that favored the 3 days/week group for the co-primary outcome of greater lower body strength [Mean (M)=27.8; 95% confidence interval (CI): -0.9 to 56.5; $p=0.057$; $d=0.72$] and the secondary outcomes of improved 30-second chair stand ($d=0.29$; $p=0.31$), sit and reach ($d=0.24$; $p=0.33$), the 6 minute walk ($d=0.21$; $p=0.42$), and the SF-36 physical component summary ($d=0.21$; $p=0.41$). Conversely, a statistical trend and/or potentially meaningful effect favoring the 2 days/week group was found for the SF-36 mental component summary ($d=-0.38$; $p=0.10$), SF-36 mental health ($d=-0.44$; $p=0.11$), SF-36 vitality ($d=-0.31$; $p=0.28$), SF-36 role-emotional ($d=-0.23$; $p=0.43$), anxiety ($d=0.32$; $p=0.29$), happiness ($d=-0.31$; $p=0.36$), and perceived stress ($d=0.23$; $p=0.39$). **Conclusions:** RT 3 days/week appeared to improve lower body strength and physical functioning more than 2 days/week but may actually suppress some aspects of psychosocial functioning since several indices of this were better with RT twice a week.

PREFACE

This thesis is an original work by Mary Norris. The research project, of which this thesis is a part, received research ethics approval from the Health Related Ethics Board of Alberta (HREBA) Cancer Committee, Project Name “Effects of resistance training frequency on muscular strength and physical functioning in prostate cancer survivors”, No. 26111, September 30, 2013.

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CHAPTER ONE

Introduction

Prostate cancer is the most common cancer among Canadian men with over 23,000 new cases expected in 2014.^[1] An estimated 1 in 8 men will be diagnosed with prostate cancer at some point during their lifetime. Advances in early detection and enhanced treatments have resulted in an improved 5 year relative survival rate which now stands at 96%.^[1] Consequently, there are now over 176,000 prostate cancer survivors in Canada diagnosed within the past 10 years, which accounts for 21% of all cancer survivors in Canada.^[1]

Surgery, radiation therapy, and androgen deprivation therapy (ADT) are common treatments for prostate cancer that improve disease-free and overall survival in localized and metastatic prostate cancer.^[2-4] Unfortunately, these treatments cause substantial side effects. ADT and radiotherapy can have adverse physiological and psychological side effects that can lead to decreases in quality of life (QOL), reduced muscular strength and lean body mass, increased fat mass, decreases in physical functioning, increased risk for fracture and osteoporosis from a loss of bone mineral density (BMD), depression and fatigue.^[2, 5] Any combination of these side effects can have a synergistic effect leading to a reduction in QOL and possible loss of independence. Therefore, any strategies to improve body composition and physical functioning are very beneficial for reducing risks of falls, fractures, and other complications. However, most treatments for adverse side effects are expensive pharmaceuticals that result in little improvement in physical function.^[6]

RT has been shown to be an effective mode in older adults for improving muscular strength and physical function and counteracting the loss of muscle mass.^[6] RT is safe and well-tolerated by prostate cancer survivors and has beneficial effects on muscle strength, physical function, balance, quality of life, and fatigue.^[6] These health-related benefits of RT could prevent declines in functional status, risk for frailty, dependence, and long-term care.^[7]

Based on these compelling data, the American College of Sports Medicine^[8] and the American Cancer Society^[9] recommend that prostate cancer survivors perform 2 to 3 days/week of RT in addition to aerobic exercise guidelines. This recommendation is based on RT trials that have shown that both 2 days/week^[6, 10-13] and 3 days/week^[2-5, 7, 14, 15] improve health outcomes in prostate cancer survivors. No study to date, however, has compared 3 days/week versus 2 days/week of RT in prostate cancer survivors. If a third day/week of RT results in additional meaningful improvements in clinical outcomes for prostate cancer survivors, then a 3 days/week RT protocol should be recommended for prostate cancer survivors. If a third day/week of RT does not result in additional meaningful improvements in clinical outcomes for prostate cancer survivors, then a recommendation for 2 days/week of RT may be more prudent because it may facilitate prostate cancer survivors adopting the aerobic exercise guidelines. Evidence for this latter “behavioral interference” was found in a previous trial which showed that prostate cancer survivors randomized to a 3 days/week RT program reported a significant decline in their aerobic exercise compared to the usual care group. This finding may suggest that prostate cancer survivors compensated for the additional time and effort of the RT program by

reducing aerobic exercise or that the RT interfered with the maintenance of aerobic fitness.

Only a limited number of studies in non-clinical populations have directly compared different RT frequencies.^[16-18] These studies have had mixed results in terms of improvements in muscular strength and physical functioning with 5 studies showing that higher RT frequency resulted in greater improvements on these outcomes. One study^[17] found that 3 and 5 days per week RT had greater increases compared to 1 and 2 days per week. Farinatti et al.^[19] observed greater improvements in strength and function following higher frequency and volume training. Hunter et al.^[20] found greater increases in maximal bench press for those that trained 4 days compared to 3 days while another study^[21] reported better lower body strength gains in the group that trained 3 times a week compared to 1 day/week. Finally, Braith et al.^[16] reported greater gains in strength for 3 times per week versus 2 times per week. These types of randomized dose-comparison trials provide the best evidence of additional benefits with increased RT frequency, however, these findings may not generalize to prostate cancer survivors because of their disease and treatments.^[22] Moreover, these studies have not included clinical outcomes that are important to prostate cancer survivors such as quality of life and symptom management. The clinical value of increased muscular strength and improved physical functioning may be questioned if it does not improve clinical outcomes important for prostate cancer survivors.

The purpose of this pilot study was to estimate the potential magnitude of any additional benefits from 3 days/week versus 2 days/week of RT in recently diagnosed prostate cancer survivors to inform a large phase III trial on this question. Outcomes of

interest included muscular strength, physical functioning, quality of life, symptoms, and psychosocial functioning. It was hypothesized that 3 days/week of RT compared to 2 days/week RT would result in potentially meaningful additional benefits to both physical and mental health outcomes in prostate cancer survivors that would support a large phase III trial on this question.

CHAPTER TWO

Review of Literature

This thesis is an integration of two main literatures: (1) studies of RT in prostate cancer patients and (2) studies of RT frequency in any population. The first literature search was for studies on the topic of RT and the prostate cancer population using the databases of TOC Premier, SPORTDiscus, CINAHL Plus, PsycEXTRA, and MEDLINE. The following key terms were used: ‘resistance training’, ‘strength training’, ‘weight training’, ‘resistance exercise’, ‘weight lifting’, ‘prostate cancer patients’, ‘cancer patients’, or a combination of them. Of the literature searched on RT and prostate cancer survivors, it was revealed that there was no literature comparing frequency with this population. The second literature search was for studies testing the effects of RT frequency in any population. The literature search was done with the same databases with these key terms: ‘exercise frequency’, ‘training frequency’, ‘2 vs 3 days training’, ‘comparison of 2 vs 3 days resistance training’, ‘differences in resistance training frequency’, ‘differences in strength training frequency’, ‘differences in weight training frequency’, or a combination of them.

The review on RT and prostate cancer begins with 12 articles of relevance found. Studies were included if participants were prostate cancer (PCa) patients, if the study involved an exercise intervention and it involved RT, if muscular strength was measured, or other clinical outcomes were measured in reference to RT.

Two of the studies^[2, 4] were 3-armed trials that involved RT vs aerobic exercise vs a usual care group. The study participants were PCa patients on ADT, with the exception of one study^[2] who had those on and off ADT, and were asked to engage in RT

3 times per week doing 2 sets of 8-12 reps at 60-70% 1RM for 10 different exercises. Weight was increased by 5 lbs once more than 12 reps was completed. The only difference between the two designs was that one trial ^[2] started with 1 set for the first two weeks and progressing to 2 sets thereafter.^[4] Alberga et al.^[2] observed differences between age of PCa patients on and off ADT and found that younger men only improved their muscular fitness with RT when compared to the aerobic and control group. However, only RT improved body composition and muscular fitness in older men (> 65 years). When comparing against the control group, despite age, those on ADT improved body composition and muscular fitness with only RT. Those not on ADT improved aerobic and muscular fitness with only RT. Whereas, Segal et al.^[4] reported that both aerobic and RT mitigate fatigue and improve cardiovascular fitness, however, RT showed longer term improvements. RT also showed additional increases in QOL, muscular strength, triglycerides and percentage body fat. There was less reduction in PSA with RT compared to the usual care group.

Three studies ^[10-12] examined combined RT and aerobic exercise versus a usual care group. All 3 studies had PCa patients undergoing hormone therapy, whereas one study involved long-term ADT^[10], another looked at ADT and radiation therapy^[11], and another examined AST^[12]. The RT protocol from Bourke et al.^[10] involved 2-4 sets of 8-12 reps starting at 60% of 1RM. Frequency went from 2 days a week during week 1-6 and dropped to 1 day a week during weeks 7-12^[10]. Bourke et al.^[10] found that there are clinically relevant improvements in disease specific QOL and fatigue for those in the intervention group. Galvao et al.'s two studies ^[11, 12] involved 8 exercises for their RT at an intensity of 12-6 RM for 2-4 sets, exercises were done 2 days a week. Galvao et al.^[11]

reported significant improvements in their RT and aerobic group when compared to control in cardio fitness, chair rise, muscle strength, and QOL for physical functioning at both 6 month and 12 month marks. Role physical, social function and mental health composite of QOL increased at 6 months with role emotional increasing at 12 months. Galvao et al.^[12] showed a combination RT and aerobic intervention yielded improvements in muscle strength and endurance with borderline improvements in cardio fitness. Physical performance and balance improved in the exercise group for 6-m usual walk and 6-m backward walk with a trend for chair rise. There were no differences in PSA, testosterone, glucose, insulin, lipids or homocysteine. The exercise group also improved in several areas of QOL including general health, vitality and physical health composite. There were also better change scores for role, cognitive, fatigue, nausea and dyspnea with borderline differences for physical, emotional, pain, and insomnia. Lastly, total body and regional lean mass significantly increased in the exercise group.

A study done by Culos-Reed et al.^[3] examined a RT, walking, light stretching intervention that only involved one group of ADT treated PCa patients. Participants were encouraged to engage in their exercise 3-5 times per week with booster sessions occurring every 2 weeks. They discovered that their intervention increased over all physical activity and leisure time activity. There was also a significant increase in moderate and strenuous exercise frequency. Walking distance improved as did post exercise HR and RPE. Fatigue decreased significantly and there was a positive trend toward change in overall QOL.

Mina et. al^[14] studied group based exercise (GBE) vs personal training (PT) on PCa patients undergoing ADT. Exercise sessions were 60 minutes in length and offered 3

times a week for 8 weeks. Intensity was set at 6-12 reps for RT and all sessions, for both groups, included a warm-up, 25 minute aerobic component, 25 minute RT component, and cool down. RT exercises included upper, lower body and core. They reported a trend toward significance for fatigue in the PT group, with no differences for fatigue or HRQOL. PT group improved in resting SBP, body fat percentage, and maximal lower body strength from baseline to post, with a trend toward better waist circumference. GBE reported borderline significant improvements in max upper body and lower body strength after 8 weeks. However, PT had significantly greater improvements in lower body strength than GBE, while GBE had better upper body strength after 8 weeks.

Two studies examined RT vs a control group.^[13, 15] Park et al.^[13] had participants who had undergone laparoscopic radical prostatectomies while Segal et al.^[15] had a population of those on ADT therapy. Park et al.^[13] had an intervention done 2 times a week for 60 minutes with an intensity of 50-70% 1RM when using the elastic bands, 45-75% of HRR max, or 9-13 on the RPE scale. Sessions included RT, pelvic flex, and kegel exercises. They found that functional physical fitness, flexibility, and balance were more improved in those that exercised. Depression decreased and the mental composite score of the SF-36 improved after 12 weeks for the exercisers. Physical composite score decreased in both groups after surgery but recovered in those that exercised versus those that didn't. Continence rate also increased in the group that exercised. Segal et al.^[15] protocol involved 3 times a week commitment with 9 exercises being performed at 60-70% of 1RM for 2 sets of 8-12 reps. Weight would increase once more than 12 reps were completed. Benefits were observed for those that participated in RT in areas of fatigue, HRQOL, upper body fitness, and lower body fitness regardless with whether participants

were treated with curative or palliative intent or if ADT had been received for less than or more than 1 year. There were no significant differences in testosterone or PSA levels.

Three studies were single group interventions that involved only RT.^[5-7] All 3 studies involved PCa patients on ADT with the exception of one trial^[5] that looked at half on ADT vs. half not on ADT. One intervention^[6] involved concentric muscle contractions for the first 10 weeks of the study before moving onto isotonic resistance for the last 10 weeks, with all exercises being done 2 days a week. Overall intensity was set at 12-6 RM for 2-4 sets but with a more detailed breakdown for the first 10 weeks. Week 1-2 consisting of 2 sets of 12 reps, week 3-4 consisting of 3 sets of 10 reps, week 5-7 consisting of 3 sets of 8 reps, week 8-10 consisted of 4 sets of 6 reps. Hansen et al.^[5] performed exercises 3 times a week on a recumbent high-force eccentric ergometer for 12 weeks. Hanson et al.^[7] had participants training 3 times a week for 12 weeks for 60 minutes. Single training sessions were sets of 15 reps at 5RM. The first 4-5 reps would be performed and once the participant could no longer complete the movement the weight was lowered to complete 1-2 reps more. The process continued until all 15 reps were completed with weight being progressed throughout the program. Galvao et al.^[6] showed significant improvements in muscle strength, endurance, and muscle thickness in the quadriceps. Increases also occurred in many of the functional performance tests such as 6-m usual walk, 6-m backwards walk, chair rise, stair climbing, 400-m walk, and balance. PSA levels were measured along with testosterone, GH, cortisol, and hemoglobin yielding no significant changes from RT. Body composition and bone mass were preserved with the intervention as well. Hansen et al.^[5] discovered that those on ADT had significant improvements with RT in 6 minute walk, and isometric knee

extension. While Hanson et al.^[7] found that the short-term, high-intensity RT improved muscle mass, power, strength, endurance, physical function, and QOL, while also reducing fatigue perception.

In summary of the articles done on prostate cancer and RT, it is strongly recommended that prostate cancer survivors should include some kind of RT in their physical activity regimen for 2-3 days/week.

Due to the fact that there is no literature on frequency in RT for prostate cancer survivors, the literature on RT frequency is reviewed separately. Out of the articles searched and found, 11 were used. Studies were included if they examined the difference between days of training frequency whether it be 1 vs 3, 2 vs 3 or any combination, preferably 2 vs 3.

Gillam^[17] examined 5 different RT frequencies: 1 vs 2 vs 3 vs 4 vs 5 days a week. Subjects were high school males who volunteered during a physical activity class and were randomized into 1 of the 5 intervention groups. All groups trained at the same intensity of 1RM for 18 sets on the bench press for 9 weeks. Sessions began with a weight equivalent to their 1RM and if subjects were unable to complete the lift the weight was reduced until successful and then the process repeated. Each subject rested 1 minute between sets. Gillam et al.^[17] found that the individuals that trained between 3 and 5 days/week had significantly greater strength increases than those who exercised only 1 day per week. Three and 5 days a week were found to be more beneficial compared to 2 and 4 days a week. There were no significant differences found in strength between 1 and 2 days/week or 3 and 4 days/week.

Three studies investigated 1, 2, 3 days per week frequency of RT vs a control group.^[18, 19, 23] Farinatti et al.^[19] examined active women 60+ years and involved a low volume protocol that consisted of 1 set of each exercise. The first 2 weeks each participant only performed 1 set of 4 exercises for 10 reps at 70% 1RM. In the third week the remaining 6 exercises were added. Farinatti et al.^[19] found that both strength and functional ability improved following training with higher frequencies (and therefore increased training volume). Nakamura et al.^[18] studied older adult women and sessions were 90 minutes in length and consisted of a 10 minute warm up, 20 minutes of walking, 30 minutes of recreational activities, 20 minutes of RT and a 10 minute cool down. RT consisted of push-ups, leg squats, sit-ups, and back extensions using self-weight or elastic bands. Three sets of 10 reps were completed with 30 seconds of rest in between sets. They found interactions between groups by time in grip strength, arm curl, sit and stand, functional reach, walking around two cones and 6 minute walk. Greatest improvements in body weight, body fat, and BMI were found in the group that exercised 3 days/week. It was also observed that the exercise program performed twice a week was not enough to improve functional fitness. Taaffe et al.^[23] had older adult subjects performing 3 sets of 8 exercises at 80% of 1RM. The first week was set at an intensity of 60% 1RM and then progressing to 80% intensity. 1RM testing was conducted every 4 weeks to adjust individualized training loads and these monthly 1RM's replaced the scheduled training session. Taaffe et al.^[23] reported no differences at any time point among their 3 exercise groups for upper, lower, or whole body strength. RT twice a week or even 1 day/week showed strength gains similar to those that exercise 3 days/week. These strength gains were also accompanied by improved neuromuscular performance.

Two studies examined the effects of 3 vs 4 days week of RT.^[20, 24] Benton et al.^[24] trained middle aged women; their intervention included equal number of sets per week with an 8 week training period. Sessions that were 3 days a week were compiled of 3 sets of 8-12 reps for 8 exercises. Both training protocols included a total of 72 sets per week. The 4 times a week group had 4 bouts of RT weekly on consecutive days where each session included either 3 sets of 8-12 reps for 6 exercises (either upper or lower body). To provide adequate rest between sessions, subjects alternated between upper and lower body exercises. Initial intensity was set at 10 reps at 50% of 1RM for the first set of each exercise and 8-12 reps for 80% of 1RM. The load was increased by 5-10% when participants were able to complete 10-12 reps. Benton et al.^[24] found that 8 weeks of RT had a significant increase in lean mass and was unaffected by training frequency when weekly training sets were equated. Hunter et al.^[20] examined both male and female students from two weight training classes. In both groups the protocol involved 7-10 RM for 7 exercises. Once 10 reps were completed for an exercise, the weight was increased by 5 lbs. The 3 day a week group did 3 sets of each exercise while the 4 times a week group did 2 sets of each exercise for 3 days out of the week and on their fourth day 3 sets to equate for volume. Hunter et al.^[20] discovered that their 4 days/week group increased maximal bench press and bench press endurance more than the 3 days/week group but there were no differences for standing long jump. Muscular endurance also increased more rapidly for 4 days/week group as well as chest circumference.

DiFrancisco et al.^[25] examined the difference between RT for 1 or 2 days a week. The participants were both men and women that completed a 5 minute warm-up followed by one set to muscular fatigue for each exercise at 75% of 1RM. This resulted in the

completion of 10-15 reps and the weight was increased after more than 15 reps was achieved. Both groups trained for 9 weeks and there were no differences found in strength gains between groups.

One study^[21] examined RT 1 vs 3 days per week in experienced recreational weightlifters. Subjects were both men and women, with groups being split between 1 day a week performing 3 sets to failure or 3 days per week doing 1 set to failure. Intensity was set at 80% of 1RM with the 1 day a week group having 2 minute rest in between each set. Once 10, 9, and 8 reps were completed by the 1 day group, weight was increased by 2.3-9.1 kg to lower the number of reps performed on the first set to 5. As for the 3 days a week group, once 10 reps were completed the load increased so that reps were lowered to 3. The program consisted of 9 exercises: supine bench press, triceps press, standing lateral arm raise, lat pull, bicep curl, leg press, leg extension, leg curl, and calf raise. McLester^[21] found that all upper and lower body 1RM's increased significantly over 12 weeks for both groups. The 1 day group gained about half as much upper body strength as the 3 day group at 6 weeks and near 62% of the improvements by week 12. As for the lower body, 1 day gained almost 58% of the improvements experienced by the 3 day group at week 6 and 63% at week 12. There was a significant interaction for leg press, suggesting that the 3 day group increased more leg strength than the 1 day group after 12 weeks.

Three studies looked at 2 vs 3 days a week of RT,^[16, 26, 27] with one having a third arm control group in their study^[16]. Braith et al.^[16] examined high-intensity RT for either 10 or 18 weeks. The experimental groups consisted of both men and women and each training session involved a single set of bilateral knee extensions performed to volitional

fatigue with a load that allowed 7-10 reps to be completed. When subjects could complete more than 10 reps the weight was increased by 5%. Braith et al.^[16] observed an increase across all groups in strength when compared to controls. The 3 days/week group increased peak isometric strength to a greater extent than those that trained 2 days/week. Those that trained for 18 weeks had significantly greater strength changes than those that trained for 10 weeks. RT weight increased significantly for those who trained 3 days/week in both the 10 and 18 week interventions. Candow et al.^[26] examined short-term, equal volume RT in untrained men and women. Both groups performed 9 exercises, 2 or 3 sets of 10 reps at 60-90% 1RM to fatigue. No differences in strength were found between the groups. Murlasits et al.'s^[27] included individuals aged >60 years that performed RT for 8 weeks. Each session consisted of a 5 minute warm-up, a warm-up lift of 6-8 reps at 50% of 1RM, 3 sets of 8 reps completed for 7 exercises and 2 minutes of rest between each set. Training load was set to allow 8 reps and then increased so that no more than 8 reps could be completed during the entire program. Murlasits et al.^[27] found that both 2 and 3 days/week RT elicited similar muscle strength and lean body mass adaptations in older adults. Both groups had increases in force production and showed slight improvement in lean mass.

In summary of the articles done on RT frequency in non-clinical populations, it appears that there are mixed results when it comes to the benefits found in frequency per week for RT. It appears that for older women more frequency is better, as with high school males, and experienced weight lifters. However, when it comes to middle-aged healthy males and females, results appear to be inconclusive.

CHAPTER THREE

Effects of Resistance Training Frequency on Physical Functioning and Quality of Life in Prostate Cancer Survivors: A Pilot Randomized Controlled Trial

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Introduction

Prostate cancer is the most common cancer among Canadian men with over 23,000 new cases expected in 2014.^[1] An estimated 1 in 8 men will be diagnosed with prostate cancer at some point during their lifetime. Advances in early detection and enhanced treatments have resulted in an improved 5 year relative survival rate which now stands at 96%.^[1] Consequently, there are now over 176,000 prostate cancer survivors in Canada diagnosed within the past 10 years, which accounts for 21% of all cancer survivors in Canada.^[1]

Surgery, radiation therapy, and androgen deprivation therapy (ADT) are common treatments for prostate cancer that improve disease-free and overall survival in localized and metastatic prostate cancer.^[2-4] Unfortunately, these treatments cause substantial side effects including decreases in musculoskeletal fitness, muscle strength, and physical functioning that may lead to dependent living and a reduction in quality of life (QOL).^[5] Most treatments for these adverse side effects are expensive pharmaceuticals that result in little improvement in physical function.^[6] RT is safe and well-tolerated by prostate cancer survivors and has beneficial effects on muscle strength, physical function, balance, quality of life, and fatigue.^[6] These health-related benefits of RT could prevent declines in functional status, risk for frailty, dependence, and long-term care.^[7]

Based on these compelling data, the American College of Sports Medicine^[8] and the American Cancer Society^[9] recommend that prostate cancer survivors perform 2 to 3 days/week of RT in addition to aerobic exercise guidelines. This recommendation is based on RT trials that have shown that both 2 days/week^[6, 10-13] and 3 days/week^[2-5, 7, 14, 15] improve health outcomes in prostate cancer survivors. No study to date, however, has

compared 3 days/week versus 2 days/week of RT in prostate cancer survivors. If a third day/week of RT results in additional meaningful improvements in clinical outcomes for prostate cancer survivors, then a 3 days/week RT protocol should be recommended for prostate cancer survivors. If a third day/week of RT does not result in additional meaningful improvements in clinical outcomes for prostate cancer survivors, then a recommendation for 2 days/week of RT may be more prudent because it may facilitate prostate cancer survivors adopting the aerobic exercise guidelines. Evidence for this latter “behavioral interference” was found in a previous trial which showed that prostate cancer survivors randomized to a 3 days/week RT program reported a significant decline in their aerobic exercise compared to the usual care group. This finding may suggest that prostate cancer survivors compensated for the additional time and effort of the RT program by reducing aerobic exercise or that the RT interfered with the maintenance of aerobic fitness.

Only a limited number of studies in non-clinical populations have directly compared different RT frequencies^[16-21, 23-27]. These studies have had mixed results in terms of improvements in muscular strength and physical functioning with 5 studies showing that higher RT frequency resulted in greater improvements on these outcomes. One study^[17] found that 3 and 5 days per week RT had greater increases compared to 1 and 2 days per week. Farinatti et al.^[19] observed greater improvements in strength and function following higher frequency and volume training. Hunter et al.^[20] found greater increases in maximal bench press for those that trained 4 days compared to 3 days while another study^[21] reported better lower body strength gains in the group that trained 3 times a week compared to 1. Finally, Braith et al.^[16] reported greater gains in strength for

3 times per week versus 2. These types of randomized dose-comparison trials provide the best evidence of additional benefits with increased RT frequency, however, these findings may not generalize to prostate cancer survivors because of their disease and treatments.^[22] Moreover, these studies have not included clinical outcomes that are important to prostate cancer survivors such as quality of life and symptom management. The clinical value of increased muscular strength and improved physical functioning may be questioned if it does not improve clinical outcomes important for prostate cancer survivors.

The purpose of this pilot study was to estimate the potential magnitude of any additional benefits from a dose-response of 3 days/week versus 2 days/week of RT in recently diagnosed prostate cancer survivors to inform a large phase III trial on this question. Outcomes of interest included muscular strength, physical functioning, quality of life, symptoms, and psychosocial functioning. It was hypothesized that 3 days/week of RT compared to 2 days/week RT would result in potentially meaningful additional benefits to both physical and mental health outcomes in prostate cancer survivors that would support a large phase III trial on this question.

Methods

Setting and Participants

Prospective participants were identified using the Alberta Cancer Registry. The registry was asked to identify 500 prostate cancer survivors living in Edmonton or the surrounding area diagnosed as recently as possible. Men were eligible if they (1) had histologically confirmed prostate cancer (non-metastatic) but were cured or in remission, (2) had no outstanding medical conditions that could be exacerbated with physical

exertion, (3) were able to complete all questionnaires in English, (5) were able to complete baseline strength testing with proper technique, (6) lived within an hour of the University of Alberta, (7) were between the ages of 18 and 80, and (8) were not currently performing RT for ≥ 2 days/week. Men were excluded if they had a recurrence of their cancer, the doctor felt that the participant was unable to participate in the exercise program, and/or the participant could not complete the physical fitness assessments. The trial received ethics approval from the Health Related Ethics Board of Alberta (HREBA) Cancer Committee and written informed consent was obtained from all participants.

Design and Procedures

This study piloted a 2-arm, randomized controlled trial that compared 3 days/week versus 2 days/week of RT. Stratification was based on the original primary treatment (surgery versus radiation versus active surveillance) and current ADT use (no versus yes). Randomization occurred after baseline measurements were completed using a computer-generated random numbers list. A research assistant not otherwise involved in the study generated the group assignment.

Prospective participants were mailed a recruitment package from the cancer registry that contained a letter from the research team explaining the nature of the study. Interested participants were asked to contact the research coordinator for further details. The research coordinator screened interested participants over the telephone to determine their eligibility. Eligible participants completed a questionnaire and baseline fitness testing consisting of anthropometrics, physical functioning, and maximal strength.

Intervention

The RT intervention was identical for both groups except for the frequency (3 days/week versus 2 days/week) and overall volume (see Appendix F for strength training table). Participants were asked to complete 12 weeks of RT with at least one rest day between sessions. Sessions consisted of a 5-10 minute warm-up on cardio equipment and a 2-5 minute cool-down after their RT program was completed. The exercises included the chest press, leg press, latissimus pull-down, leg curl, shoulder press, leg extension, abdominal flexion, core and back-extension exercises. The program was divided into four 3 week phases. During the first phase participants trained at 60-70% of their predicted 1-RM calculated using the formula of Meyhew^[28], performing 2 sets and 8-12 reps with 1-2 minutes rest between sets. All participants progressed from 2 to 3 sets after the first phase of the program and continued to perform 8-12 repetitions at an intensity of 60-80%. Participants were encouraged to increase their weight to 80% 1RM if they could complete more than 12 repetitions. At the end of each 3 week phase, participants performed a self-administered multiple repetition maximum (mRM) assessment to calculate new predicted 1-RMs and new 60-80% intensity ranges. All RT sessions were supervised by qualified exercise specialists and completed at the Behavioral Medicine Fitness Center at the University of Alberta. Adherence to RT sessions was facilitated by an attractive and well-equipped fitness facility with available equipment, flexibility in scheduling the exercise sessions (e.g., time of day, days of the week), scheduled/booked appointments, immediate follow-up and re-booking of missed sessions, friendly and personable exercise trainers, one-on-one attention, free parking, and regular positive feedback on progress. Attendance was monitored by the exercise trainers. It should also

be noted that we allowed a maximum of two weeks' worth of make-up sessions to account for any sickness during the trial or vacation time.

Measures

All measures were completed at baseline (prior to randomization) and post-intervention (after the 12 week intervention). Outcome assessors for muscular strength, physical functioning, and anthropometrics were not blinded to group assignment.

Primary outcome

The co-primary outcomes were upper and lower body muscular strength assessed by a mRM test for bilateral bench and leg press exercises^[29]. 1-RM strength was predicted from the mRM test using the previously validated equation of Mayhew et al.^[28]

Secondary outcomes

Secondary outcomes included physical functioning, body composition, and patient-reported outcomes. The Seniors' Fitness Test^[30] was used to assess physical functioning. The test consisted of 6 assessment items used to determine mobility-related fitness. The 30-second chair stand assessed lower body strength. The arm curl test assessed upper body strength. The chair sit-and-reach test assessed lower body flexibility (primarily influenced by the hamstring muscle group). The back scratch test assessed upper body flexibility (primarily shoulder joint and associated musculature). The 8-foot up-and-go test assessed agility and dynamic balance. Lastly, the 6-minute walk assessed aerobic endurance.

Body mass, height and waist circumference were used to assess body composition. Body mass was measured using a Health o meter[®] balance beam scale to the nearest 0.10 kg. Height measurements were taken using a stadiometer to the nearest

0.10 cm. Height and body mass were used to calculate body mass index (BMI) (weight ÷ height squared [kg/m²]). Waist circumference was measured with a horizontal measure taken directly above the iliac crest to the nearest 0.10 cm using an anthropometric tape measure.

Health-related quality of life (HRQOL) was assessed using the Medical Outcomes Study 36-Item Short Form (SF-36).^[31] The SF-36 has eight subscales that can be combined and weighted to provide a physical component summary (PCS) score and a mental component summary (MCS) score. These two scores are calculated using a three step procedure. First, the eight subscales are standardized using the means and standard deviations from the U.S. general population. Second, the scores are aggregated using weights (factor score coefficients) from the 1990 U.S. general population. Third, aggregated PCS and MCS scores are standardized using linear T-score transformations with a mean of 50 and a standard deviation of 10. A higher score indicates better functioning.

Prostate cancer symptoms were assessed by the Functional Assessment of Cancer Therapy-Prostate (FACT-P) subscale.^[32] This subscale consists of 12 items that are relevant to patients with prostate cancer. These 12 prostate cancer-specific items include questions regarding sexuality, bowel/bladder function, and pain. Fatigue was measured using the Functional Assessment of Cancer Therapy-Fatigue (FACT-F) scale.^[33] The FACT-F is a 13 item questionnaire with a 5 point scale that is summed for an overall fatigue score. Higher scores indicate less fatigue.

Psychosocial functioning was assessed using the Rosenberg Self-Esteem Scale^[34], the Center for Epidemiological Studies Depression Scale (CES-D)^[35], the Spielberger

State Anxiety Inventory^[36], the Perceived Stress Scale (PSS)^[37], and the Happiness Scale^[38]. The Rosenberg Self-Esteem Scale is a 10 item questionnaire with a 4 point scale (1 = strongly disagree, 2 = disagree, 3 = agree, 4 = strongly agree). The Rosenberg Self-Esteem scale is scored by the sum of the 10 items, where a higher score indicates higher self-esteem. The CES-D scale is a 10 item questionnaire with a 4 point scale (0 = rarely or none of the time <1 day, 1 = some of the time 1-2 days, 2 = much of the time 3-4 days, 3 = most or all of the time 5-7 days). The CES-D is scored by the sum of the 10 items, where a higher score indicates more depressive symptoms. The Spielberger State Anxiety Inventory is a 10 item questionnaire with a 4 point scale (1 = not at all, 2 = somewhat, 3 = moderately so, 4 = very much so). The Spielberger State Anxiety Inventory is scored by the sum of the 10 items, where a higher score indicates more anxious symptoms. The PSS is a 14 item questionnaire with a 5 point scale (0 = never, 1 = almost never, 2 = sometimes, 3 = fairly often, 4 = very often). PSS scores are calculated by summing the 14 items. A higher score indicates a higher degree and longer duration of perceived stress. The Happiness Scale consists of two, self-reporting items measuring emotional well-being. One is rated on an 11 point happiness/unhappiness scale. The second is a question asking for the percentage of time spent in a “happy”, “unhappy”, and “neutral” mood. The combination score is calculated by the formula: $[\text{scale score} \times 10 + \text{happy \%}] / 2$.

Sleep was assessed using the Pittsburgh Sleep Quality Index (PSQI)^[39, 40]. The PSQI is a 19 item self-report scale that measures sleep quality over the past month. Seven sleep components are assessed. These seven components include: subjective sleep quality, latency, duration, efficiency, disturbances, medication use, and daytime dysfunction. The components are all rated on a 0-3 scale where lower scores indicate

better sleep quality. The seven components can be summed to calculate a global sleep quality score that ranges from 0-21. Scores >5 on the global sleep quality scale are reflective of poor sleep quality. Given the length of the questionnaire we excluded the sleep disturbances component of the PSQI because it required 9 of the 19 items. Due to this change our global sleep quality score was based on the remaining six component scores.

Covariates

Demographic and medical information were assessed using self-report. Demographics included age, education level, marital status, annual income, employment status, and ethnicity. Medical information included time since diagnosis, lymph node involvement, previous and current treatments, previous recurrence, and current disease status.

Baseline exercise was assessed using a modified version of the Leisure Score Index from the Godin Leisure-Time Exercise Questionnaire^[41, 42]. Participants were asked to recall their average weekly frequency and duration of light (minimal effort, no perspiration), moderate (not exhausting, light perspiration), and vigorous (heart beats rapidly, sweating) aerobic exercise performed for ≥ 10 minutes during free time over the past month. Aerobic exercise minutes was calculated as weekly sum of moderate minutes plus 2 times the weekly sum of vigorous minutes and a cut-point of 150 aerobic exercise minutes was used to indicate meeting the aerobic exercise guidelines. Participants were also asked to report the frequency and duration of any resistance exercises prior to starting the trial (lifting weights, push ups, sit-ups or therabandsTM). Meeting strength exercise guidelines was defined as a frequency of at least 2 days/week of RT.^[8]

Program evaluation

Perceived benefits were measured at post intervention using a 14 item questionnaire with a 7 point scale (1 = very much worse, 2 = somewhat worse, 3 = slightly worse, 4 = no change, 5 = slightly improved, 6 = somewhat improved, 7 = very much improved). The 14 benefits were the primary and secondary endpoints that were measured in the study. A higher score indicated a higher perceived benefit after the RT program. Perceived barriers were measured at post-intervention using a 12 item questionnaire with a 7 point scale (1 = not at all, 3 = somewhat, 5 = a fair bit, 7 = very much). The barriers were identified from previous research soliciting the main exercise barriers in cancer survivors.^[43] A higher score indicated higher perceived barriers.

At the end of the 12 week intervention, a motivational evaluation of the RT programs was undertaken using the theory of planned behavior.^[44] Participants were asked to evaluate their program in terms of how beneficial, enjoyable, supported, motivated, and difficult they found the supervised RT program. They were also asked to anticipate how beneficial, enjoyable, supported, motivated, and difficult it would be to continue their RT program on their own over the next six months. Evaluations were made using a 5 point scale (1 = not at all, 2 = a little bit, 3 = somewhat, 4 = quite a bit, 5 = very much).

Satisfaction with participating in the clinical study was measured using a 9 item questionnaire with a 7 point scale (1 = not at all, 3 = somewhat, 5 = a fair bit, 7 = very much) that has been used in a previous study of exercise in cancer patients.^[45] The items focused on overall satisfaction with trial participation and the burden of various testing and intervention procedures.

Statistical Analyses

The purpose of this pilot study was to estimate the potential magnitude of the effects of 3 days/week versus 2 days/week of RT in prostate cancer survivors. Consequently, the efficacy results for this trial were interpreted for both statistical trends and potential clinical significance. A statistical trend was defined as a two-tailed alpha of $p < 0.10$. Given this p value, the trial had 80% power to detect only a large standardized effect size d of 0.90 given the modest sample size of 30 participants. Potential clinical significance was defined as a standardized effect size of $d = 0.20$. Reports of mean change were given with each group including the 95% confidence interval. Analysis of covariance (one-way ANCOVA) was used to compare the two groups at post-intervention on all primary and secondary outcomes with adjustment for baseline value of the outcome, current ADT use, and previous treatments (surgery, radiotherapy, hormone therapy). All statistical analyses were performed using SPSS 21 (SPSS Inc., Chicago, IL). For all analyses, the intention-to-treat approach was adopted to include all participants in their randomized condition regardless of adherence.

Results

Participant flow throughout the trial is outlined in **Figure 1**. Of the 502 recruitment letters mailed by the registry, 113 (23%) prostate cancer survivors contacted the study team. Of the 113 contacts, 42 men were ineligible with the 3 most common reasons being (1) currently performing RT ≥ 2 days/week, (2) away during the trial, and (3) medical/health problems. Of the 71 eligible men, 41 declined with the two most common reasons being (1) no response (i.e., the participant initially expressed interest but did not contact the study team again despite multiple attempts by the study team) and (2)

too far to travel. In total, 30 men were randomized which was 6% of all men initially contacted and 27% of all men screened. Fourteen men were randomized to the 2 days/week RT group and 16 to the 3 days/week group. Of the 14 randomized to the 2 days/week group, 100% completed at least 80% of the 24 supervised RT sessions and 100% completed all the post intervention assessments. In the 3 days/week group, 94% completed at least 80% of the 36 supervised RT sessions and 100% completed the post intervention assessments. Mean adherence for the 3 days/week group was 97.2% while the 2 days/week groups had 100% adherence. No adverse events related to exercise were observed or reported.

Baseline clinical characteristics of the sample are reported in **Table 1**. Overall, participants had a mean age of 63 ± 7 SD with the range between 46-76 years, 70% were married, and the mean BMI was 29.6 ± 4.8 kg/m². The mean number of months since diagnosis was 14 ± 5 SD with a range of 2-22 months.

Primary and secondary endpoints

Table 2 reports the data for muscular strength and physical functioning. The 3 days/week group showed a statistical trend toward a larger increase in lower body strength compared to the 2 days/week group [Mean (M)=27.8; 95% confidence interval (CI): -0.9 to 56.5; $p=0.057$; $d=0.72$]. Whereas there were no differences between groups in upper body strength. Potentially meaningful effects in favor of the 3 days/week group were noted for the 30-second chair stand [M=1.1; 95% CI: -1.1 to 3.2; $p=0.31$; $d=0.29$], sit and reach [M=2.1; 95% CI: -2.2 to 6.5; $p=0.33$; $d=0.24$], and the 6 minute walk [M=18.8; 95% CI: -28.2 to 65.9; $p=0.42$; $d=0.21$].

Table 3 provides the health related quality of life data. The 2 days/week group showed a statistical trend toward a larger increase in the MCS compared to the 3 days/week group [M=-3.8; 95% CI: -8.5 to 0.8; p=0.10; d =-0.38]. Potentially meaningful effects in favor of the 2 days/week group were found for mental health [M=-3.5; 95% CI: -7.8 to 0.8; p=0.11; d = -0.44], vitality [M=-3.1; 95% CI: -8.9 to 2.7; p = 0.28; d = -0.31], and role-emotional A potentially meaningful effect in favor of the 3 days/week group was found for the PCS [M=1.6; 95% CI: -2.3 to 5.5; p=0.41; d =0.21].

Table 4 reports the symptom and psychosocial functioning scales. Potentially meaningful effects in favor of the 2 days/week group were found for anxiety [M=1.4; 95% CI: -1.3 to 4.1; p=0.29; d =0.32], happiness [M=-5.6; 95% CI: -17.8 to 6.7; p=0.36; d =-0.31], and perceived stress [M=1.5; 95% CI: -2.0 to 4.9; p=0.39; d =0.23].

Program evaluation

The perceived benefits of supervised RT are presented in **Table 5** with statistically significant findings favoring the 2 days/week group for self-esteem (p=0.010; d = -0.92), physical functioning (p=0.012; d = -0.82), and fatigue (p=0.041; d = -0.73). Statistical trends in favor of the 2 days/week group were found for cardiovascular endurance (p=0.058; d = - 0.67) and happiness (p=0.066; d = -0.64). Potentially meaningful effects in favor of the 2 days/week group were found for anxiety (d = -0.55; p=0.15), stress (d = -0.50; p=0.16), sleep quality (d = -0.45; p=0.19), overall quality of life (d = -0.44; p=0.22), depressed feelings (d = -0.42; p=0.19), body weight or shape (d = -0.33; p=0.39), and ability to complete treatments (d = -0.31; p=0.39).

Perceived barriers are reported in **Table 6**. Potentially meaningful effects were found that favored the 3 days/week group for feeling tired or fatigued (d = 0.50; p=0.12);

and favored the 2 days/week group for feeling sick/not feeling well ($d = -0.42$; $p=0.27$) and traveling to the fitness center ($d = -0.36$; $p=0.32$).

Motivational evaluations of the RT programs are presented in **Table 7**. In terms of the supervised RT program over the past 12 weeks, there were potentially meaningful effects favoring the 2 days/week group for perceived support ($d = -0.40$; $p=0.27$) and difficulty ($d = -0.36$; $p=0.34$). In terms of a supervised RT program over the next 6 months, there was a statistical trend showing that the 2 days/week group anticipated it would be less difficult ($p=0.069$; $d = -0.56$) and potentially meaningful differences showing that the 2 days/week group anticipated it would be more beneficial ($d = -0.43$; $p=0.18$), enjoyable ($d = -0.40$; $p=0.23$), supported ($d = -0.38$; $p=0.26$), and they would be more motivated ($d = -0.56$; $p=0.14$).

Satisfaction with participation in the trial is presented in **Table 8**. The 2 days/week group reported participation in the trial to be significantly more rewarding ($p=0.039$; $d = -0.86$). They also reported a potentially meaningful greater likelihood of recommending the trial to other prostate cancer survivors ($d = -0.43$; $p=0.18$) and of being less likely to view trial participation as a waste of time ($d = -0.43$; $p=0.26$). In terms of burden, there was a potentially meaningful difference showing that the 3 days/week group were less likely to report the supervised training sessions as a burden ($d = 0.42$; $p=0.36$).

Discussion

The purpose of this pilot study was to estimate the potential magnitude of any additional benefits from 3 days/week versus 2 days/week of RT in recently diagnosed prostate cancer survivors. Our primary outcome was muscular strength, with secondary

outcomes including physical functioning, quality of life, symptoms, and psychosocial functioning. Our hypothesis was that 3 days/week of RT would yield potentially more meaningful benefits than 2 days/week for both physical and mental health outcomes in prostate cancer survivors. Consistent with our hypotheses, we found a statistical trend in favor of the 3 days/week group for lower body strength and potentially meaningful effects in favor of the 3 days/week group for the 30-second chair stand, sit and reach, 6 minute walk, and SF-36 PCS. Contrary to our hypotheses, we found a statistical trend in favor of the 2 days/week group for the SF-36 MCS and potentially meaningful effects in favor of the 2 days/week for the SF-36 scales of mental health, vitality, and role-emotional as well as anxiety, happiness, and perceived stress.

The improved muscular strength in the lower body for the 3 days/week group is consistent with McLester et al.^[21] and their finding of higher increase in leg press for those that trained 3 days/week versus 1 day/week in experienced recreational weightlifters. Moreover, our findings follow similarly to Farinatti et al.^[19] who reported higher increases in both strength and functional ability following higher RT frequency in active senior women. Hunter et al.^[20] observed increased maximal and endurance bench press in male and females for those that trained 4 days/week instead of 3 days/week, however our study did not find any additional benefit in upper body strength with a third day of RT. Gillam et al.,^[17] who only trained upper body with bench press, found that groups training 5 or 3 times per week had greater strength increases than those who trained only 1 or 2 times per week. While these studies show a trend of higher frequencies resulting in greater strength gains, there have also been more reports on training frequency having no significant impact on strength gains or physical

functioning.^[18, 23-27] The literature is somewhat divided and when comparing only 2 days/week versus 3 days/week it is very limited.^[16, 26, 27] Three studies have looked at a direct comparison of 2 versus 3 days per week and out of those studies only one found results that favored 3 days training over 2 days^[16]. It should also be noted that this study^[16], like ours, did not equate for training volume and thus, why their results are similar to our trial. Our study also found similar findings to those that looked at other prostate cancer RT interventions, particularly when it came to increases in muscular strength and physical functioning^[2, 4-7, 11-15]. While we did not observe any statistical significant findings, the 2 days/week and 3 days/week increased in upper body strength 29% and 31%, respectfully. Lower body strength increases were 24% and 36% for 2 days/week and 3 days/week respectfully. These increases are similar to what Galvao et al.^[12] found in their RT intervention, with leg press strength increasing by 37%. Upper body only increased 11%, however, Segal et al.^[4] reported increases in upper body of 22% and lower body 24%. Physical functioning items were similar to one study^[12] in chair rise and 6-minute walk. Our reports indicate a 6% increase and 11% increase for the 6-minute walk and a 12% and 18% increase in 30 second chair stand for the 2 days/week and 3 days/week groups respectively. Galvao et al.^[12] observed an increase of 9% in chair rise and 6% increase in the 6-minute usual walk.

Both groups in our study experienced significant increases in upper body strength, however, these changes were similar in magnitude which was unexpected. One study^[46] reported significant increases in upper body strength, but again, there was no difference between the group that performed 1 set and 3 sets. Their rationale was that it could be a result of the greater use of leg muscles for daily activities more so than the upper body,

leading to some of the growth potential in the leg to already be reached through those daily activities in untrained individuals. Our findings are similar to Ronnestad et al.,^[46] who also found no significant differences in upper body strength between their groups after a 12 week RT intervention, but did find significant differences in leg muscle strength. Our program required our participants to complete 3 sets of each exercise for 12 weeks, which might not be enough to elicit significant differences between groups training 2 days/week and 3 days/week for upper body, according to Ronnestad et al.^[46] However, this information is taken from only one study and there could be a counter argument made that the lack of use in upper body through daily activities could allow for bigger gains in strength to be made as the upper body is going from very little stimulus to a regimented training program. Based on this later point, it could be argued that higher volume is needed to increase gains in upper body strength.^[46] While there were no differences in strength gains between the two groups, both groups did find improvements in upper body strength; 29% and 31% for 2 days/week and 3 days/week group. The lack of significant findings between groups might be due to different reasons, some of which could be the intensity was not high enough, initial strength at baseline was already quite high, participants were not motivated to push themselves, and/or interference or side effects from medications, including ADT.

Patient-reported physical functioning as assessed by the PCS had a potentially meaningful effect in favor of the 3 days/week group. This is expected as objective physical functioning showed some improvements in the 3 days/week group. Patient-reported mental health as assessed by the MCS improved in both groups with increases of nearly 7 points for 2 days/week and nearly 5.5 points for 3 days/week. Mental health

improved by 6 points for 2 days/week and 5.5 points for 3 days/week. Vitality had a 5 point increase for 2 days/week and a 4.5 point increase for 3 days/week. Role-emotional reported nearly 5 points improved for 2 days/week with a nearly 3 point improvement for 3 days/week. While the 3 days/week group observed improvements it seems that there is a potential blunting effect for the 3 days/week group when it comes to some of the mental HRQOL components.

Symptoms and psychosocial functioning outcomes included both groups observing some improvements in prostate cancer symptoms, a 5 point and 4 point increase for the 2 days/week and 3 days/week respectfully. Happiness increased by 5 points and nearly 3.5 points for 2 days/week and 3 days/week while both groups had decreases in perceived stress and anxiety. However, again there seems to have been dampening effect on these outcomes for those that were in the 3 days/week group, as they reported less benefit than 2 days/week. These trends in our study for improvements in HRQOL and psychosocial outcomes were similar to other studies that have examined the prostate cancer population.^[3, 4, 7, 10-15] Specifically similar findings were observed in two studies^[11, 12] for improvements in QoL, role emotional, and mental health composite, as well as self-reported physical functioning and mental health for those that participated in an RT and aerobic intervention.

Of the studies that examined the effects of RT frequency^[16-21, 24-27], there were none that examined self-reported measures, producing a gap in the literature of whether or not increased frequency has any additional benefits to patient-reported physical functioning, psychosocial functioning, symptoms, or quality of life. However, this lack of knowledge could potentially be because the studies to report on frequency differences

were not studying clinical populations, although several studied older adults where quality of life might be important.

Speculation into why 3 days/week seems to be less beneficial mentally could be because fitting in one extra day of training is a more taxing task. Therefore, trying to plan in one extra day could be leading to higher stress levels and higher anxiety levels. The addition of a third day could also be more fatiguing overall, and could cause more generalized pain in relation to muscle soreness or minor injury. Also, an added day takes away time from family and friends as well as possible time from work or other errands; this could be a potential link to why it might be more of a mental strain. Time away from family and friends could be worse for mental health. On the other end of the spectrum, 2 days/week might be experiencing higher increases in perceived benefits because the participants were able to complete their weekly goals of getting to the gym twice a week easier and thus felt accomplished by meeting their goals along with less muscle soreness.

Both groups reported finding the trial rewarding, useful for research, useful personally, and would recommend it to other prostate cancer survivors, with the 2 days/week finding it more rewarding, would highly recommend it more to others, and found it less of a waste of time than the 3 days/week. While the 3 days/week found the supervised training sessions to be less of a burden. Motivational evaluation of the RT program observed the 2 days/week group finding better support but found the supervised exercise intervention to be more difficult. When examining the responses to an unsupervised RT program over the next 6 months, following the RT intervention, there was a trend showing the 2 days/week group anticipated that a RT program would be less difficult, more beneficial, more enjoyable, they'd have support, and they would be more

motivated. Both groups, while non-significant, have slightly lower scores when answering if they have a detailed plan for the next 6 months. This could be in part to not having any kind of behavioral intervention component to the study. Perhaps a behavioral support session with proper planning, goal setting, and facility information could provide this population with a better grasp on what to do once the intervention is over. This would then hopefully lead to the participants continuing their exercise after the trial.

Our trial's strengths include being the first to directly compare RT frequency in prostate cancer survivors, the clinical importance of the question, the exceptional adherence rates, the excellent follow-up rate, and the comprehensive assessment of important outcomes with validated measures. Limitations of the study include the modest recruitment rate, small sample size, relatively short intervention with no follow-up, failure to blind the outcome assessors, the lack of a 1RM strength test, and our failure to measure other important outcomes such as body composition, biomarkers of recurrence, and survival outcomes.

Our results also raise several questions for future research. First, our study manipulated one component of the RT prescription to increase weekly RT volume (i.e., frequency). Additional studies manipulating other components of the RT prescription to increase RT volume in prostate cancer survivors are also warranted (e.g., number of exercises, sets, repetitions, weight). Moreover, there is also the potential for equating the amount of volume used in this study to examine the effects of days per week alone. A longer study could potentially examine if there is any increase in upper body strength with the addition of a longer intervention period. Also, an addition of a follow-up could

provide valuable information into how active these men are staying and if their patient-reported outcomes continue to stay at increased levels or if there is any other changes.

In conclusion, our trial provides preliminary evidence that 3 days/week of RT compared to 2 days/week of RT may result in additional improvements in lower body muscular strength and physical functioning in prostate cancer survivors, but may actually impede improvements in mental health and psychosocial functioning. A phase III trial is critical to determine if these outcomes are indeed an accurate depiction of the effects of RT frequency in prostate cancer survivors. If these results are confirmed in a large phase III trial, then exercise specialists, oncologists, and prostate cancer survivors will need to weigh the potential additional gains in physical functioning with the potential blunting of gains in psychosocial functioning when determining the optimal frequency of RT for a given prostate cancer survivor.

Table 1. Baseline Demographic and Clinical Characteristics of Prostate Cancer Survivors, Overall and by Group Assignment.

Variable	Overall (N=30)	2 days/week (n=14)	3 days/week (n=16)
<u>Demographic Profile</u>			
Age, Mean (range), yrs	63 (46-76)	63 (54-76)	63 (46-74)
≥ 60 yrs, No. (%)	20 (67%)	9 (64%)	11 (69%)
Married, No. (%)	21 (70%)	9 (64%)	12 (75%)
Completed university, No. (%)	13 (43%)	7 (50%)	6 (38%)
Income ≥\$100,000/year, No. (%)	15 (50%)	6 (46%)	9 (60%)
Employed, No. (%)	18 (60%)	9 (64%)	9 (56%)
White ethnicity, No. (%)	26 (87%)	11 (79%)	15 (94%)
<u>Cancer Profile</u>			
Disease stage, No. (%)			
Localized	27 (90%)	13 (93%)	14 (88%)
Metastasized	1 (3%)	1 (7%)	0 (0%)
Unsure	2 (7%)	0 (0%)	2 (12.5%)
Previous treatments, No. (%)			
Surgery	5 (17%)	3 (21%)	2 (13%)
Radiation therapy	19 (63%)	10 (72%)	9 (56%)
Hormone therapy	12 (40%)	7 (50%)	5 (31%)
Current hormone therapy, No. (%)	6 (20%)	3 (21%)	3 (19%)
Months since diagnosis, Mean (range)	14 (2-22)	14 (5-22)	14 (2-21)
≤12 months, No. (%)	15 (50%)	8 (57%)	7 (44%)
<u>Behavioral/Health Profile</u>			
Most common comorbidities, No. (%)			
Hypercholesteremia	14 (47%)	6 (43%)	8 (50%)
Arthritis	13 (43%)	8 (57%)	5 (31%)
Hypertension	12 (40%)	7 (50%)	5 (31%)
Weight, Mean (SD), kg	90.5 (16.1)	89.8 (16.5)	91.1 (16.3)
BMI, Mean (SD), kg/m ²	29.6 (4.8)	29.9 (4.9)	29.4 (4.7)
Healthy weight, No. (%)	3 (10%)	1 (7%)	2 (12%)
Overweight, No. (%)	16 (53%)	9 (64%)	7 (44%)
Obese, No. (%)	11 (37%)	4 (29%)	7 (44%)
Current smoker, No. (%)	3 (10%)	1 (7%)	2 (13%)
Current aerobic exerciser, No. (%)	10 (33%)	5 (36%)	5 (31%)
Current resistance exerciser, No. (%)	2 (7%)	0 (0%)	2 (13%)

Note: BMI=body mass index.

Table 2. Effects of 3 days/week versus 2 days/week of supervised resistance training on physical fitness in prostate cancer survivors.

	Baseline M (SD)	Posttest M (SD)	Mean change M [95% CI]	Unadjusted group differences in mean change: M [95% CI]; p Standardized effect size <i>d</i>	¹ Adjusted group differences in mean change: M [95% CI]; p Standardized effect size <i>d</i>
Upper body strength, kg					
2 days/week	56.9 (11.3)	73.5 (10.4)	+ 16.6 [12.5 to 20.7]	+0.6 [-5.0 to 6.2]; p=0.83 <i>d</i> =0.04	+2.1 [-4.1 to 8.3]; p=0.49 <i>d</i> =0.15
3 days/week	55.5 (16.4)	72.7 (17.3)	+ 17.2 [13.4 to 21.0]		
Lower body strength, kg					
2 days/week	162.4 (34.3)	201.1 (43.2)	+ 38.7 [19.5 to 58.0]	+16.2 [-10.6 to 43.0]; p=0.23 <i>d</i> =0.42	+27.8 [-0.9 to 56.5]; p=0.057 <i>d</i> =0.72
3 days/week	153.6 (43.6)	208.6 (69.6)	+ 54.9 [36.3 to 73.6]		
6-minute walk, m					
2 days/week	518.4 (76.6)	551.5 (93.5)	+33.0 [1.4 to 64.7]	+25.4 [-17.3 to 68]; p=0.23 <i>d</i> =0.28	+18.8 [-28.2 to 65.9]; p=0.42 <i>d</i> =0.21
3 days/week	518.8 (103.0)	577.3 (89.7)	+58.4 [29.9 to 87.0]		
30-second chair stands, no.					
2 days/week	13.8 (3.7)	14.8 (4.1)	+1.0 [-0.5 to 2.5]	+1.1 [-1.0 to 3.1]; p=0.29 <i>d</i> =0.29	+1.1 [-1.1 to 3.2]; p=0.31 <i>d</i> =0.29
3 days/week	13.5 (4.0)	15.5 (3.4)	+2.1 [0.7 to 3.5]		
30-second arm curls, no.					
2 days/week	16.4 (4.1)	18.2 (3.6)	+1.9 [0.2 to 3.5]	+0.9 [-1.3 to 3.1]; p=0.42 <i>d</i> =0.22	+0.8 [-1.8 to 3.3]; p=0.54 <i>d</i> =0.19
3 days/week	15.9 (4.3)	18.7 (5.1)	+2.8 [1.2 to 4.3]		
Sit and reach, cm					
2 days/week	-4.5 (8.0)	-1.3 (11.2)	+3.1 [0.3 to 6.0]	+1.0 [-2.9 to 5.0]; p=0.59 <i>d</i> =0.11	+2.1 [-2.2 to 6.5]; p=0.33 <i>d</i> =0.24
3 days/week	-6.0 (9.9)	-1.8 (10.5)	+4.2 [1.5 to 6.9]		
Back scratch, cm					
2 days/week	-10.3 (12.2)	-10.6 (13.3)	-0.4 [-2.6 to 1.9]	+1.0 [-2.1 to 4.0]; p=0.53 <i>d</i> =0.07	+1.6 [-1.8 to 4.9]; p=0.34 <i>d</i> =0.12
3 days/week	-12.5 (14.6)	-11.9 (14.3)	+0.6 [-1.5 to 2.7]		
8-foot up and go, s					
2 days/week	5.7 (1.3)	5.2 (1.5)	-0.5 [-0.7 to -0.2]	+0.1 [-0.3 to 0.5]; p=0.58 <i>d</i> =0.07	-0.0 [-0.4 to 0.4]; p=0.99 <i>d</i> =0.00
3 days/week	5.0 (1.4)	4.7 (1.1)	-0.4 [-0.6 to -0.1]		

Note: ¹Adjusted for baseline value of the outcome, current hormone therapy, and previous treatments (surgery, radiotherapy, and hormone therapy).

Table 3. Effects of 2 days/week versus 3 days/week of supervised resistance training on health-related quality of life in prostate cancer survivors.

	Baseline M (SD)	Posttest M (SD)	Mean change M [95% CI]	Unadjusted group differences in mean change: M [95% CI]; p Standardized effect size <i>d</i>	¹ Adjusted group differences in mean change: M [95% CI]; p Standardized effect size <i>d</i>
Physical Component Summary					
2 days/week	50.3 (8.4)	50.4 (7.9)	+0.1 [-2.7 to 3.0]	+0.3 [-3.6 to 4.2]; p=0.86 <i>d</i> =0.04	+1.6 [-2.3 to 5.5]; p=0.41 <i>d</i> =0.21
3 days/week	49.9 (7.3)	50.3 (6.3)	+0.5 [-2.2 to 3.1]		
Physical Functioning					
2 days/week	48.0 (8.8)	50.9 (7.0)	+2.9 [0.4 to 5.4]	-1.3 [-4.7 to 2.2]; p=0.45 <i>d</i> = -0.01	+0.4 [-2.6 to 3.4]; p=0.78 <i>d</i> =0.05
3 days/week	49.5 (6.3)	51.1 (5.3)	+1.6 [-0.8 to 3.9]		
Role-Physical					
2 days/week	51.1 (5.8)	50.7 (6.8)	-0.4 [-3.4 to 2.7]	-0.1 [-4.2 to 4.0]; p=0.96 <i>d</i> = -0.02	+0.4 [-4.2 to 5.1]; p=0.85 <i>d</i> =0.06
3 days/week	50.9 (6.8)	50.4 (7.5)	-0.5 [-3.3 to 2.4]		
Bodily Pain					
2 days/week	50.2 (9.8)	51.1 (7.6)	+0.9 [-4.3 to 6.1]	+1.7 [-5.4 to 8.9]; p=0.62 <i>d</i> =0.18	+0.8 [-5.5 to 7.1]; p=0.80 <i>d</i> =0.08
3 days/week	48.0 (9.4)	50.6 (7.4)	+2.6 [-2.2 to 7.5]		
General Health					
2 days/week	50.6 (4.6)	54.2 (6.5)	+3.6 [1.2 to 6.1]	-0.7 [-4.0 to 2.7]; p=0.69 <i>d</i> = -0.11	-0.6 [-4.4 to 3.2]; p=0.74 <i>d</i> = -0.09
3 days/week	46.7 (7.3)	49.7 (6.9)	+3.0 [0.7 to 5.3]		
Mental Component Summary					
2 days/week	49.8 (9.0)	56.5 (4.1)	+6.7 [1.9 to 11.5]	-1.3 [-7.9 to 5.3]; p=0.69 <i>d</i> = -0.13	-3.8 [-8.5 to 0.8]; p=0.10 <i>d</i> = -0.38
3 days/week	46.0 (10.7)	51.4 (7.0)	+5.4 [0.9 to 9.9]		
Vitality					
2 days/week	53.0 (9.5)	58.3 (7.0)	+5.4 [0.2 to 10.5]	-0.9 [-7.9 to 6.1]; p=0.80 <i>d</i> = -0.09	-3.1 [-8.9 to 2.7]; p=0.28 <i>d</i> = -0.31
3 days/week	48.0 (10.0)	52.5 (7.3)	+4.5 [-0.3 to 9.3]		
Social Functioning					
2 days/week	49.1 (7.6)	53.3 (5.1)	+4.3 [-0.4 to 8.6]	+0.1 [-5.8 to 6.1]; p=0.96 <i>d</i> =0.01	-0.8 [-5.5 to 4.0]; p=0.75 <i>d</i> = -0.09
3 days/week	46.3 (10.1)	50.7 (6.9)	+4.4 [0.4 to 8.4]		

Role-Emotional					
2 days/week	47.3 (8.2)	52.0 (4.0)	+4.7 [0.3 to 9.2]	-2.0 [-8.1 to 4.0]; p=0.50	-1.8 [-6.3 to 2.8]; p=0.43
3 days/week	47.1 (7.7)	49.8 (7.4)	+2.7 [-1.5 to 6.8]	<i>d</i> = -0.26	<i>d</i> = -0.23
Mental Health					
2 days/week	50.4 (6.0)	56.6 (5.1)	+6.2 [2.1 to 10.4]	-0.8 [-6.5 to 4.9]; p=0.78	-3.5 [-7.8 to 0.8]; p=0.11
3 days/week	46.8 (9.3)	52.3 (5.5)	+5.5 [1.6 to 9.3]	<i>d</i> = -0.10	<i>d</i> = -0.44

Note: ¹Adjusted for baseline value of the outcome, current hormone therapy, and previous treatments (surgery, radiotherapy, and hormone therapy).

Table 4. Effects of 3 days/week versus 2 days/week of supervised resistance training on symptoms and psychosocial functioning in prostate cancer survivors.

	Baseline M (SD)	Posttest M (SD)	Mean change M [95% CI]	Unadjusted group differences in mean change: M [95% CI]; p Standardized effect size <i>d</i>	¹ Adjusted group differences in mean change: M [95% CI]; p Standardized effect size <i>d</i>
Prostate cancer symptoms					
2 days/week	30.6 (7.0)	35.9 (5.5)	+5.2 [1.9 to 8.4]	-1.2 [-5.7 to 3.3]; p=0.58 <i>d</i> = -0.18	-1.2 [-5.4 to 2.9]; p=0.55 <i>d</i> = -0.18
3 days/week	27.9 (6.0)	31.9 (5.5)	+4.0 [0.9 to 7.1]		
Fatigue symptoms					
2 days/week	43.0 (7.4)	44.6 (4.3)	+1.6 [-3.0 to 6.3]	+1.0 [-5.4 to 7.4]; p=0.75 <i>d</i> =0.13	+0.2 [-5.8 to 6.3]; p=0.93 <i>d</i> =0.03
3 days/week	39.4 (7.7)	42.1 (8.6)	+2.6 [-1.7 to 7.0]		
Perceived stress					
2 days/week	16.9 (3.8)	16.8 (4.3)	-0.1 [-2.8 to 2.5]	-0.1 [-3.7 to 3.5]; p=0.95 <i>d</i> = -0.02	+1.5 [-2.0 to 4.9]; p=0.39 <i>d</i> =0.23
3 days/week	20.0 (8.3)	19.8 (7.1)	-0.3 [-2.7 to 2.2]		
Happiness					
2 days/week	65.0 (18.0)	70.0 (15.6)	+5.1 [-4.5 to 14.6]	-1.7 [-14.6 to 11.2]; p=0.79 <i>d</i> = -0.09	-5.6 [-17.8 to 6.7]; p=0.36 <i>d</i> = -0.31
3 days/week	60.5 (18.2)	63.9 (15.2)	+3.4 [-5.2 to 12.0]		
Self-esteem					
2 days/week	33.4 (3.8)	34.4 (3.7)	+1.0 [-0.5 to 2.5]	-0.1 [-2.1 to 1.9]; p=1.0 <i>d</i> = -0.02	+0.2 [-1.7 to 2.0]; p=0.86 <i>d</i> = 0.05
3 days/week	32.5 (4.5)	33.4 (3.9)	+0.9 [-0.4 to 2.3]		
Depression					
2 days/week	4.1 (2.9)	4.2 (1.6)	+0.1 [-1.4 to 1.6]	-1.1 [-3.2 to 1.0]; p=0.30 <i>d</i> = -0.28	+0.3 [-1.6 to 2.3]; p=0.73 <i>d</i> =0.08
3 days/week	6.6 (4.4)	5.6 (4.0)	-0.9 [-2.4 to 0.5]		
Anxiety					
2 days/week	16.4 (3.3)	14.4 (3.2)	-2.0 [-4.2 to 0.2]	+0.8 [-2.2 to 3.7]; p=0.61 <i>d</i> =0.18	+1.4 [-1.3 to 4.1]; p=0.29 <i>d</i> =0.32
3 days/week	17.6 (5.2)	16.4 (5.0)	-1.3 [-3.3 to 0.8]		
Sleep quality					
2 days/week	3.3 (2.3)	2.8 (2.6)	-0.5 [-1.7 to 0.7]	-0.3 [-1.9 to 1.3]; p=0.69 <i>d</i> = -0.08	+0.6 [-1.1 to 2.2]; p=0.48 <i>d</i> =0.17
3 days/week	5.8 (4.0)	5.0 (2.9)	-0.8 [-1.9 to 0.3]		

Note: ¹Adjusted for baseline value of the outcome, current hormone therapy, and previous treatments (surgery, radiotherapy, and hormone therapy).

Table 5. Perceived benefits of supervised resistance training in prostate cancer survivors, overall and by group assignment.

Variable	Overall (N=30)	2 days/week (n=14)	3 days/week (n=16)	p value	<i>d</i>
	Mean (SD)	Mean (SD)	Mean (SD)		
Physical functioning	6.0 (1.1)	6.5 (0.7)	5.6 (1.2)	0.012	-0.82
Overall quality of life	5.7 (0.9)	5.9 (0.9)	5.5 (0.9)	0.22	-0.44
Cardiovascular endurance	5.5 (1.2)	5.9 (1.1)	5.1 (1.1)	0.058	-0.67
Muscular strength	6.3 (0.9)	6.4 (0.8)	6.3 (1.0)	0.75	-0.01
Fatigue	5.4 (1.1)	5.9 (0.9)	5.1 (1.1)	0.041	-0.73
Happiness	5.5 (1.1)	5.9 (1.1)	5.2 (1.0)	0.066	-0.64
Sleep quality	5.1 (1.1)	5.4 (1.4)	4.9 (0.9)	0.19	-0.45
Depressed feelings	4.8 (1.2)	5.1 (1.3)	4.6 (1.1)	0.19	-0.42
Anxious feelings	5.0 (1.1)	5.3 (1.1)	4.7 (1.1)	0.15	-0.55
Self-esteem	5.4 (1.2)	6.0 (1.0)	4.9 (1.1)	0.010	-0.92
Stress	5.2 (1.2)	5.5 (1.3)	4.9 (1.1)	0.16	-0.50
Body weight or shape	5.4 (1.2)	5.6 (1.1)	5.2 (1.3)	0.39	-0.33
Ability to complete treatments	5.1 (1.3)	5.3 (1.3)	4.9 (1.3)	0.39	-0.31
Illness or injury	4.8 (1.2)	4.9 (1.2)	4.7 (1.1)	0.69	-0.17

Note: All variables were scored on a 7-point scale from 1=very much worse to 4=no change to 7=very much improved.

Table 6. Perceived barriers to supervised resistance training in prostate cancer survivors, overall and by group assignment.

Variable	Overall (N=30)	2 days/week (n=14)	3 days/week (n=16)	p value	<i>d</i>
	Mean (SD)	Mean (SD)	Mean (SD)		
Bad weather	1.1 (0.4)	1.2 (0.6)	1.1 (0.3)	0.34	0.25
Feeling tired or fatigued	1.8 (0.8)	2.0 (0.8)	1.6 (0.7)	0.12	0.50
Symptoms and side effects of treatments	1.6 (1.2)	1.5 (0.7)	1.7 (1.5)	0.67	-0.17
Other medical/health problems	1.9 (1.6)	1.7 (1.6)	2.1 (1.6)	0.49	-0.25
Too busy and had limited time	2.1 (1.5)	2.1 (1.7)	2.1 (1.4)	0.92	0.00
Pain or soreness	2.2 (1.3)	2.3 (1.1)	2.1 (1.5)	0.65	0.15
Feeling sick/not feeling well	1.5 (1.2)	1.2 (0.4)	1.7 (1.5)	0.27	-0.42
Nausea/vomiting	1.1 (0.4)	1.1 (0.5)	1.0 (0.0)	0.29	0.25
Urinary incontinence	1.7 (1.3)	1.6 (0.9)	1.7 (1.6)	0.92	-0.08
Medical appointments	1.3 (1.0)	1.3 (0.6)	1.4 (1.3)	0.81	-0.10
Lack of motivation	1.4 (0.7)	1.4 (0.5)	1.4 (0.8)	0.75	0.00
Traveling to the fitness center	1.8 (1.4)	1.5 (0.8)	2.0 (1.7)	0.32	-0.36

Note: All variables were scored on a 7-point scale from 1=not at all to 7=very much.

Table 7. Motivational evaluation of resistance training in prostate cancer survivors, overall and by group assignment.

Variable	Overall (N=30)	2 days/week (n=14)	3 days/week (n=16)	p value	<i>d</i>
	Mean (SD)	Mean (SD)	Mean (SD)		
Patient preference at baseline, No. (%)				0.56	
2 days/week	6 (20%)	2 (14%)	4 (25%)		
3 days/week	10 (33%)	5 (36%)	5 (31%)		
No preference	14 (47%)	7 (50%)	7 (44%)		
Reaction to group assignment, Mean (SD)	5.4 (1.5)	5.2 (1.6)	5.5 (1.4)	0.61	0.20
Patient preference at postintervention, No. (%)				0.55	
2 days/week	4 (13%)	3 (21%)	1 (6%)		
3 days/week	16 (53%)	6 (43%)	10 (63%)		
No preference	10 (33%)	5 (36%)	5 (31%)		
Supervised resistance training over the past 12 weeks, Mean (SD)					
Beneficial	4.4 (1.0)	4.6 (1.1)	4.3 (0.9)	0.37	-0.30
Enjoyable	4.3 (1.0)	4.4 (1.2)	4.3 (0.9)	0.91	-0.10
Supported	4.7 (0.5)	4.8 (0.6)	4.6 (0.5)	0.27	-0.40
Motivated	4.5 (0.6)	4.6 (0.5)	4.5 (0.6)	0.74	-0.17
Difficult	2.1 (1.1)	1.9 (1.1)	2.3 (1.1)	0.34	-0.36
Unsupervised resistance training over the next 6 months, Mean (SD)					
Beneficial	4.5 (0.7)	4.7 (0.5)	4.4 (0.8)	0.18	-0.43
Enjoyable	3.9 (1.0)	4.1 (0.9)	3.7 (1.1)	0.23	-0.40
Supported	4.4 (0.8)	4.6 (0.6)	4.3 (0.9)	0.26	-0.38
Motivated	4.1 (0.9)	4.4 (0.7)	3.9 (1.0)	0.14	-0.56
Difficult	2.2 (0.9)	1.9 (0.8)	2.4 (0.9)	0.069	-0.56
Detailed plan	3.5 (1.3)	3.4 (1.3)	3.6 (1.3)	0.68	0.15

Note: All variables were scored on a 5-point scale from 1=not at all to 5=very much except for reaction to group assignment which was scored from 1=extremely disappointed to 4=neutral to 7=extremely pleased.

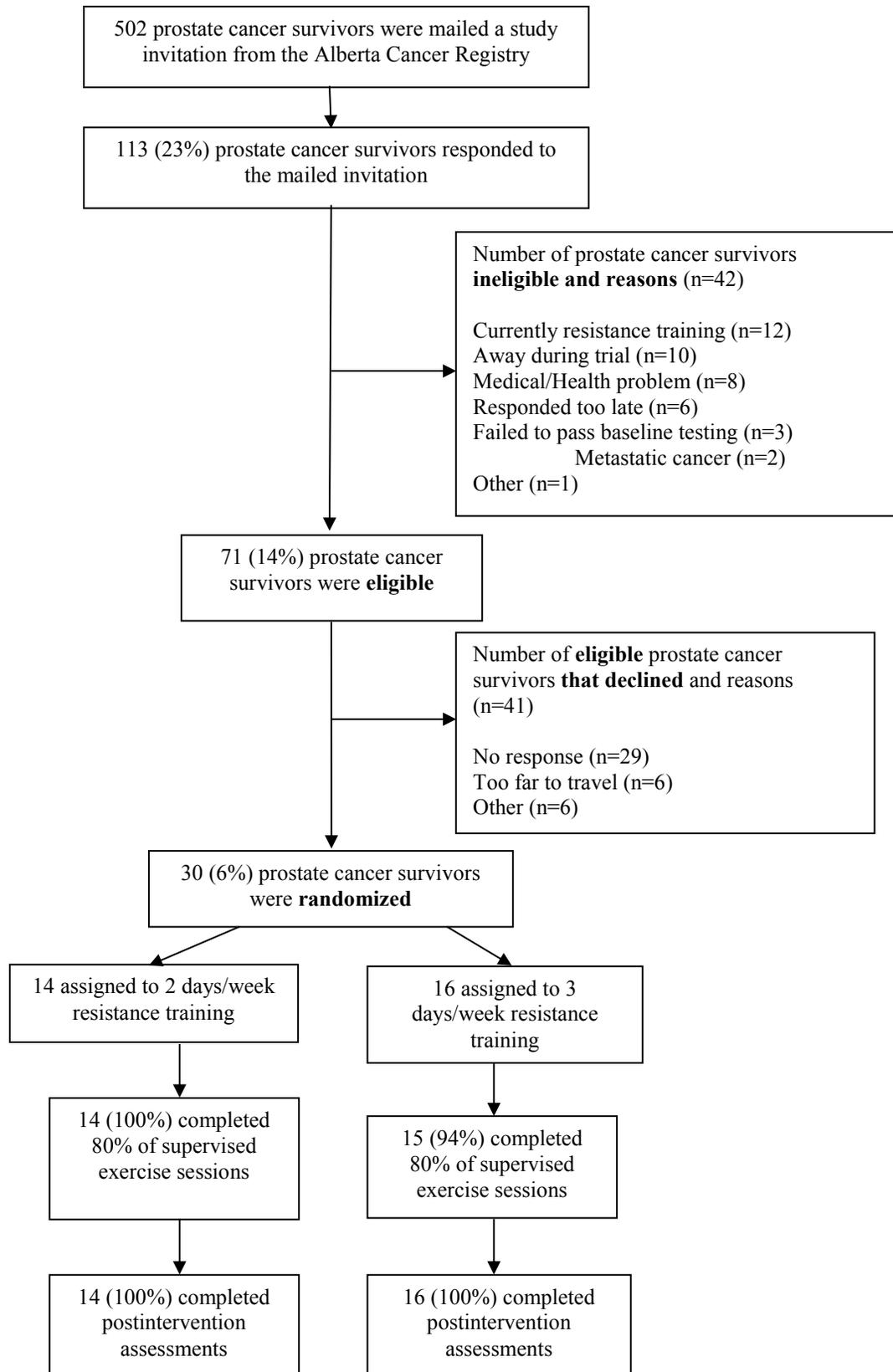
Table 8. Satisfaction with participation in a clinical trial of supervised resistance training in prostate cancer survivors, overall and by group assignment.

Variable	Overall (N=30)	2 days/week (n=14)	3 days/week (n=16)	p value	<i>d</i>
	Mean (SD)	Mean (SD)	Mean (SD)		
<u>Trial Satisfaction</u>					
Rewarding	6.6 (0.7)	6.9 (0.4)	6.3 (0.9)	0.039	-0.86
Waste of time	1.2 (0.7)	1.0 (0.0)	1.3 (1.0)	0.26	-0.43
Useful for research helping others	6.0 (1.3)	6.1 (1.4)	5.9 (1.2)	0.76	-0.15
Useful for me personally	6.5 (0.8)	6.5 (0.7)	6.6 (0.9)	0.83	0.13
Recommend to other prostate cancer survivors	6.7 (0.7)	6.9 (0.3)	6.6 (1.0)	0.18	-0.43
<u>Trial Burden</u>					
Physical function test	1.6 (0.9)	1.5 (0.8)	1.6 (1.1)	0.72	-0.11
Strength test	1.7 (1.0)	1.8 (0.9)	1.6 (1.0)	0.65	0.20
Questionnaires	1.7 (1.1)	1.9 (1.2)	1.6 (1.0)	0.47	0.27
Supervised training sessions	1.6 (1.2)	1.9 (1.6)	1.4 (0.9)	0.36	0.42

Note: All variables were scored on a 7-point scale from 1=not at all to 7=very much.

FIGURE CAPTION

Figure 1. Flow of participants through the trial.



CHAPTER FOUR

Discussion

Though many of the discussion points have already been addressed in Chapter Three, this discussion will include expanded explanations on the strengths of the study, limitations, and future directions. The purpose of this pilot study was to estimate the potential magnitude of any additional benefits from 3 days/week versus 2 days/week of RT in recently diagnosed prostate cancer survivors. The primary outcome was muscular strength, with secondary outcomes including physical functioning, quality of life, symptoms, and psychosocial functioning. The hypothesis was that 3 days/week of RT would yield potentially meaningful benefits to both physical and mental health outcomes in prostate cancer survivors. Consistent with the hypotheses, a statistical trend was found in favor of the 3 days/week group for lower body strength and potentially meaningful effects in favor of the 3 days/week group for the 30-second chair stand, sit and reach, 6 minute walk, and SF-36 PCS. Contrary to the hypotheses, a statistical trend in favor of the 2 days/week group was observed for the SF-36 MCS and potentially meaningful effects in favor of the 2 days/week for the SF-36 scales of mental health, vitality, and role-emotional as well as anxiety, happiness, and perceived stress.

The improved muscular strength in the lower body for the 3 days/week group is consistent with McLester et al.^[21] and their finding of higher increase in leg press for those that trained 3 days/week versus 1 day/week in experienced recreational weightlifters. Moreover, our findings follow similarly to Farinatti et al.^[19] who reported higher increases in both strength and functional ability following higher training frequency in active senior women. Hunter et al.^[20] observed increased maximal bench

press and bench press endurance in male and females for those that trained 4 days/week instead of 3 days/week, however the present study did not find any benefit in upper body strength with a third day of RT. Gillam et al.,^[17] who only trained upper body with bench press, found that groups training 5 or 3 times per week had greater strength increases than those who trained only 1 or 2 times per week. While these studies show a trend in higher frequency and higher gains, there have been more reports on training frequency having no significant impact on strength gains or physical functioning.^[18, 23-27] The literature is somewhat divided and limited when comparing only 2 days/week versus 3 days/week.^[16, 26, 27] Three studies have researched a direct comparison of 2 versus 3 days per week and out of those studies only one favored 3 days training over 2 days^[16]. It should also be noted that this study^[16], like the present thesis, did not equate for training volume. Our study also found similar findings to those that studied other prostate cancer RT interventions, particularly when it came to increases in muscular strength and physical functioning^[2, 4-7, 11-15]. While the present study did not observe any statistical significant findings, the 2 days/week and 3 days/week increased in upper body strength 29% and 31%, respectfully. Lower body strength increases were 24% and 36% for 2 days/week and 3 days/week respectfully. These increases are similar to what Galvao et al.^[12] found in their RT intervention, with leg press strength increasing by 37%. Upper body only increased 11%; however, Segal et al.^[4] reported increases in upper body of 22% and lower body 24%. Physical functioning items were similar to one study^[12] in chair rise and 6-minute walk. This thesis found a 6% increase and 11% increase for the 6-minute walk and a 12% and 18% increase in 30second chair stand for the 2 days/week and 3

days/week groups respectively. Galveo et al.^[12] observed an increase of 9% in chair rise and 6% increase in the 6-minute usual walk.

Both groups in this study experienced significant increases in upper body strength, however, these changes were similar in magnitude which was unexpected. One study^[46] reported significant increases in upper body strength, but again, there was no difference between the group that performed 1 set and 3 sets. Their rationale was that it could be a result of the greater use of leg muscles for daily activities more so than the upper body, leading to some of the growth potential in the leg to already be reached through those daily activities in untrained individuals. The findings in this study are similar to Ronnestad et al.,^[46] who also found no significant differences in upper body strength between their groups after a 12 week RT intervention, but did find significant differences in leg muscle strength. The present studies program required participants to complete 3 sets of each exercise for 12 weeks, which might not be enough to elicit significant differences between groups training 2 days/week and 3 days/week for upper body, according to Ronnestad et al.^[46] However, this information is taken from only one study and there could be a counter argument made that the lack of use in upper body through daily activities could allow for bigger gains in strength to be made as the upper body is going from very little stimulus to a regimented training program. Based on this later point, it could be argued that higher volume is needed to increase gains in upper body strength.^[46] While there were no differences in strength gains between the two groups, both groups did find improvements in upper body strength; 29% and 31% for 2 days/week and 3 days/week group. The lack of significant findings between groups might be due to different reasons, some of which could be the intensity was not high enough,

initial strength at baseline was already quite high, participants were not motivated to push themselves, and/or interference or side effects from medications, including ADT.

Patient-reported physical functioning as assessed by the PCS had a potentially meaningful effect in favor of the 3 days/week group. This was expected as objective physical functioning showed some improvements in the 3 days/week group. Patient-reported mental health as assessed by the MCS improved in both groups with increases of nearly 7 points for 2 days/week and nearly 5.5 points for 3 days/week. Mental health improved by 6 points for 2 days/week and 5.5 points for 3 days/week. Vitality had a 5 point increase for 2 days/week and a 4.5 point increase for 3 days/week. Role-emotional reported nearly 5 points improved for 2 days/week with a nearly 3 point improvement for 3 days/week. While the 3 days/week group observed improvements it seems that there was a potential blunting effect for the 3 days/week group when it comes to some of the mental HRQOL components.

Symptoms and psychosocial functioning outcomes included both groups observing some improvements in prostate cancer symptoms, a 5 point and 4 point increase for the 2 days/week and 3 days/week, respectfully. Happiness increased by 5 points and nearly 3.5 points for 2 days/week and 3 days/week while both groups had decreases in perceived stress and anxiety. However, there seems to have been dampening effect on these outcomes for those that were in the 3 days/week group, as they reported less benefit than 2 days/week. These trends in the present study for improvements in HRQOL and psychosocial outcomes were similar to other studies that have examined the prostate cancer population.^[3, 4, 7, 10-15] Specifically similar findings were observed in two studies^[11, 12] for improvements in QoL, role emotional, and mental health composite, as

well as self-reported physical functioning and mental health for those that participated in an RT and aerobic intervention.

Of the studies that observed differences in RT frequency^[16-21, 24-27], there were none that examined self-reported measures, producing a gap in the literature of whether or not increased frequency has any additional benefits to patient-reported physical functioning, psychosocial functioning, symptoms, or quality of life. However, this lack of knowledge could potentially be because the studies that have reported on frequency differences were not studying clinical populations. Speculation into why 3 days/week seems to be less beneficial mentally could be because one extra day of training can be more taxing of a task to some. Therefore, trying to plan in one extra day could be leading to higher stress levels and higher anxiety levels if completion of this goal is not met. The addition of a third day could also be more fatiguing overall, and could cause more muscle pain and soreness. Also, an added day takes away time from family and friends as well as possible time from work or other errands; this could be a potential link to why it might be more of a mental strain. Time away from family and friends could also be worse for mental health. Conversely, 2 days/week might be experiencing higher increases in perceived benefits because the participants were able to complete their weekly goals of getting to the gym twice a week easier and thus felt accomplished by meeting their goals.

Both groups reported finding the trial rewarding, useful for research, useful personally, and would recommend it to other prostate cancer survivors, with the 2 days/week finding it more rewarding, would highly recommend it more to others, and found it less of a waste of time than the 3 days/week. While the 3 days/week found the supervised training sessions to be less of a burden. Motivational evaluation of the RT

program observed the 2 days/week group finding better support but harder difficulty for the supervised exercise intervention. When examining the responses to an unsupervised RT program over the next 6 months there was a trend showing the 2 days/week group anticipated that it would be less difficult, more beneficial, more enjoyable, they'd have support, and they would be more motivated. Both groups, while non-significant, have slightly lower scores when answering if they have a detailed plan for the next 6 months. This could be in part to not having any kind of behavioral component to the study. Perhaps a behavioral support session with proper planning, goal setting, and facility information could provide this population with a better grasp on what to do once the intervention is over. This would then hopefully lead to the participants continuing their exercise after the trial.

The present thesis strengths include being the first to directly compare RT frequency in prostate cancer survivors. The optimum dose for RT is unknown and the current guidelines offer a range of 2-3 days for prostate cancer patients. However, this thesis helps unveil the benefits of these two frequencies when compared against each other. This provides insight into what the optimum dose could be for this population. The present trial also had exceptional adherence rates, reporting 100% for the 2 days/week group and 97.2% for the 3 days/week group. This is higher than any adherence rate to date in the exercise oncology literature. These findings could be due to the very motivated group. These men were contacted in a large mail out and it was up to them to contact the researcher if they were interested, resulting in most of them being very motivated to begin exercise. A two week make-up session period was also allowed, where participants could complete two weeks' worth of sessions if they missed some

because of sickness or vacation. Quite a few participants took advantage of this option that improved their adherence rates. Another explanation could be that participants had access to a well-equipped, private gym with free parking. This excellent follow-up rate, and the comprehensive assessment of important outcomes with validated measures were also strengths on the present study.

Limitations of the study include the modest recruitment rate and small sample size. A mail out of 502 invitations received a 23% response rate of 113 men. These men were already motivated to contact the researcher and could be potentially viewed as a bias. However, out of the 14% that were eligible, a total of 71 men, 29 of those did not respond to phone calls or email after that first initial contact. Phone messages were left, at least two within a 5 day week. Emails were sent in the same regard if email addresses were provided. Due to the sheer number of volume in which responses came, there was only one last follow-up to these responses before the trial closed recruitment. Perhaps if more follow-ups were provided, recruitment numbers might have increased.

The relatively short intervention was a limitation. A longer intervention could have provided more time to observe greater benefits in strength, functioning and other clinical outcomes. The comparison between 2 days/week and 3 days/week may need a longer duration to detect significant differences between outcomes. Also a longer training period could be required to detect significant resulted in upper body strength gains.

Lack of follow-up after the intervention was another limitation. This is a tricky limitation in that this project was a master's thesis and therefore a longer intervention and/or follow-up could prolong the graduate program. However, a 3 month or 6 month

follow-up could have provided valuable information into how the participants continue to fare after the intervention.

There was also a failure to blind the assessors of the measured outcomes and this has the potential to lead to biased results. As the tester was aware of which participant was assigned to which group, potential to bias the data to report desirable outcomes could lead to the tester pushing the 3 days/week group harder during assessments. However, the assessors applied the same encouragement to each even though a blinded tester would have been ideal.

Also, multiple RM strength tests were performed as opposed to completion of an actual 1RM and this could have influenced final results and the expected training gains in the participants. The multiple RM strength testing was done for safety reasons; however, other studies^[6, 7, 11, 12, 14] performed 1RM to assess muscular strength in this same population and reported no adverse events. Therefore, 1RM testing may be a possibility for future research and may provide more accurate measurements and prescriptions that could potentially produce different results.

Finally, several other important outcomes such as body composition, biomarkers of recurrence, and survival outcomes were not measured in the present thesis. The reason for this was a practical since there was limited funding available. However, these outcomes would provide valuable additional information into how RT affects muscle and fat mass, especially because aging muscle mass decreases and hormone therapies for prostate cancer are known to increase the rate of sarcopenia. Biomarkers of recurrence is another area that could provide further insight. There are many prostate cancer patients that are concerned about testosterone levels increasing with exercise and potentially

fueling growth of their tumor. Examining the biomarkers could put many men at rest. Though 3 studies have reported no ill effects of RT on testosterone or PSA levels, more research into the area with comparison to how much RT an individual does could be very useful. Lastly, survival outcomes are a very important concern for cancer survivors. Researching into how RT can affect the rest of their survival is very important.

Delimitations included restricting the population to prostate cancer survivors between the age of 18-80 years who were diagnosed within the last 2 years. Due to these delimitations, results are not generalizable to survivors outside of the age range, who have a longer time since diagnosis, and other cancer survivors.

This thesis research also raises several questions for future research. First, this study manipulated one component of the RT prescription to increase RT volume (i.e., frequency). It would be interesting to compare mental and physical outcomes if frequency was set between two groups and only the volume was manipulated. Could there be potential for having improvements in both physical and mental outcomes with a 2 days/week group doing more volume than another? Also, would similar findings be observed in a study that had both groups training 3 days/week but again with different volumes? Also, additional studies manipulating other components of the RT prescription to increase RT volume in prostate cancer survivors are also warranted (e.g., number of exercises, sets, repetitions, weight). Moreover, there is also the potential for equating the amount of volume used in this study to examine the effects of days per week alone. A longer study could potentially examine if there is any increase in upper body strength with the addition of a longer intervention period. Also, an addition of a follow-up evaluation could provide valuable information into how active individuals remain and if

their patient-reported outcomes continue to stay at increased levels or if there is any other changes.

In conclusion, this thesis provides preliminary evidence that 3 days/week of RT compared to 2 days/week of RT may result in additional improvements in muscular strength and physical functioning, but may actually undermine improvements in mental health and psychosocial functioning. A phase III trial is critical to determine if these outcomes are indeed an accurate depiction of the effects of RT frequency in prostate cancer survivors. Based on the compelling data, a phase III trial is warranted. If these results are confirmed in a large phase III trial, then exercise specialists, oncologists, and prostate cancer survivors will need to weigh the potential additional gains in physical functioning with the potential blunting of gains in psychosocial functioning when determining the optimal frequency of RT for a given prostate cancer survivor.

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Appendix A. Baseline Questionnaire

Identification # _____

Date: _____

Effects of resistance training on muscular strength and physical functioning in prostate cancer survivors

Baseline Questionnaire

Investigators: M. Norris, BSc, G. Bell, PhD, S. North, MD, K. Courneya, PhD

Instructions

Thank you for agreeing to participate in this study. In this questionnaire, we are going to ask you a series of questions about yourself. Many of the questions ask you about your physical and mental health, and some may be viewed as personal. It is important to answer as many of these questions as possible, however, if you feel uncomfortable answering certain questions please leave them blank. All responses are completely confidential and will never be used in any way that could link them to you. Many of the questions may seem similar but it is important to treat each question separately and provide an answer for each. There are no right or wrong answers and all we ask is that you provide responses that are as honest and accurate as possible. The questionnaire should take about 30-45 minutes of your time to complete. If you have any questions about completing the questionnaire, please contact Mary Norris (Research Coordinator) at (780) 492-2829 (call collect from out of town) or mnorris@ualberta.ca.

This set of questions asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Answer every question by marking a single answer. If you are unsure about how to answer a question please give the best answer you can.

1. In general, would you say your health is:

1	2	3	4	5
Excellent	Very good	Good	Fair	Poor

2. Compared to one year ago, how would you rate your health in general now?

1	2	3	4	5
Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. Vigorous Activities , such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b. Moderate Activities , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
c. Lifting or carrying groceries	1	2	3
d. Climbing several flights of stairs	1	2	3
e. Climbing one flight of stairs	1	2	3
f. Bending, kneeling or stooping	1	2	3
g. Walking more than a mile	1	2	3
h. Walking several hundred yards	1	2	3
i. Walking one hundred yards	1	2	3
j. Bathing or dressing yourself	1	2	3

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the amount of time you spent on work or other activities	1	2	3	4	5
b. Accomplished less than you would like	1	2	3	4	5
c. Were limited in the kind of work or other activities	1	2	3	4	5
d. Had difficulty performing the work or other activities (e.g., it took extra effort)	1	2	3	4	5

5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the amount of time you spent on work or other activities	1	2	3	4	5
b. Accomplished less than you would like	1	2	3	4	5
c. Did work or other activities less carefully than usual .	1	2	3	4	5

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

1	2	3	4	5
Not at all	Slightly	Moderately	Quite a bit	Extremely

7. How much bodily pain have you had during the past 4 weeks?

1	2	3	4	5	6
None	Very mild	Mild	Moderate	Severe	Very severe

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

1	2	3	4	5
Not at all	A little bit	Moderately	Quite a bit	Extremely

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Did you feel full of life?	1	2	3	4	5
b. Have you been very nervous?	1	2	3	4	5
c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5
d. Have you felt calm and peaceful?	1	2	3	4	5
e. Did you have a lot of energy?	1	2	3	4	5
f. Have you felt downhearted and depressed?	1	2	3	4	5
g. Did you feel worn out?	1	2	3	4	5
h. Have you been happy?	1	2	3	4	5
i. Did you feel tired?	1	2	3	4	5

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

1	2	3	4	5
All of the time	Most of the time	Some of the time	A little of the time	None of the time

11. How TRUE or FALSE is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a. I seem to get sick a little easier than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

Below is a list of statements that people with prostate cancer have said are relevant to their way of life. Please indicate the extent to which you have experienced each of the statements during the past 7 days by circling the appropriate number using the following scale. Please complete the questions even if you believe the symptom(s) are not associated with your previous prostate cancer diagnosis and even if it has been many years since your prostate cancer diagnosis. If you do not experience any of the particular symptoms, please indicate so by circling 0 (not at all).

0	1	2	3	4
not at all	a little bit	somewhat	quite a bit	very much

During the PAST WEEK:

1. I am losing weight	0	1	2	3	4
2. I have a good appetite	0	1	2	3	4
3. I have aches and pains that bother me	0	1	2	3	4
4. I have certain parts of my body where I experience pain	0	1	2	3	4
5. My pain keeps me from doing things I want to do	0	1	2	3	4
6. I am satisfied with my present comfort level	0	1	2	3	4
7. I am able to feel like a man	0	1	2	3	4
8. I have trouble moving my bowels	0	1	2	3	4
9. I have difficulty urinating	0	1	2	3	4
10. I urinate more frequently than usual	0	1	2	3	4
11. My problems with urinating limit my activities	0	1	2	3	4
12. I am able to have and maintain an erection	0	1	2	3	4

During the PAST WEEK:

FATIGUE SYMPTOMS

	not at all	a little bit	some- what	quite a bit	very much
1. I feel fatigued	0	1	2	3	4
2. I feel weak all over	0	1	2	3	4
3. I feel listless (“washed out”)	0	1	2	3	4
4. I feel tired	0	1	2	3	4
5. I have trouble <u>starting</u> things because I am tired	0	1	2	3	4
6. I have trouble <u>finishing</u> things because I am tired	0	1	2	3	4
7. I have energy	0	1	2	3	4
8. I am able to do my usual activities	0	1	2	3	4
9. I need to sleep during the day	0	1	2	3	4
10. I am too tired to eat	0	1	2	3	4
11. I need help doing my usual activities	0	1	2	3	4
12. I am frustrated by being too tired to do the things I want to do	0	1	2	3	4
13. I have to limit my social activity because I am tired	0	1	2	3	4

The questions in this scale ask you about your feelings and thoughts during the last month. Although some of the questions are similar, there are differences between them and you should treat each one as a separate question. The best approach is to answer each one fairly quickly. For each question, please choose from the following alternatives:

	0	1	2	3	4
	never	almost never	some- times	fairly often	very often
In the last month, how often have you...					
1. been upset because of something that happened unexpectedly	0	1	2	3	4
2. felt that you were unable to control the important things in your life	0	1	2	3	4
3. felt nervous and stressed	0	1	2	3	4
4. dealt successfully with irritating life hassles	0	1	2	3	4
5. felt that you were effectively coping with important changes that were occurring in your life	0	1	2	3	4
6. felt confident about your ability to handle your personal problems	0	1	2	3	4
7. felt that things were going your way	0	1	2	3	4
8. found that you could not cope with all the things that you had to do	0	1	2	3	4
9. been able to control irritations in your life	0	1	2	3	4
10. felt that you were on top of things	0	1	2	3	4
11. been angered because of things that happened that were outside of your control	0	1	2	3	4
12. found yourself thinking about things that you have to accomplish	0	1	2	3	4
13. been able to control the way you spend your time	0	1	2	3	4
14. felt difficulties were piling up so high that you could not overcome them	0	1	2	3	4

The following question asks you to rate, on average, how happy or unhappy you felt over the past week. Please read all the statements first and then check the one statement (between 0 and 10) that best describes your average level of happiness over the past week. Check only ONE item.

On average, over the PAST WEEK I have felt:

- _____ 10. Extremely happy (feeling ecstatic, joyous, fantastic!).
- _____ 9. Very happy (feeling really good, elated!).
- _____ 8. Pretty happy (spirits high, feeling good).
- _____ 7. Mildly happy (feeling fairly good, somewhat cheerful).
- _____ 6. Slightly happy (just a bit above neutral).
- _____ 5. Neutral (not particularly happy or unhappy).
- _____ 4. Slightly unhappy (just a bit below neutral).
- _____ 3. Mildly unhappy (just a little low).
- _____ 2. Pretty unhappy (somewhat "blue," spirits down).
- _____ 1. Very unhappy (depressed, spirits very low).
- _____ 0. Extremely unhappy (utterly depressed, completely down).

This next question asks you to estimate the percentage of time, on average, that you felt happy, unhappy, and neutral (neither happy nor unhappy) over the past week. Write down your best estimates in the spaces below. Make sure the three figures add up to 100 percent.

Over the PAST WEEK:

The percentage of time I felt happy was: _____ %

The percentage of time I felt unhappy was: _____ %

The percentage of time I felt neutral was: _____ %

Total: 100 %

The following questions concern the general perceptions that you currently have about yourself. Please circle the number that best reflects your current view of yourself using the following scale as a guide for your responses.

	strongly disagree	disagree	agree	strongly agree
1. On the whole I am satisfied with myself.	1	2	3	4
2. At times I think that I am no good at all.	1	2	3	4
3. I feel that I have a number of good qualities.	1	2	3	4
4. I am able to do things as well as most other people.	1	2	3	4
5. I feel I do not have much to be proud of.	1	2	3	4
6. I certainly feel useless at times.	1	2	3	4
7. I feel that I am a person of worth, at least on an equal plane with others.	1	2	3	4
8. I wish I could have more respect for myself.	1	2	3	4
9. All in all, I am inclined to feel that I am a failure.	1	2	3	4
10. I take a positive attitude toward myself.	1	2	3	4

Below is a list of statements concerning how you might have felt or behaved in the past week. Please use the following scale to indicate how often you felt or behaved in these ways in the past week.

0	1	2	3
Rarely or none of the time (< 1 day)	Some of the time (1-2 days)	Much of the time (3-4 days)	Most or all of the time (5-7 days)

During the PAST WEEK:

1. I felt depressed.	0	1	2	3
2. I felt that everything I did was an effort.	0	1	2	3
3. My sleep was restless.	0	1	2	3
4. I was happy.	0	1	2	3
5. I felt lonely.	0	1	2	3
6. People were unfriendly.	0	1	2	3
7. I enjoyed life.	0	1	2	3
8. I felt sad.	0	1	2	3
9. I felt that people disliked me.	0	1	2	3
10. I could not get "going".	0	1	2	3

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number that best indicates how you have felt during the past week. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer that best describes how you felt.

During the PAST WEEK:

	not at all	somewhat	moderately so	very much so
1. I felt calm	1	2	3	4
2. I was tense	1	2	3	4
3. I felt at ease	1	2	3	4
4. I worried over possible misfortunes	1	2	3	4
5. I felt frightened	1	2	3	4
6. I felt self-confident	1	2	3	4
7. I was jittery	1	2	3	4
8. I was relaxed	1	2	3	4
9. I was worried	1	2	3	4
10. I felt steady	1	2	3	4

The following questions relate to your usual sleep habits during the past month. Your answers should indicate the most accurate reply for the majority of days and nights in the past month.

1. During the past month, when have you usually gone to bed at night?

USUAL BED TIME _____

2. During the past month, how long has it usually taken you to fall asleep each night?

NUMBER OF MINUTES _____

3. During the past month, when have you usually gotten up in the morning?

USUAL GETTING UP TIME _____

4. During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spend in bed.)

HOURS OF SLEEP PER NIGHT _____

5. During the past month, how would you rate your sleep quality overall?

____ Very good ____ Fairly good ____ Fairly bad ____ Very bad

6. During the past month, how often have you taken medicine (prescribed or “over the counter”) to help you sleep?

Not during the past month ____ Less than once a week ____ Once or twice a week ____ Three or more times a week ____

7. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

Not during the past month ____ Less than once a week ____ Once or twice a week ____ Three or more times a week ____

8. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

No problem at all ____ Only a very slight problem ____

Somewhat of a problem ____ A very big problem ____

For this next question, we would like you to recall the amount of exercise you have done SINCE you were diagnosed with prostate cancer.

When answering these questions please:

- only count exercise sessions that lasted 10 minutes or longer in duration.
- only count exercise that was done during free time (i.e., not occupation or housework).
- note that the main difference between the first three categories is the intensity of the endurance (aerobic) exercise and the fourth category is for strength (resistance) exercise.
- please write the average frequency on the first line and the average duration on the second.
- if you did not do any exercise in one of the categories, please write in "0".

Considering a typical week (7 days) how many times on the average did you do the following kinds of exercise in the months SINCE you were diagnosed with prostate cancer?

	Times Per Week	Average Duration
a. VIGOROUS/STRENUOUS EXERCISE (HEART BEATS RAPIDLY, SWEATING) (e.g., running, aerobics classes, cross country skiing, vigorous swimming, vigorous bicycling).	_____	_____
b. MODERATE EXERCISE (NOT EXHAUSTING, LIGHT PERSPIRATION) (e.g., fast walking, tennis, easy bicycling, easy swimming, popular and folk dancing).	_____	_____
c. LIGHT/MILD EXERCISE (MINIMAL EFFORT, NO PERSPIRATION) (e.g., easy walking, yoga, bowling, lawn bowling, shuffleboard).	_____	_____
d. RESISTANCE EXERCISE (e.g., lifting weights, push ups, sit ups therabands).	_____	_____

This next part of the questionnaire is needed to help understand the medical profile for those participating in the study. For this reason it is very important information. All information is held in strict confidence. Please answer the questions to the best of your knowledge.

1. When were you diagnosed with prostate cancer (month/year)?

2. Did your cancer involve the lymph nodes (please check)?

_____ Yes _____ No _____ Unsure

3. Was your cancer described as “localized” (confined to the prostate) or “metastasized” (spread to other parts of the body)?

_____ Localized _____ Metastasized _____ Unsure

4. If your cancer was described as metastasized, where else in your body was it?
(check all that apply)

_____ Lung _____ Lymph nodes _____ Brain _____ Liver
_____ Bone _____ Other (Please specify: _____) _____ Unsure

5. Have you received any treatments for your prostate cancer yet?

_____ Yes, I have received treatments
_____ No, I am currently in watchful waiting (active surveillance)

If, yes, complete questions 6-11. If no, skip questions 6-11.

6a. Did your treatment include surgical removal of the prostate (please check)?

_____ Yes _____ No

6b. If yes, was it laparoscopic surgery?

_____ Yes _____ No

7a. Did your treatment include radiation therapy (please check)?

_____ Yes _____ No

7b. If yes, was it external beam radiation or brachytherapy (pellets)?

_____ External Beam Radiation _____ Brachytherapy

8a. Did your treatment include drug therapy (please check)?

_____ Yes _____ No

8b. If yes, what kind of drug therapy did you receive? (check all that apply)

Hormonal Therapy
(i.e. hormone shots such as Eligard or pills such as bicalutamide)

Chemotherapy

Don't know/not sure

8c. If you received hormone therapy, were you treated for more than 6 months?

Yes No

9. What is the current status of your cancer treatments?

I am not currently receiving any treatments.

I am currently still receiving cancer treatments.

If currently on treatment, what treatment? _____

10. Have you ever had a recurrence of your prostate cancer? Yes No

11. What is the current status of your prostate cancer?

the doctors have told me that the cancer is gone from my body.

the doctors have told me that I still have some cancer in my body.

This next question asks you about what exercise program you would prefer to do if you had the choice. Of course, we will assign you to an exercise program by chance and we do not have any control over which exercise program you will be asked to do, but we would still like to know if you have a preference. Which exercise program would you prefer if you had the choice?

I would prefer to do the weight training program twice per week

I would prefer to do the weight training program three times per week

I have no preference, either one is fine with me

If you did note that you had a preference for one of the exercise groups, how strong is your preference for that program?

1
a slight preference

2
a moderate preference

3
a strong preference

This part of the questionnaire is needed to help understand the characteristics of the people participating in the study. For this reason it is very important information. All information is held in strict confidence and its presentation to the public will be group data only.

1. Age: _____

2. Current Marital Status: Never Married _____ Married _____ Common Law _____
Separated _____ Widowed _____ Divorced _____

3. Education (Please check highest level attained):

_____ Some High School _____ Completed High School _____ Some University/College
_____ Completed Univ/Coll _____ Some Graduate School _____ Completed Grad School

4. Annual Family Income: < 20,000 _____ 20-39,999 _____ 40-59,999 _____
60-79,999 _____ 80-99,999 _____ > 100,000 _____

5. Current Employment Status: Disability _____ Retired _____ Part Time _____
Full Time _____ Sick Leave _____

6. What is your primary ethnic origin or race (please circle)?

White Black Hispanic Asian Aboriginal Other _____

7. Which of the following best describes your current smoking status?

_____ Never Smoked _____ Ex-Smoker _____ Current Smoker

8. Has a doctor or nurse ever told you that you had any of the following conditions? (check all that apply):

High blood pressure	_____ No	_____ Yes	High cholesterol	_____ No	_____ Yes
Heart attack	_____ No	_____ Yes	Stroke	_____ No	_____ Yes
Emphysema	_____ No	_____ Yes	Chronic bronchitis	_____ No	_____ Yes
Diabetes	_____ No	_____ Yes	Other cancer	_____ No	_____ Yes
Angina (chest pains)	_____ No	_____ Yes	Arthritis	_____ No	_____ Yes

Any other long term health condition? _____

9. In the past month, was your ability to exercise limited by a health condition, injury, or disability?

1	2	3	4	5
No, Not at All	A Little	Somewhat	Quite a lot	Completely

10. Are you currently taking any medications for health problems? (e.g., for anxiety, depression, blood pressure, constipation, pain, to help with sleep, etc.).

What is the medication?

What is it for? (e.g., blood pressure, anxiety)

1. _____	_____
2. _____	_____
3. _____	_____

Others? _____

Anything else you would like to tell us? On this final page, please feel free to make any comments concerning your prostate cancer, your treatments, the questionnaire, the exercise program, or anything else you think may be helpful to us. All comments are welcome.

Thank you very much for participating in this research. Please bring the completed questionnaire to your fitness testing appointment at the Behavioural Medicine Fitness Centre.

Appendix B. Post-Intervention Questionnaire

Identification # _____
Date: _____

Effects of resistance training on muscular strength and physical functioning in prostate cancer survivors

Postintervention Questionnaire

Investigators: M. Norris, BSc, G. Bell, PhD, S. North, MD, K. Courneya, PhD,

Instructions

Thank you for your continued participation in this study. At this postintervention assessment, we are going to ask you many of the same questions as in the previous questionnaires. However, it is important to answer these questions based on what you are thinking and feeling right now, and not on how you answered the questions the last time. This will give us important information about how your thoughts and feelings have changed. Many of the questions may seem similar but it is important to treat each question separately and provide an answer for each. Also, if at all possible, it is important to answer all questions. However, if you feel uncomfortable answering certain questions please leave them blank. All responses are completely confidential and will never be used in any way that could link them to you. There are no right or wrong answers and all we ask is that you provide responses that are as honest and accurate as possible. The questionnaire should take about 30-45 minutes of your time to complete. If you have any questions about completing the questionnaire, please contact Mary Norris (Research Coordinator) at (780) 492-2829 (call collect from out of town) or mnorris@ualberta.ca.

This set of questions asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Answer every question by marking a single answer. If you are unsure about how to answer a question please give the best answer you can.

1. In general, would you say your health is:

1	2	3	4	5
Excellent	Very good	Good	Fair	Poor

2. Compared to one year ago, how would you rate your health in general now?

1	2	3	4	5
Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. Vigorous Activities , such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b. Moderate Activities , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
c. Lifting or carrying groceries	1	2	3
d. Climbing several flights of stairs	1	2	3
e. Climbing one flight of stairs	1	2	3
f. Bending, kneeling or stooping	1	2	3
g. Walking more than a mile	1	2	3
h. Walking several hundred yards	1	2	3
i. Walking one hundred yards	1	2	3
j. Bathing or dressing yourself	1	2	3

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the amount of time you spent on work or other activities	1	2	3	4	5
b. Accomplished less than you would like	1	2	3	4	5
c. Were limited in the kind of work or other activities	1	2	3	4	5
d. Had difficulty performing the work or other activities (e.g., it took extra effort)	1	2	3	4	5

5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the amount of time you spent on work or other activities	1	2	3	4	5
b. Accomplished less than you would like	1	2	3	4	5
c. Did work or other activities less carefully than usual .	1	2	3	4	5

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

1	2	3	4	5
Not at all	Slightly	Moderately	Quite a bit	Extremely

7. How much bodily pain have you had during the past 4 weeks?

1	2	3	4	5	6
None	Very mild	Mild	Moderate	Severe	Very severe

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

1	2	3	4	5
Not at all	A little bit	Moderately	Quite a bit	Extremely

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Did you feel full of life?	1	2	3	4	5
b. Have you been very nervous?	1	2	3	4	5
c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5
d. Have you felt calm and peaceful?	1	2	3	4	5
e. Did you have a lot of energy?	1	2	3	4	5
f. Have you felt downhearted and depressed?	1	2	3	4	5
g. Did you feel worn out?	1	2	3	4	5
h. Have you been happy?	1	2	3	4	5
i. Did you feel tired?	1	2	3	4	5

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

1	2	3	4	5
All of the time	Most of the time	Some of the time	A little of the time	None of the time

11. How TRUE or FALSE is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a. I seem to get sick a little easier than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

Below is a list of statements that people with prostate cancer have said are relevant to their way of life. Please indicate the extent to which you have experienced each of the statements during the past 7 days by circling the appropriate number using the following scale. Please complete the questions even if you believe the symptom(s) are not associated with your previous prostate cancer diagnosis and even if it has been many years since your prostate cancer diagnosis. If you do not experience any of the particular symptoms, please indicate so by circling 0 (not at all).

0	1	2	3	4
not at all	a little bit	somewhat	quite a bit	very much

During the PAST WEEK:

1. I am losing weight	0	1	2	3	4
2. I have a good appetite	0	1	2	3	4
3. I have aches and pains that bother me	0	1	2	3	4
4. I have certain parts of my body where I experience pain	0	1	2	3	4
5. My pain keeps me from doing things I want to do	0	1	2	3	4
6. I am satisfied with my present comfort level	0	1	2	3	4
7. I am able to feel like a man	0	1	2	3	4
8. I have trouble moving my bowels	0	1	2	3	4
9. I have difficulty urinating	0	1	2	3	4
10. I urinate more frequently than usual	0	1	2	3	4
11. My problems with urinating limit my activities	0	1	2	3	4
12. I am able to have and maintain an erection	0	1	2	3	4

During the PAST WEEK:

FATIGUE SYMPTOMS

	not at all	a little bit	some- what	quite a bit	very much
1. I feel fatigued	0	1	2	3	4
2. I feel weak all over	0	1	2	3	4
3. I feel listless (“washed out”)	0	1	2	3	4
4. I feel tired	0	1	2	3	4
5. I have trouble <u>starting</u> things because I am tired	0	1	2	3	4
6. I have trouble <u>finishing</u> things because I am tired	0	1	2	3	4
7. I have energy	0	1	2	3	4
8. I am able to do my usual activities	0	1	2	3	4
9. I need to sleep during the day	0	1	2	3	4
10. I am too tired to eat	0	1	2	3	4
11. I need help doing my usual activities	0	1	2	3	4
12. I am frustrated by being too tired to do the things I want to do	0	1	2	3	4
13. I have to limit my social activity because I am tired	0	1	2	3	4

The questions in this scale ask you about your feelings and thoughts during the last month. Although some of the questions are similar, there are differences between them and you should treat each one as a separate question. The best approach is to answer each one fairly quickly. For each question, please choose from the following alternatives:

	0	1	2	3	4
	never	almost never	some- times	fairly often	very often
In the last month, how often have you...					
1. been upset because of something that happened unexpectedly	0	1	2	3	4
2. felt that you were unable to control the important things in your life	0	1	2	3	4
3. felt nervous and stressed	0	1	2	3	4
4. dealt successfully with irritating life hassles	0	1	2	3	4
5. felt that you were effectively coping with important changes that were occurring in your life	0	1	2	3	4
6. felt confident about your ability to handle your personal problems	0	1	2	3	4
7. felt that things were going your way	0	1	2	3	4
8. found that you could not cope with all the things that you had to do	0	1	2	3	4
9. been able to control irritations in your life	0	1	2	3	4
10. felt that you were on top of things	0	1	2	3	4
11. been angered because of things that happened that were outside of your control	0	1	2	3	4
12. found yourself thinking about things that you have to accomplish	0	1	2	3	4
13. been able to control the way you spend your time	0	1	2	3	4
14. felt difficulties were piling up so high that you could not overcome them	0	1	2	3	4

The following question asks you to rate, on average, how happy or unhappy you felt over the past week. Please read all the statements first and then check the one statement (between 0 and 10) that best describes your average level of happiness over the past week. Check only ONE item.

On average, over the PAST WEEK I have felt:

- _____ 10. Extremely happy (feeling ecstatic, joyous, fantastic!).
- _____ 9. Very happy (feeling really good, elated!).
- _____ 8. Pretty happy (spirits high, feeling good).
- _____ 7. Mildly happy (feeling fairly good, somewhat cheerful).
- _____ 6. Slightly happy (just a bit above neutral).
- _____ 5. Neutral (not particularly happy or unhappy).
- _____ 4. Slightly unhappy (just a bit below neutral).
- _____ 3. Mildly unhappy (just a little low).
- _____ 2. Pretty unhappy (somewhat "blue," spirits down).
- _____ 1. Very unhappy (depressed, spirits very low).
- _____ 0. Extremely unhappy (utterly depressed, completely down).

This next question asks you to estimate the percentage of time, on average, that you felt happy, unhappy, and neutral (neither happy nor unhappy) over the past week. Write down your best estimates in the spaces below. Make sure the three figures add up to 100 percent.

Over the PAST WEEK:

The percentage of time I felt happy was: _____ %

The percentage of time I felt unhappy was: _____ %

The percentage of time I felt neutral was: _____ %

Total: 100 %

The following questions concern the general perceptions that you currently have about yourself. Please circle the number that best reflects your current view of yourself using the following scale as a guide for your responses.

	strongly disagree	disagree	agree	strongly agree
1. On the whole I am satisfied with myself.	1	2	3	4
2. At times I think that I am no good at all.	1	2	3	4
3. I feel that I have a number of good qualities.	1	2	3	4
4. I am able to do things as well as most other people.	1	2	3	4
5. I feel I do not have much to be proud of.	1	2	3	4
6. I certainly feel useless at times.	1	2	3	4
7. I feel that I am a person of worth, at least on an equal plane with others.	1	2	3	4
8. I wish I could have more respect for myself.	1	2	3	4
9. All in all, I am inclined to feel that I am a failure.	1	2	3	4
10. I take a positive attitude toward myself.	1	2	3	4

Below is a list of statements concerning how you might have felt or behaved in the past week. Please use the following scale to indicate how often you felt or behaved in these ways in the past week.

0	1	2	3
Rarely or none of the time (< 1 day)	Some of the time (1-2 days)	Much of the time (3-4 days)	Most or all of the time (5-7 days)

During the PAST WEEK:

1. I felt depressed.	0	1	2	3
2. I felt that everything I did was an effort.	0	1	2	3
3. My sleep was restless.	0	1	2	3
4. I was happy.	0	1	2	3
5. I felt lonely.	0	1	2	3
6. People were unfriendly.	0	1	2	3
7. I enjoyed life.	0	1	2	3
8. I felt sad.	0	1	2	3
9. I felt that people disliked me.	0	1	2	3
10. I could not get "going".	0	1	2	3

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number that best indicates how you have felt during the past week. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer that best describes how you felt.

During the PAST WEEK:

	not at all	somewhat	moderately so	very much so
1. I felt calm	1	2	3	4
2. I was tense	1	2	3	4
3. I felt at ease	1	2	3	4
4. I worried over possible misfortunes	1	2	3	4
5. I felt frightened	1	2	3	4
6. I felt self-confident	1	2	3	4
7. I was jittery	1	2	3	4
8. I was relaxed	1	2	3	4
9. I was worried	1	2	3	4
10. I felt steady	1	2	3	4

The following questions relate to your usual sleep habits during the past month. Your answers should indicate the most accurate reply for the majority of days and nights in the past month.

1. During the past month, when have you usually gone to bed at night?

USUAL BED TIME _____

2. During the past month, how long has it usually taken you to fall asleep each night?

NUMBER OF MINUTES _____

3. During the past month, when have you usually gotten up in the morning?

USUAL GETTING UP TIME _____

4. During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spend in bed.)

HOURS OF SLEEP PER NIGHT _____

5. During the past month, how would you rate your sleep quality overall?

_____ Very good _____ Fairly good _____ Fairly bad _____ Very bad

6. During the past month, how often have you taken medicine (prescribed or “over the counter”) to help you sleep?

Not during the past month _____ Less than once a week _____ Once or twice a week _____ Three or more times a week _____

7. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

Not during the past month _____ Less than once a week _____ Once or twice a week _____ Three or more times a week _____

8. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

No problem at all _____ Only a very slight problem _____

Somewhat of a problem _____ A very big problem _____

For this next question, we would like you to recall the amount of exercise you have done SINCE you were diagnosed with prostate cancer.

When answering these questions please:

- only count exercise sessions that lasted 10 minutes or longer in duration.
- only count exercise that was done during free time (i.e., not occupation or housework).
- note that the main difference between the first three categories is the intensity of the endurance (aerobic) exercise and the fourth category is for strength (resistance) exercise.
- please write the average frequency on the first line and the average duration on the second.
- if you did not do any exercise in one of the categories, please write in "0".

Considering a typical week (7 days) how many times on the average did you do the following kinds of exercise in the months SINCE you were diagnosed with prostate cancer?

	Times Per Week	Average Duration
a. VIGOROUS/STRENUOUS EXERCISE (HEART BEATS RAPIDLY, SWEATING) (e.g., running, aerobics classes, cross country skiing, vigorous swimming, vigorous bicycling).	_____	_____
b. MODERATE EXERCISE (NOT EXHAUSTING, LIGHT PERSPIRATION) (e.g., fast walking, tennis, easy bicycling, easy swimming, popular and folk dancing).	_____	_____
c. LIGHT/MILD EXERCISE (MINIMAL EFFORT, NO PERSPIRATION) (e.g., easy walking, yoga, bowling, lawn bowling, shuffleboard).	_____	_____
d. RESISTANCE EXERCISE (e.g., lifting weights, push ups, sit ups therabands).	_____	_____

The next set of questions on this page relate to how you felt about taking part in this study. Please answer each one as honestly as possible using the following scale:

1 2 3 4 5 6 7
 not at all somewhat a fair bit very much

1. How much of a burden was it for you to complete each of the following assessments in this study?

- | | | | | | | | |
|--------------------------------------|---|---|---|---|---|---|---|
| (a) the treadmill fitness test | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| (b) the physical function test | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| (c) the strength test | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| (d) the questionnaires | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| (e) the supervised training sessions | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

2. With hindsight, how do you feel about participating in this study?

- | | | | | | | | |
|---|---|---|---|---|---|---|---|
| (a) rewarding | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| (b) a waste of my time | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| (c) useful for research helping others | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| (d) useful for me personally | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| (e) something that I would recommend to other prostate cancer survivors | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

3. How beneficial was the resistance training program?

1	2	3	4	5
Not at all	A little bit	Somewhat	Quite a bit	Very much

4. How enjoyable was the resistance training program?

1	2	3	4	5
Not at all	A little bit	Somewhat	Quite a bit	Very much

5. How supportive were your family/friends of the resistance training program?

1	2	3	4	5
Not at all	A little bit	Somewhat	Quite a bit	Very much

6. How motivated were you to do the resistance training program?

1	2	3	4	5
Not at all	A little bit	Somewhat	Quite a bit	Very much

7. How difficult was it to do the resistance training program?

1	2	3	4	5
Not at all	A little bit	Somewhat	Quite a bit	Very much

8. Looking back, now that the resistance training program is over, which group do you wish you had been assigned to? I wish I had been assigned to...

_____ the twice per week resistance training group

_____ the three times per week resistance training group

_____ I have no preference, either one of them would have been fine with me

If you did note that you had a preference for one of the resistance training programs (by checking one of the first 2 choices above), how strong is your preference for that program?

1	2	3
a slight preference	a moderate preference	a strong preference

9. Thinking back, how did you feel when you found out which resistance training group you were randomly assigned to?

1	2	3	4	5	6	7
extremely disappointed	quite disappointed	slightly disappointed	neutral	slightly pleased	quite pleased	extremely pleased

We are interested in knowing about any benefits or negative effects you feel that resulted from participating in the resistance training program. Please use the following scale to guide your responses.

1	2	3	4	5	6	7
Very much worse	Somewhat worse	Slightly worse	No change	Slightly imporved	Somewhat improved	Very much improved

What affect, if any, did the resistance training program have on each of the following for you?

(a) physical functioning	1	2	3	4	5	6	7
(b) overall quality of life	1	2	3	4	5	6	7
(c) cardiovascular endurance	1	2	3	4	5	6	7
(d) muscular strength	1	2	3	4	5	6	7
(e) fatigue	1	2	3	4	5	6	7
(f) happiness	1	2	3	4	5	6	7
(g) sleep quality	1	2	3	4	5	6	7
(h) depressed feelings	1	2	3	4	5	6	7
(i) anxious feelings	1	2	3	4	5	6	7
(j) self-esteem	1	2	3	4	5	6	7
(k) stress	1	2	3	4	5	6	7
(l) body weight or shape	1	2	3	4	5	6	7
(m) ability to complete treatments	1	2	3	4	5	6	7
(n) illness or injury	1	2	3	4	5	6	7

Any other positive or negative effects you experienced? _____

We are also interested in knowing what, if any, barriers you felt made it difficult for you to do the exercise program. Please use the scale below to guide your responses.

1	2	3	4	5	6	7
Not at all		Somewhat		A fair bit		Very much

How much of a barrier was each of the following factors for you in trying to do the resistance training program?

(a) bad weather	1	2	3	4	5	6	7
(b) feeling tired or fatigued	1	2	3	4	5	6	7
(c) symptoms and side effects of treatments	1	2	3	4	5	6	7
(d) other medical/health problems	1	2	3	4	5	6	7
(e) too busy and had limited time	1	2	3	4	5	6	7
(f) pain or soreness	1	2	3	4	5	6	7
(g) feeling sick/not feeling well	1	2	3	4	5	6	7
(h) nausea/vomiting	1	2	3	4	5	6	7
(i) urinary incontinence	1	2	3	4	5	6	7
(j) medical appointments	1	2	3	4	5	6	7
(k) lack of motivation	1	2	3	4	5	6	7
(l) travelling to the fitness centre	1	2	3	4	5	6	7

Any other barriers you experienced? _____

The following questions ask you to rate how you feel about exercising over the next six months on your own now that the supervised program is over. Please pay careful attention to the words and descriptors for each scale and circle the number that best represents how you feel.

1. How beneficial do you think it will be for you to resistance train over the next six months?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

2. How enjoyable do you think it will be for you to resistance train over the next six months?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

3. How supportive do you think your family/friends will be if you try to resistance train over the next six months?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

4. How motivated are you to resistance train over the next six months?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

5. How difficult do you think it will be for you to resistance train over the next six months?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

6. Do you have a specific plan for where, when, and how you are going to resistance train over the next six months?

1	2	3	4	5
not at all	a little bit	somewhat	quite a bit	very much

Anything else you would like to tell us? On this final page, please feel free to make any comments concerning your prostate cancer, your treatments, the questionnaire, the exercise program, or anything else you think may be helpful to us. All comments are welcome.

Any suggestions on how to improve the resistance training program?

Thank you very much for participating in this research. Please bring the completed questionnaire to your fitness testing appointment at the Behavioural Medicine Fitness Centre.

Appendix C. Letter of Invitation

Kerry S. Courneya, PhD

E-488 Van Vliet Center

Edmonton, Alberta, Canada T6G 2H9

Tel: 780.492.1031

Fax: 780.492.8003

E-mail:

kerry.courneya@ualberta.ca

Dear Sir,

My name is Kerry Courneya and I am a Professor and Canada Research Chair at the University of Alberta. I am also a Scientific Staff member of the Cross Cancer Institute in Edmonton. As part of my responsibilities, I conduct research on the health of cancer survivors. The Alberta Cancer Registry is contacting you on my behalf to see if you might be interested in participating in an exercise intervention study which requires the voluntary participation of prostate cancer survivors. The study has been approved by the Alberta Cancer Research Ethics Committee and the University of Alberta Health Research Ethics Board, and has met rigorous requirements for ethical approval.

Research has shown that weight training improves certain health outcomes in prostate cancer survivors, however, the optimal weight training program is unknown. One important question relates to the frequency of weight training. Some studies suggest that weight training twice/week is sufficient whereas others suggest that three times/week is needed. No study has directly compared the two frequencies to determine any differences in clinical benefit. The purpose of this study is to compare the benefits of two versus three days/week of weight training on muscular strength, physical functioning, and fatigue.

If you decide to participate in this study, you will be asked to attend supervised weight training sessions either 2 or 3 days a week for 12 weeks. The program will consist of a full body workout that will target all the major muscle groups of the body, providing an overall program targeted to increase physical fitness.

The program will take place at the Behavioural Medicine Fitness Centre at the University of Alberta. This is a fully equipped fitness facility dedicated for research purposes only, and available to you free of charge for the 12 week program. Your personal exercise trainer and supervised exercise program are also free. We will also pay for your parking at the Behavioural Medicine Fitness Centre when you come for your exercise testing and training sessions.

Your participation in this study is completely voluntary. Any information that you provide will be held in strict confidence. It is only through voluntary participation in research projects that we increase our knowledge about developing physical activity programs to improve quality of life among prostate cancer survivors. We hope that you find the time to assist us. If you are interested in participating in this study, or have any questions about the study, please contact my Research Co-ordinator, Mary Norris, at (780) 492-2829 or e-mail mnorris@ualberta.ca for more information.

Thank you for considering our study.

Sincerely,



Kerry S. Courneya, PhD
Professor and Canada Research Chair in PA and Cancer
University of Alberta

Appendix D. Letter from Registry



Dear Sir:

From time to time on behalf of researchers, the Alberta Cancer Registry contacts individuals who may be eligible for research studies. This letter is to introduce you to a research study being undertaken by an affiliate of the Alberta Health Services. These types of studies *must* be approved by the Alberta Cancer Research Ethics Committee. Information on new cancer cases and cancer-related deaths is recorded in the Alberta Cancer Registry. The Alberta Health Services is mandated by the Regional Health Authorities Act, please read the enclosed letter for further information describing the Registry.

We are enclosing information from a research study that has been recently approved by the Ethics Board and which may be of interest to you. Please note, this is a random sample generated by the computer and your name was selected, however, depending upon your diagnosis, this study may not apply to you. We have not disclosed any of your personal information to the researchers and are simply contacting you on their behalf to provide you with an opportunity to participate in a research study. Your participation in this or any research study is absolutely voluntary. Enclosed is some information from the researchers describing the study in order to help you make an informed choice about whether or not you would like to participate. If you are interested in finding out more about the study, please follow the enclosed instructions. If you are not interested in participating, simply ignore the materials that we have sent you or return the unanswered questionnaire in the envelope provided by the researchers.

The Alberta Cancer Registry is very supportive of research studies conducted with its registry, as voluntary participation in research projects helps to improve our knowledge about issues that are important to cancer patients and survivors. We hope that you find time to read the enclosed materials closely and participate in the study if you feel it is of interest to you.

If you have further questions regarding the Alberta Cancer Registry, please call me at (780) 432-8781 or email me at carol.russell@albertahealthservices.ca

Sincerely,

Carol Russell, CHIM
Director, Alberta Cancer Registry
Cancer Measurement Outcomes & Evaluation
Cancer Care, Alberta Health Services
Cross Cancer Institute

Appendix E. Consent Form

Cross Cancer Institute

11560 University Avenue Edmonton, Alberta T6G 1Z2 Tel
780.432.8771

A study to see effects of resistance training frequency on muscular strength and physical functioning in prostate cancer survivors

CONSENT FORM

This form is part of the process of informed consent. It is designed to explain this research study and what will happen to you if you choose to be in this study.

If you would like to know more about something mentioned in this consent form, or have any questions at anytime regarding this research study, please be sure to ask your doctor or nurse. Read this consent form carefully to make sure you understand all the information it provides. You will get a copy of this consent form to keep. You do not have to take part in this study and your care does not depend on whether or not you take part.

Your participation in this study is entirely voluntary. Please take your time to make your decision. It is recommended that you discuss with your friends and/or family about whether to participate in this study.

“WHY IS THIS STUDY BEING DONE?”

You are being asked to take part in this study because you had prostate cancer.

Research has shown that resistance training improves quality of life and fitness outcomes in prostate cancer patients. However, the exact prescription for optimal gains is unknown. Few studies have examined the frequency at which resistance training should be undertaken in one week. Findings from this type of study that compares frequency could provide added knowledge to this under studied field and further the exercise prescription for this population.

This study is being done because currently there are no studies that directly compare the effects of 2 versus 3 days of resistance training and any differences in clinical benefit for prostate cancer survivors.

“WHAT DO WE HOPE TO LEARN?”

We hope to learn if resistance training one extra day in a week has any additional benefits to muscular strength and physical functioning in prostate cancer survivors, as well as other clinical outcomes.

The purpose of this study is to examine the effects of a two versus three day/week RT program on muscular strength, physical functioning, and fatigue. The primary outcomes will be muscular strength and physical functioning. Secondary outcomes assessed through questionnaires will include fatigue, health related quality of life, depression and post treatment cancer symptoms.

This is a Phase I/II study which is designed to find out the effects of 3 days versus 2 days/week resistance training has on muscular strength and physical functioning in prostate cancer survivors.

“WHAT IS INVOLVED IN THIS STUDY?”

In this study, you may receive one of two supervised resistance training programs. You will be “randomized” to receive one of the groups described below. Randomization means the treatment that you are assigned will be determined by chance. It is like flipping a coin. Randomization is done by a computer. Neither you nor the researcher will choose which group you will be assigned. You will have an equal chance of being assigned to either group.

Following your initial (baseline) assessments, you will be randomly assigned to 1 of 2 resistance training groups: (1) 3 days a week of resistance training (2) 2 days a week of resistance training.

For both groups, you will be given a customized and supervised resistance training program. You will be given an individualized prescription at a moderate-to-vigorous intensity where the duration and intensity will be increased slowly over the 12 week program.

“HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?”

Overall we hope to recruit about 52 people for this study from Edmonton, Alberta.

“WHAT WILL MY PARTICIPATION INVOLVE?”

You will be asked to complete the following tasks over the course of your involvement in the study:

- You will have a muscular strength test that involves lifting a designated weight a total of 6 times. Participants will assess upper body muscular strength with a 6-repetition maximum (RM) chest press and lower body with a 6-RM leg press (6RM defined as the maximal amount of weight that can be lifted six times). Participants will be warmed up by completing several submaximal repetitions on the designated machines. Once a warm-up is complete 6-RM will be determined within four trials with rest of 3 to 5 minutes between each attempt. An initial weight will be selected for each participant based on their perceived capacity. Weight will progressively increase until the participant cannot complete the repetitions. The last successful repetition weight will be recorded. You will be required to complete two test assessments, one at the beginning (baseline) and one at the end of the program (at 12 weeks).
- You will be required to complete two physical function assessments, one at the beginning (baseline) and one at the end of the physical activity program (at 12 weeks). The physical function assessment should take no longer than 45 minutes to complete, and will consist of chair stands, arm curls, sit and reach and back scratch flexibility tests, walking around an 8-foot course, and walking for 6 minutes.
- Complete two body composition assessments, one at the beginning (baseline), and one at the end of the physical activity program (at 12 weeks). Your body composition will be estimated by measurements of height, weight, and circumferences. Height and weight will be obtained using a balance beam scale and stadiometer. Waist and hip circumference will be measured using a nonstretching tape measure. This assessment will take approximately 5 minutes to complete.
- Complete self-administered questionnaires (which will take about 20-45 minutes each to fill out). The questionnaires will be completed at the beginning of the program (baseline), at the end of the supervised portion of the program (at 12 weeks).

For both physical activity groups, you will be given a customized and supervised physical activity program. You will be given an individualized prescription where the intensity will be increase slowly over the 12 week program.

All physical activity sessions will take place at the Behavioural Medicine Fitness Centre (University of Alberta campus) for the 12-week program. Physical activity training sessions will be available any time

between 8 am and 6 pm, Monday to Friday and is flexible depending on when you want to come in. Trained staff will supervise all training sessions.

	Baseline	Post-Intervention
Muscular Strength	X	X
Anthropometrics	X	X
Clinical Outcome Questionnaires	X	X
Physical Functioning Testing	X	X

“HOW LONG WILL I BE INVOLVED IN THE STUDY?”

You may be in this study for as long as 12 weeks.

“WHAT ARE THE SIDE EFFECTS?”

There are a few risks associated with participating in this research. Some risk is associated with adoption of physical activity. It is possible that some people will experience muscle soreness and fatigue in the beginning of the program, particularly following the fitness testing. This type of response is usual, and generally poses no threat to health. Do not take any over the counter medications without speaking to your doctor first. If the soreness persists more than five days, or might be associated with a muscle or joint injury, participants should make an appointment to see their general physician.

There is some risk associated with the physical function fitness tests. During and immediately after the tests, it is possible to experience symptoms such as abnormal blood pressure, fainting, light-headedness, muscle cramps or strain, nausea, and in very rare cases heart rhythm disturbances or heart attack. While serious risk to healthy participants is highly unlikely, such risks must be acknowledged, and participants must willingly assume the risks associated with very hard exercise.

Unique Side Effects/Special Precaution

There are no unforeseeable special precautions that should be taken other than the side effects listed above.

“WHAT ARE MY RESPONSIBILITIES?”

You must be willing to attend all scheduled study visits and undergo all of the procedures described above. It is very important that you inform the physical activity specialist and research co-ordinator of any side effects or health problems that you may be experiencing as well as any medications (prescribed or holistic) that you are taking while on this study.

“WHAT ARE MY ALTERNATIVES?”

Your doctor will discuss with you other options for increasing your physical activity and enhancing quality of life, and explain the risks and benefits of these options to you. Current options are for you to exercise on your own or join a private fitness center. We encourage all participants to continue to exercise on their own, even when the study is finished.

“ARE THERE ANY BENEFITS TO PARTICIPATING IN THIS STUDY?”

Participation in this study may or may not be of personal benefit to you. However, based on the results of this study, it is hoped that, in the long-term, patient care can be improved. Being a part of this study will allow you to receive a free 12 week exercise program including a personal fitness trainer and access to a well-equipped fitness facility at no cost. If you follow the program, it is likely that your fitness level, quality of life and your health may improve with participation.

“CAN I WITHDRAW FROM THIS STUDY?”

Taking part in this study is voluntary; you may withdraw from the study at any time if you wish to do so. If you decide to stop participating in the study, we encourage you to talk to the research co-ordinator first.

The researchers can take you off the study group early for reasons such as:

- Your cancer comes back.
- Your doctor (general practitioner) feels that you are unable to participate in a physical activity program and/or participate in the follow up fitness testing.

Should you decide to withdraw from the study at any time, information collected on you up until that point would still be utilized in this study unless you request to remove the information. The information collected in this study will be used for research and teaching purposes, and to help develop guidelines for helping improve the quality of life and health for people with cancer.

“ARE THERE COSTS TO ME FOR TAKING PART IN THIS STUDY?”

There are no financial costs to you for participating in this study. The quality of life assessments, fitness assessments, body composition assessments, and physical activity program are free. We will also pay for your parking at the Behavioural Medicine Fitness Centre when you come for your physical activity training sessions as well as your exercise testing. Your personal physical activity trainer and supervised physical activity program are also free.

“WHAT ARE MY RIGHTS AS A PARTICIPANT?”

If you suffer an injury or become ill as a result of participating in this research, you will receive all medical treatments (or services) recommended by your doctors. No compensation will be provided beyond this point. However, it is important to note that nothing said in this consent form alters your legal rights to recover damages (e.g. legal action).

If new information becomes available or there are changes to the study that may affect your health or willingness to continue in the study, you will be told in a timely manner.

“WILL MY PERSONAL INFORMATION BE KEPT CONFIDENTIAL?”

Identifiable health information will be collected from you and from your Provincial Electronic Health Record (NetCare) during this study. This information may be used by the researchers who are carrying out this study, and may be disclosed to others as described below. Any research proposal to use information that identifies you for a purpose other than this study must be approved in advance by the Alberta Cancer Research Ethics Committee.

Direct access to your identifiable health information collected for this study will be restricted to the researchers who are directly involved in this study except in the following circumstances:

Your identifiable health information may need to be inspected or copied from time to time for quality assurance (to make sure the information being used in the study is accurate) and for data analysis (to do statistical analysis that will not identify you). The following organizations may do this inspection:

- Health Canada, the Canadian regulatory body
- Alberta Cancer Research Ethics Committee, the institutional review board at this centre
- Members of the Regulatory/Audit team at the Cross Cancer Institute for quality assurance purposes

Any disclosure of your identifiable health information will be in accordance with the Alberta Health Information Act. As well, any person from the organizations listed above looking at your records on-site at the Cross Cancer Institute will follow the relevant Alberta Health Services - Alberta Cancer Research Ethics Committee policies and procedures that control these actions. Any disclosure of your identifiable

health information to another individual or organization not listed here will need the approval of the Alberta Cancer Research Ethics Committee.

Your identifiable health information collected as part of this study which includes records of your progress, your responses to the questionnaires and your diaries will be kept confidential in a secure AHS facility.

The researchers who are directly involved in your study may share information about you with other researchers, but you will not be identified in that shared information except by a number. The key that indicates what number you have been assigned will be kept secure by the researchers directly involved with your study and will not be released.

Although absolute confidentiality can never be guaranteed, Alberta Health Services will make every effort to keep your identifiable health information confidential, and to follow the ethical and legal rules about collecting, using and disclosing this information in accordance with the Alberta Health Information Act and other regulatory requirements.

The information collected during this study will be used in analyses and will be published and/or presented to the scientific community at meetings and in journals, but your identity will remain confidential. It is expected that the study results will be published as soon as possible after completion.

“WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?”

For information about your disease and/or research related injury/illness, you may contact the Principal Investigator Dr. Kerry Courneya at (780) 492-1031, the Research Co-ordinator Mary Norris at 780-492-2829, to answer any questions regarding this study.

If the above mentioned individuals have not been able to answer or resolve your questions and/or concerns about this study, or if you feel at any time that you have not been informed to your satisfaction about the risks, benefits, or alternatives to this study, or that you have been encouraged to continue in this study after you wanted to withdraw, you can call the Alberta Health Services Patient Relations Department toll free at 1-855-550-2555.

UNDERSTANDING OF PARTICIPANTS

I can refuse to take part or withdraw from this study at any time without jeopardizing my health care. If I continue to take part in the study, I will be kept informed of any important new developments and information learned after the time I gave my original consent.

I also give consent for the Principal Investigator and Alberta Health Services (the Custodian) to disclose identifiable health information, as per the Alberta Health Information Act, to the organizations mentioned on the previous pages.

I have read and understood all of the information in this consent form. I have asked questions, and received answers concerning areas I did not understand. I have had the opportunity to take this consent form home for review and discussion. My consent has not been forced or influenced in any way. I consent to participate in this research study. Upon signing this form I will receive a signed copy of the consent.

(PRINT NAMES CLEARLY)

Name of Patient

Signature of Patient

Date

Name of Person Obtaining
Consent

Signature of Person
Obtaining Consent

Date

Patient Study Number or Hospital Number: _____

Was the patient assisted during the consent process in one of the ways listed below?

- Yes No

If yes, please check the relevant box and complete the signature space below:

- The consent form was read to the patient, and the person signing below attests that the study was accurately explained to, and apparently understood by the patient.

Signature of person assisting Date
In the consent discussion

Please note: More information regarding the assistance provided during the consent process should be noted in the medical record for the patient if applicable.

Appendix F. Strength Training Table

	0-3 weeks (lead-in training)		4-6 weeks		7-9 weeks		10-12 weeks	
Frequency	Group 1: 2 d/wk	Group 2: 3 d/wk	Group 1: 2 d/wk	Group 2: 3 d/wk	Group 1: 2 d/wk	Group 2: 3 d/wk	Group 1: 2 d/wk	Group 2: 3 d/wk
Intensity (% of p1RM)	60-70%		60-80%		60-80%		60-80%	
Number of Sets	2		3		3		3	
Number of Reps	8-12		8-12		8-12		8-12	
Rest between sets	1-2 min		1-2 min		1-2 min		1-2 min	
Number of Exercises	3 upper body + 2 lower body + core exercises		3 upper body + 3 lower body + core exercises		3 upper body + 3 lower body + core exercises		3 upper body + 3 lower body + core exercises	
Progression	Once 12 reps completed at a given intensity, weight increases		Once 12 reps completed at a given intensity, weight increases		Once 12 reps completed at a given intensity, weight increases		Once 12 reps completed at a given intensity, weight increases	