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A Multicentre Year-long Randomised Controlled Trial of Exercise Training Targeting Physical Functioning in Men with Prostate Cancer Previously Treated with Androgen Suppression and Radiation from TROG 03.04 RADAR

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Abstract

Background: Long-term prostate cancer (PCa) survivors are at increased risk for comorbidities and physical deconditioning.
Objective: To determine the effectiveness of a year-long randomised controlled trial of exercise training in PCa survivors >5 yr postdiagnosis on physical functioning.
Design, setting, and participants: Between 2010 and 2011, 100 long-term PCa survivors from Trans-Tasman Radiation Oncology Group 03.04 Randomised Androgen Deprivation and Radiotherapy previously treated with androgen-deprivation therapy and radiation therapy were randomly assigned to 6 mo of supervised exercise followed by 6 mo of a home-based maintenance programme ($n = 50$) or printed educational material about physical activity ($n = 50$) for 12 mo across 13 university-affiliated exercise clinics in Australia and New Zealand.
Intervention: Supervised resistance and aerobic exercise or printed educational material about physical activity.
Outcome measurements and statistical analysis: The primary end point was a 400-m walk as a measure of cardiovascular fitness. Secondary end points were physical function, patient-reported outcomes, muscle strength, body composition, and biomarkers. Analysis of covariance was used to compare outcomes for groups at 6 and 12 mo adjusted for baseline values.
Results and limitations: Participants undergoing supervised exercise showed improvement in cardiorespiratory fitness performance at 6 mo (−19 s [$p = 0.029$]) and 12 mo (−13 s [$p = 0.028$]) and better lower-body physical function across the 12-mo period ($p < 0.01$). Supervised exercise also improved self-reported physical functioning at 6 ($p = .006$) and 12 mo ($p = 0.002$), appendicular skeletal muscle at 6 mo ($p = 0.019$), and objective measures of muscle strength at 6 and 12 mo ($p < 0.050$). Limitations included the restricted number of participants undertaking body composition assessment, no blinding to group assignment for physical functioning measures, and inclusion of well-functioning individuals.
Conclusions: Supervised exercise training in long-term PCa survivors is more effective than physical activity educational material for increasing cardiorespiratory fitness, physical function, muscle strength, and self-reported physical functioning at 6 mo. Importantly, these benefits were maintained in the long term with a home-based programme with follow-up at 12 mo.
Clinical trial registry: The effect of an exercise intervention on cardiovascular and metabolic risk factors in prostate cancer patients from the RADAR study, ACTRN: ACTRN12609000729224.

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1. Introduction

Men with prostate cancer (PCa) undergoing androgen-deprivation therapy (ADT) are recognised to gain fat mass, lose lean mass, and be subject to a series of adverse effects from therapy [1–4]. These risks are especially important for men with long life expectancies, such as those undertaking ADT as neoadjuvant or adjuvant programmes with curative radiation. Moreover, testosterone may fail to recover in some older men (≥70 yr of age) following cessation of ADT; hence, ADT-related complications that arise may not be temporary [5,6]. Regular exercise is established for primary and secondary prevention of several chronic diseases, including cardiovascular disease (CVD) and diabetes, and even premature death [7,8]. These men could benefit from exercise by reducing risk factors for metabolic complications, therapy-related comorbidities, and physical function declines [9], all clinically relevant factors for long-term cancer survivors [10].

Our team [11,12] and others [13,14] in tightly controlled laboratory-based trials have established exercise as an intervention that can prevent and even reverse adverse effects in men with PCa receiving ADT, but these studies have examined only the immediate effects of short-term interventions. No information exists about longer-term impacts and exercise response of those who have been previously treated with ADT. This information is of vital interest to long-term PCa survivors and their clinical attendants. Further, there have been few attempts to initiate multicentre international studies with PCa survivors undertaking supervised exercise training [15]. Such studies are critical for determining the potential of translating smaller efficacy trials into more representative real-life programmes.

We report the effectiveness of a multicentre year-long randomised controlled trial (RCT) of exercise training (resistance and aerobic) in long-term PCa survivors previously treated with ADT from the Trans-Tasman Radiation Oncology Group (TROG) 03.04 Randomised Androgen Deprivation and Radiotherapy (RADAR) trial. Changes in cardiorespiratory fitness over 6 mo and 12 mo served as the primary study end point. Secondary end points included physical functioning, patient-reported outcomes, blood biomarkers, and body composition.

2. Patients and methods

2.1. Patients

TROG 03.04 RADAR is a randomised trial examining the effect of adjuvant ADT duration on recurrence-free survival [16]. Eight hundred forty-three men enrolled in the RADAR trial from three centres in Australia and New Zealand were contacted by a letter of invitation from their oncologist. Three hundred forty-seven men responded to the letter of invitation and were screened for participation. Their progress through the study is shown in Figure 1. Inclusion criteria consisted of being enrolled in the RADAR trial with no structured exercise within the past 6 mo (meeting current exercise oncology guidelines of 150 min of aerobic and twice resistance training sessions per week) [15]. Participants had been previously treated with ADT and radiation therapy (RT), were able to walk 400 m, and obtained medical clearance from their physician. Exclusion criteria consisted of bone metastases; acute illness; or any musculoskeletal, cardiovascular, or neurologic disorder that could inhibit or put them at risk from exercising. The study was approved by the University Human Research Ethics Committee, and all subjects provided written informed consent.

2.2. Study design and random assignment

This trial was a two-armed, prospective RCT. After completion of the baseline assessment, participants were randomly allocated to one of the two study arms: supervised exercise (EX) or physical activity with printed material (PA). The recommendation was in a ratio of 1:1 by a computer random assignment programme, with the allocation sequence using the minimisation technique and stratification according to treatment centre, age (<69, 69–74, >74 yr of age), original RADAR study arm (A: 6 mo of ADT and RT; B: 6 mo of ADT and RT and 18 mo of bisphosphonate; C: 18 mo of ADT and RT; and D: 18 mo of ADT and RT and 18 mo of bisphosphonate), current levels of testosterone (<3, 3–8, >8 nmol/l), whether disease relapse occurred, and waist circumference (<102 cm).

2.3. Exercise training programme

Participants in the EX group undertook combined progressive resistance and aerobic training twice per week for 6 mo. Exercise training was undertaken in 13 exercise clinics across Western Australia, New South Wales, and Wellington. The resistance exercises included the chest press, seated row, shoulder press, triceps extension, leg press, leg extension and leg curl, and abdominal crunches. The programme was designed to progress in loading from 12- to 6-repetition maximum (RM) for two to four sets per exercise [11,17]. The aerobic training component included 20–30 min of cardiovascular exercises (cycling and walking or jogging) at 70–85% maximum heart rate and perceived exertion at 11–13 (6- to 20-point Borg scale). Individual heart rate monitors and a pedometer were provided to each participant. Sessions were conducted in small groups of participants under the direct supervision of an exercise physiologist. In addition, two exercise sessions were completed at home each week involving aerobic exercise. During months 7–12, the EX group received a home-based exercise programme that consisted of a booklet with detailed information about a home exercise prescription but no longer received direct exercise supervision. The home exercise programme was designed to replicate the exercises performed in the supervised sessions and included resistance, aerobic, and flexibility exercises.

The PA group received a pedometer and a modified educational booklet with a general recommendation to perform 150 min per week of moderate physical activity during the entire 12-mo period. During the course of the

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