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2 prostate cancer: Outcomes to 12 months of the ENGAGE cluster randomised controlled trial

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Abstract

Background: The ENGAGE (efficacy of a referral and physical activity programme for survivors of prostate cancer) study established that a clinician referral and 12-week exercise training programme increased vigorous physical activity at 12 weeks among men with prostate cancer. Here, we report the 6- and 12-month outcomes.

Methods: In this multicentre cluster randomised controlled trial, we compared a clinician referral and exercise training programme to usual care. Discounted gym membership was offered to men in the intervention condition on completion of the 12-week exercise programme. Self-reported physical activity at 6 and 12 months was the primary outcome. Quality of life, anxiety, and depressive symptoms were secondary outcomes.

Results: A total of 147 men meeting eligibility criteria agreed to participate (54 intervention, 93 control). A positive interaction effect for vigorous physical activity was observed at 6 months, but not 12 months. No significant effects for the secondary outcomes were found.

Conclusion: A clinician referral and community-based supervised and unsupervised exercise training programme, along with discounted gym membership, had a positive short-term effect on vigorous physical activity levels, but did not improve quality of life, in men with prostate cancer.

Introduction

Exercise training has clear psychological and physiological benefits for men with prostate cancer.¹ Health promotion guidelines recommend that clinicians advise survivors to be physically active for at least 150 minutes per week, which may include weight-bearing exercises.² An important challenge is to assist men with prostate cancer to meet this level of physical activity. Evidence suggests that exercise training counselling from clinicians can be an effective way of increasing physical activity in various patient populations,³ and could have potential for men with prostate cancer.^{4,5}

We trialled a clinician referral and 12-week community-based supervised and unsupervised exercise training programme to establish whether this intervention increased physical activity levels among men with prostate cancer.^{6,7} We previously reported that, at 12 weeks, men in the intervention condition were undertaking significantly more vigorous physical activity than those in the control (usual care) condition ($M_{diff} = 45\text{mins/wk}$, 95% CI [11, 79]).⁷ Positive effects of the intervention were also found on measures of cognitive functioning (a component of quality of life) and depressive symptoms. No changes were found for anxiety or other components of quality of life. On completion of the exercise training programme at 12 weeks, each participant in the intervention condition was offered discounted gym membership. Here, we extend our analysis of the impact of the intervention to include 6- and 12-month data. With social cognitive theory⁸ informing our intervention, we anticipated that the effects of the intervention may endure beyond the cessation of the training programme. Social cognitive theory constructs (e.g., self-efficacy, outcome expectations) have been shown to predict long term maintenance of physical activity.⁹ We hypothesized that men in the intervention condition would be more physically active than those in the control condition. We also hypothesized that the intervention would continue to have a

1 positive effect on the cognitive functioning component of quality of life and on depressive
2 symptoms.

3 **Methods**

4 **Design**

5 This study was a multicentre, cluster randomised controlled trial to determine the efficacy of
6 a clinician referral and 12-week exercise programme, along with discounted gym
7 membership on completion of this programme, for improving the physical activity levels
8 (mins/wk) of men with prostate cancer.^{6,7} Secondary outcomes were sufficient moderate-to-
9 vigorous physical activity (≥ 150 mins/wk), quality of life, anxiety, and depressive symptoms.
10 A detailed description of the study methods is available from the published protocol.⁶ Briefly,
11 15 clinicians (71% of those approached) agreed to participate in the trial. Clinicians were
12 eligible for inclusion in the trial if they (a) treated men for prostate cancer and (b) practised at
13 one of the outpatient clinics for which we had ethics approval. The clinicians were
14 predominantly male registrars, aged between 30 and 50, with weekly caseloads that included
15 between 10 and 19 men with prostate cancer; there were no statistically significant
16 differences between the clinicians in the two conditions with respect to these characteristics
17 (Table S1). Using an online random number generator, clinicians were randomised to either
18 the intervention condition (referring eligible men with prostate cancer to a 12-week exercise
19 training programme; $n=8$) or control condition (providing usual care; $n=7$). Patients were,
20 therefore, entered into the trial by either the intervention or control condition, depending on
21 the condition to which their clinicians had been allocated.

22 The protocol received human research ethics approval and each participant provided
23 written informed consent.

1 **Participants**

2 Participants were recruited through urology and radiation oncology outpatient clinics across
3 three major public health services and four private clinics located across Melbourne,
4 Australia. The inclusion criteria were: men diagnosed with stage I, II, or III prostate cancer
5 and who had (a) completed active treatment for prostate cancer within the previous 3 to 12
6 months (patients on hormone treatment were eligible to participate) and (b) the ability to
7 complete surveys in the English language. The exclusion criteria were: men with any
8 musculoskeletal, cardiovascular, or neurological disorders that could limit them from
9 exercising.

10 **Intervention condition**

11 Using a standardised process, clinicians in the intervention condition provided usual care
12 with respect to advice about physical activity and referred patients to a 12-week community-
13 based exercise training programme. Usual care typically involved providing verbal advice to
14 be physically active (Table S1). These referrals occurred during routine follow-up
15 consultations. Clinicians were trained in making referrals, which involved following a
16 standard script and handing patients a referral slip to the programme.⁶ The exercise training
17 programme comprised two supervised sessions and one unsupervised, home-based session
18 per week. The supervised sessions were conducted at community gyms local to each
19 participant under the guidance of post-graduate students supervised by accredited exercise
20 physiologists. Social cognitive theory⁸ informed the development of the intervention. To
21 facilitate adherence to exercise following the programme, each participant was offered a
22 written exercise programme and discounted gym membership on completion of the 12-week
23 programme.

1 **Control condition**

2 Clinicians in the control condition provided usual care with respect to advice about physical
3 activity. Usual care typically involved providing verbal advice to be physically active (Table
4 S1).

5 **Measures**

6 Participants completed the following measures at baseline, 12 weeks, 6 months, and 12
7 months: an adapted Godin-Shepherd Leisure Time Exercise Questionnaire¹⁰ (modifications
8 included having participants report the average duration of exercise at each intensity in
9 addition to frequency,¹¹ and removing examples of physical activities that were not common
10 in Australia), European Organization for Research and Treatment of Cancer Quality of Life
11 Questionnaire¹² and Prostate Tumor–Specific Module,¹³ Memorial Anxiety Scale for Prostate
12 Cancer,¹⁴ and the Center for Epidemiological Studies Depression Inventory.¹⁵ At baseline and
13 12 weeks (not the focus of the present paper), measures also included objective assessments
14 of physical activity⁷ and fitness.¹⁶

15 **Data analysis**

16 Analyses were performed on an intention-to-treat basis with baseline, 12-week, 6 month, and
17 12 month data. For continuous outcome variables, repeated measures split plot in time
18 analysis of variance models were estimated using a generalized estimation equation (GEE)
19 approach with exchangeable working correlation matrix. Model adjusted mean effects and
20 95% confidence intervals were used to determine follow-up by intervention impacts. For the
21 binary outcome (whether or not men had undertaken ≥ 150 min moderate-to-vigorous physical
22 activity in the previous week), repeated measures logistic regression models using the GEE
23 technique were used to evaluate follow-up by intervention interactions.

1 **Results**

2 Screening of patients who had completed active treatment for prostate cancer occurred from
3 October 2011 to June 2013. Of the 443 patients meeting eligibility criteria, 147 men agreed to
4 participate in the main study, with 54 being patients of clinicians randomised to the
5 intervention condition and 93 being patients of clinicians randomised to the control condition.
6 Details of participant flow through the trial are provided in Figure 1. Demographic and
7 clinical characteristics have been reported previously.⁷ Overall, the mean age was 66 ± 9 years,
8 and the time since active treatment was 25 ± 10 weeks. Adverse events (musculoskeletal
9 injuries) were reported for two participants. One man (intervention condition) aggravated a
10 previous rotator cuff injury (left shoulder, grade I strain) during exercise training. He
11 withdrew from the study, which prevented follow up. The other man (control condition),
12 aggravated a previous meniscus injury (right knee, inflammation) during baseline testing. He
13 completed the 12 week testing with no pain or discomfort.

14 The positive interaction effect for vigorous physical activity observed at 12 weeks
15 was sustained at 6 months (Table 1). The effects of the intervention on secondary outcomes at
16 6 and 12 months were not significant (Table S2).

17 **Discussion**

18 This trial demonstrated that the effect of the intervention on vigorous physical activity
19 continued to strengthen after the exercise training programme was completed (i.e., between
20 12 weeks and 6 months), but diminished between 6 and 12 months. Although not statistically
21 significant, taking baseline levels into account, the men in the intervention condition were
22 engaged in, on average, 33 minutes per week more vigorous physical activity than those in
23 the control condition at 12 months. Although men in the intervention condition were
24 performing, on average, 55 minutes more vigorous physical activity at 12 months (compared
25 with baseline levels), they undertook, on average, 37 minutes less moderate physical activity.

1 Such a finding is particularly pertinent, because 58% of men in the intervention condition
2 remained insufficiently active with respect to physical activity guidelines for this population.²

3 Two observations from this trial were that “lack of time” was the most frequent
4 reason men gave for not participating⁷ and, for those who completed the intervention,
5 declines in the number of men engaged in sufficient physical activity occurred at 6 and 12
6 months. These findings seem to echo a comment from one of the clinicians that patients were
7 not taking verbal advice to be physically active seriously enough; that is, patients may not
8 view physical activity as a “medical intervention”, which can improve outcomes. Patients
9 should be routinely prescribed exercise as part of regular patient care, with clear pathways
10 into specialised exercise training programmes. Clinicians need to move to a treatment model
11 where exercise is a standard part of routine care that is discussed at every consultation, rather
12 than an optional extra. In addition, exercise training programmes could be enhanced through
13 integrating other components shown to facilitate adherence to exercise referral schemes (e.g.,
14 encouragement and support from family and friends, variety of exercise options, flexible
15 session times, and perceived benefits to physical and mental health).¹⁷

16 A limitation of this research was that the men recruited engaged in more minutes of
17 moderate-to-vigorous physical activity per week at baseline than expected, had higher quality
18 of life scores compared with age-group norms, and had negligible anxiety and depressive
19 symptoms. These favourable baseline levels may explain the very limited changes in scores
20 for the secondary measures. They also point to the challenge of increasing physical activity
21 levels of men with prostate cancer who are less active and have poorer levels of functioning.

22 Data were not available on the percentage of men in the intervention condition who
23 took up the offer of discounted gym membership. At the completion of this programme,
24 however, 45% of these men reported their intention to join a gym in the coming month.⁷

1 In summary, positive short-term increases in the volume (up to 12 weeks) and
2 intensity (up to 6 months) of physical activity were observed for men who clinicians referred
3 to, and undertook, a 12-week supervised exercise programme, and who then were offered
4 discounted gym membership. Declines in physical activity at 12 months, however, point to
5 the need for ongoing clinician focus on the physical activity levels of men with prostate
6 cancer (e.g., monitoring physical activity levels at each consultation), follow-up sessions with
7 exercise professionals, and better community-based programmes that promote long term
8 behaviour change. For those men who were unable to commit to 12-weeks of scheduled
9 sessions, briefer programmes or periodic consultations with exercise professionals should be
10 encouraged. Clinicians and exercise professionals need to keep reinforcing messages about
11 the importance of physical activity for health and wellbeing to all men with prostate cancer.
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ENGAGE

1 **Table 1.** Effect of the intervention on the primary outcome measure (mins/wk of self-reported physical activity) at 12 weeks, 6 months, and 12 months

	Descriptive Statistics ^a				p ^b	Follow-up by Intervention Interactions ^c					
	Intervention		Control			Baseline – 12 weeks ^d		Baseline – 6 months ^d		Baseline – 12 months ^d	
	6 months	12 months	6 months	12 months		Interaction effect	Effect	Interaction effect	Effect	Interaction effect	Effect
						(95% CI)	size ^e	(95% CI)	size ^e	(95% CI)	size ^e
n	43	43	78	74							
Moderate physical activity	142±231	97±130	88±133	80±133	.612	-2.5(-91.1, 86.1)	-0.01	-6.8(-87.2, 73.6)	-0.04	-30.7(-87.2, 25.8)	-0.23
Vigorous physical activity	111±196	88±143	45±156	53±184	.025	43.5(9.4, 77.7)	0.46	55.8(14.2, 97.5)	0.66	32.7(-4.0, 69.4)	0.42
Moderate-to-vigorous physical activity	253±389	186±219	133±207	132±252	.746	49.1(-46.8, 144.9)	0.18	43.8(-56.6, 144.2)	0.18	8.7(-55.6, 73.1)	0.05

2 Notes.

3 ^a Presented as M±SD. Descriptive statistics for baseline and 12 weeks have been published previously.⁷

4 ^b Overall follow-up by intervention interaction p value.

5 ^c Follow-up by intervention interactions, with control condition at baseline as reference condition.

6 ^d Interaction effects and effect sizes were calculated using model-based mean differences and standard errors (i.e., not the raw means and standard deviations).

7 ^e Cohen's d effect size.

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1 **Table S1.** Clinician characteristics.

Characteristics	Intervention (<i>n</i> = 8)	Control (<i>n</i> = 7 ^a)	<i>P</i> ^b
	<i>n</i> (%)	<i>n</i> (%)	
Demographic characteristics			
Gender			.605
Male	6 (75.0)	6 (85.7)	
Female	2 (25.0)	1 (14.3)	
Age (years)			.227
< 30	1 (12.5)	1 (20.0)	
30-40	1 (12.5)	3 (60.0)	
41-50	4 (50.0)	1 (20.0)	
51-60	2 (25.0)	0 (0.0)	
Profession			.875
Urologist	2 (25.0)	2 (28.6)	
Registrar	4 (50.0)	4 (57.1)	
Urology nurse	2 (25.0)	1 (14.3)	
Number of men with prostate cancer in weekly caseloads			.123
< 10	3 (37.5)	1 (20.0)	

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10-19	2 (25.0)	4 (80.0)	
> 19	3 (37.5)	0 (0.0)	
Frequency of providing advice on physical activity			.788
Sometimes	4 (50.0)	3 (60.0)	
Often	3 (37.5)	1 (20.0)	
Always	1 (12.5)	1 (20.0)	
Method of providing advice on physical activity			
Verbal			-
Yes	8 (100.0)	5 (100.0)	
No	0 (0.0)	0 (0.0)	
Literature/pamphlets			.252
Yes	1 (12.5)	2 (40.0)	
No	7 (87.5)	3 (60.0)	
Refer to physiotherapist			.506
Yes	3 (37.5)	1 (20.0)	
No	5 (62.5)	4 (80.0)	

1 ^a Data for two clinicians (control condition) were missing for all characteristics except for gender and profession.

2 ^b Pearson chi squared test.

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1 **Table S2.** Effect of the intervention on the secondary outcome measures (sufficient physical activity, quality of life, anxiety, and depressive symptoms) at 12
 2 weeks, 6 months, and 12 months

	Descriptive Statistics ^a					p ^b	Follow-up by Intervention Interactions ^c					
	Intervention		Control		Baseline – 12 weeks ^d		Baseline – 6 months ^d		Baseline – 12 months ^d			
	6 months	12 months	6 months	12 months	Interaction effect		Effect	Interaction effect	Effect	Interaction effect	Effect	
					(95% CI)		size ^e	(95% CI)	size ^e	(95% CI)	size ^e	
n	43	43	78	74								
Sufficient physical activity	20(46.5)	18(41.9)	28(35.9)	20(27.0)	.589	1.60(0.73, 3.55) ^f	0.25	0.72(0.34, 1.53) ^e	-0.18	1.03(0.46, 2.34) ^e	0.02	
n	43	43	78	74								
Physical functioning	95.7±10.1	92.2±14.5	93.7±11.3	91.5±12.9	.993	0.2(-2.4, 2.8)	0.03	0.5(-3.0, 4.0)	0.05	0.2(-3.6, 4.1)	0.02	
Cognitive functioning	86.4±23.3	85.7±18.0	86.1±16.4	85.8±19.4	.300	4.0(-0.2, 8.2)	0.34	1.3(-4.2, 6.8)	0.09	2.2(-3.5, 7.9)	0.15	
Emotional functioning	87.4±19.6	86.9±16.0	85.1±19.4	83.7±20.4	.355	-4.4(-9.7, 0.9)	0.3	-2.5(-8.3, 3.3)	0.16	-1.3(-7.3, 4.6)	0.08	
Social functioning	93.0±17.5	87.2±20.2	89.7±18.1	85.8±23.4	.764	3.2(-4.8, 11.2)	0.14	3.2(-4.7, 11.2)	0.15	1.1(-8.0, 10.2)	0.04	
Role functioning	95.0±18.7	89.5±24.1	91.2±21.1	90.3±21.7	.848	1.7(-5.1, 8.5)	0.09	2.3(-6.9, 11.6)	0.09	-0.6(-10.0, 8.7)	-0.03	
Global quality of life	81.2±16.4	79.3±17.8	78.6±16.0	79.3±16.4	.590	2.1(-2.6, 6.9)	0.16	3.3(-2.3, 8.8)	0.22	1.0(-4.7, 6.6)	0.06	
n	43	42	78	74								
Prostate cancer anxiety	3.3±5.0	4.0±6.5	5.2±7.5	4.8±7.3	.679	0.7 (-1.0, 2.5)	0.15	0.9 (-0.9, 2.6)	0.18	1.1 (-0.7, 3.0)	0.23	

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PSA anxiety	0.1±0.5	0.1±0.6	0.4±1.0	0.3±0.9	.130	0.4 (0.0, 0.8)	0.4	0.2 (-0.1, 0.6)	0.23	0.2 (-0.2, 0.5)	0.15
Fear of recurrence anxiety	3.0±2.6	3.6±3.6	3.8±3.7	3.7±3.3	.070	1.6 (0.3, 2.9)	0.43	-0.1 (-1.3, 1.2)	-0.01	0.5 (-0.8, 1.9)	0.15
Total anxiety	6.3±6.3	7.6±8.8	9.2±9.8	8.9±9.8	.056	2.7 (0.7, 4.9)	0.47	1.2 (-1.2, 3.6)	0.18	1.8 (-0.6, 4.2)	0.28
n	43	42	78	74							
Depression symptoms	6.6±6.5	7.7±6.9	7.2±7.1	8.2±7.4	.332	-1.7 (-3.7, 0.2)	-0.61	-1.2 (-2.9, 0.5)	-0.26	-1.3 (-3.5, 1.0)	-0.22

1 Notes.

2 ^a Presented as M±SD, except for sufficient physical activity, which is reported as n(%). Descriptive statistics for baseline and 12 weeks have been published previously.⁷

3 ^b Overall follow-up by intervention interaction p value.

4 ^c Follow-up vs baseline by intervention condition interactions, with control condition at baseline as reference condition.

5 ^d Interaction effects and effect sizes were calculated using model-based mean differences and standard errors (i.e., not the raw means and standard deviations).

6 ^e Cohen's d effect size.

7 ^f Model-adjusted odds ratios for follow-up by intervention interaction effects for sufficient physical activity.

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