

Mechanisms of Physical Activity Behavior Change for Prostate Cancer Survivors: a
Cluster Randomized Controlled Trial

Abstract

Background: Exercise is beneficial for prostate cancer survivors. Therefore, understanding the mechanisms of physical activity behavior change is imperative.

Purpose: The ENGAGE study was an exercise intervention for prostate cancer survivors, which improved vigorous physical activity at post-intervention and follow-up. The purpose of this study was to assess (a) whether the intervention improved social cognitive determinants of behavior, and (b) the extent to which social cognitive determinants mediated the effect of the exercise intervention on vigorous physical activity.

Methods: Overall, 147 men consented to be involved in the study (intervention = 54, usual care = 93). Data from baseline, post-intervention (12 weeks) and follow-up (6 months) were used in this analysis. Social cognitive determinants were measured using appropriate measures. Vigorous physical activity was measured using an adapted version of the Leisure-Time Exercise Questionnaire.

Results: Compared to the control condition, men in the intervention condition had higher task self-efficacy post-intervention (+16.23; 95% confidence interval [CI] +9.19 to +23.31; effect size [d] = 0.85, $P < .001$) and at follow-up (+12.58; 95% CI = +4.45 to +20.71, $d = 0.50$, $P = 0.002$). Task-self efficacy partially mediated the effect of the exercise intervention on vigorous physical activity (indirect effect: $B = 19.90$; 95% CI 1.56 to 38.25, $P = 0.033$).

Conclusion: The intervention improved the belief among prostate cancer survivors that they could perform challenging exercises for longer periods of time, which partially explained the positive effect of the intervention on vigorous physical activity.

This trial was registered with the Australia and New Zealand Clinical Trials Register (ACTRN12610000609055).

Keywords: cancer, oncology, physical activity, social cognitive theory

Introduction

With earlier detection and more effective treatments, more men with prostate cancer are living longer post-diagnosis. For example, in Australia, five-year relative survival rates increased to 93.0% for the years 2007-2011 (1). Prostate cancer survivors, however, experience significant physical and psychological morbidity following their diagnosis and subsequent treatment (2, 3). Physical activity (PA) has a role in alleviating this morbidity (4, 5), but engagement in PA is markedly lower than what is recommended (3, 6). A recent study of 463 prostate cancer survivors, for example, revealed that only 12.3% were sufficiently active (6). To improve participation in PA among this population, theory-based behavior change interventions must be designed (7) to target the most pertinent mechanisms that will facilitate change in behavior (8).

Behavior change interventions that aim to support PA participation in prostate cancer survivors are scarce. In one study, researchers examined the effect of a home-based intervention on PA for prostate cancer survivors, which utilised implementation intentions (9), and reported an increase in PA participation at one month but not at the 3 month follow-up (10). Furthermore, the mediators of behavior change were not examined (10). To date, most trials among prostate cancer survivors have focused on the efficacy of exercise programs for improving health outcomes during and following treatment (4, 5, 11). Consequently, there is now a substantial body of evidence that supports the positive effect of exercise for improving incontinence, fitness, fatigue, body composition, muscular endurance, aerobic endurance, and quality of life among prostate cancer survivors (4, 5, 11). For these

men to achieve the health benefits of exercise, research must also focus on interventions to support them to participate in PA and explore the mechanisms of behavior change.

The use of theories to guide behaviour change interventions is important because theory provides a generalizable framework, facilitates an understanding why interventions do, or do not, work, and assists the accumulation of knowledge (8). Social cognitive theory (SCT) (12, 13) is well suited to exercise programs that aim to change behavior (14). According to SCT, the main determinants of behaviour are self-efficacy, outcome expectations, goals, and socio-structural factors (13, 14). SCT-based exercise interventions have shown promise in increasing PA participation for cancer survivors (15-18). There are several limitations of existing research in this area, however. Few researchers have conducted mediation analyses or reported changes in SCT determinants, which has resulted in limited understanding how interventions affect behavior change; follow-up PA is rarely reported, thus there is uncertainty about the longer-term impact of exercise interventions; and finally, researchers have focused on home-based interventions and breast cancer survivors, which limit the generalisability of findings of SCT-based PA interventions to other types of intervention delivery modes (such as supervised or combined supervised and home-based interventions) and other cancer populations (18).

In the ENGAGE study, we examined the efficacy of a clinician-referred 12-week exercise intervention for prostate cancer survivors. The primary outcome was self-reported minutes of moderate-vigorous PA per week and the main outcomes of the study have been previously reported (19). In terms of PA participation, the intervention, compared to usual care, did not significantly improve minutes of moderate-vigorous PA per week. However, the intervention significantly increased vigorous physical activity (VPA) and the proportion of men meeting PA guidelines post-intervention (12 weeks) (19). The effect of the intervention on VPA was maintained at follow-up (6 months); men in the intervention condition

participated in 56 minutes (95% CI 14.2, 97.5) minutes per week more VPA than those in the control condition. However, the difference in VPA at 12 months was not significant (20). This paper addresses secondary aims of the ENGAGE study: (a) to assess whether the exercise intervention improved social cognitive determinants of PA behavior (i.e., self-efficacy, outcome expectations, goals, and socio-structural factors) between baseline and post-intervention (12 weeks) and to see if these changes were maintained at follow-up (6 months), and (b) to assess the extent to which social cognitive determinants mediated the effect of the intervention on VPA (21). Because the intervention did not have a significant effect on the primary outcome of moderate-vigorous PA, but an effect on VPA was found, we used minutes of VPA at follow-up as our outcome.

Methods

This trial was registered with the Australia and New Zealand Clinical Trials Register (ACTRN12610000609055).

Design and Procedures

Details of the ENGAGE study methods have been reported elsewhere (21) and are briefly presented here. The study was a two-arm multicenter, cluster randomized controlled trial. The eligibility criteria for inclusion in this study were: completed active treatment for prostate cancer within the previous 3-12 months (patients on hormone treatment were eligible to participate); treated with curative intent; and the ability to complete surveys in the English language. The exclusion criteria for this study included musculoskeletal, cardiovascular, or neurological disorders that could limit exercising. The patients' treating clinicians provided medical clearance prior to involvement in the study.

Patients were identified through urology and radiation oncology outpatient clinics across three public health services and four private clinics located in Melbourne, Australia. Recruitment occurred from October 2011 to June 2013. Patients were approached and

provided with information about the study prior to their consultation with their treating clinicians. During the consultation, clinicians randomized to the intervention condition determined the suitability of the patient for the intervention, provided a blue referral slip and recommended that the patient be involved in the exercise program. Clinicians randomized to the control condition provided usual care regarding PA advice (typically, minimal information) and did not provide a referral to the exercise program. A study researcher later phoned eligible patients to gain informed consent.

Sample size calculations were based on the primary outcome of the main study (self-reported participation in moderate-vigorous PA) (19, 21), rather than the secondary analysis reported here.

Ethical approval was obtained from the university and each of the health services involved in the study. All participants provided written informed consent.

Intervention

The 12-week exercise program was based on PA guidelines for cancer survivors (22, 23), which recommend 150 minutes per week of moderate-vigorous PA. Participants were asked to complete three, 50 minute sessions of PA per week. Two of these sessions were supervised sessions in community gyms and one session was an unsupervised, home-based session. Sessions were predominantly one-on-one sessions, with men occasionally training in pairs.

The social cognitive determinants of behavior informed our design of the intervention (14, 24). The 12-week exercise program was intended to increase PA through, in part, enhancing exercise-related self-efficacy in prostate cancer survivors and assisting them to develop positive outcome expectations, set beneficial goals, and reduce perceived impediments to exercise participation. Our previous research suggested that the involvement of clinicians in referring men to the program improved men's confidence in performing PA

(25) , which might increase self-efficacy through increasing men's belief in their ability to undertake exercise. Exercise trainers, who conducted the gym sessions, were trained in the principles of SCT and their application to PA uptake and adherence for prostate cancer survivors through an induction session prior to their commencement in the project. Exercise trainers were postgraduate exercise physiology students and were supervised by an accredited exercise physiologist. In the first exercise session, exercise trainers were instructed to encourage participants to set short-term and longer-term SMART (i.e. specific, measurable, attainable, realistic, timely) exercise goals; incorporate discussions of the participant's beliefs in their ability to exercise, benefits of exercise, outcome expectations from exercise, factors that facilitate their participation and how to maximise these; and identify potential barriers and strategies for overcoming them. Exercise trainers were instructed to revisit these discussions periodically throughout the training sessions and regularly counselled participants throughout the 12-week program. The topics for these discussions were based on the main concepts of the SCT (14, 24) Exercise trainers were provided with checklists to ensure that they were regularly addressing the key topics, including setting goals, aligning activity with outcome expectations, overcoming barriers and drawing on facilitators, during exercise sessions over the 12-week period.

For the unsupervised sessions, men were provided with a home-based PA program instruction sheet, instructions on how to perform the home-based exercises, and a Thera-Band to complete the exercises. These home-based sessions were designed to increase adherence to PA following completion of the intervention for those who preferred to exercise at home. To facilitate adherence to PA following the program, participants were also offered an exercise program and discounted gym membership..

The intervention included supervised and home-based PA. The supervised component was important because participants had regular contact and encouragement from exercise

trainers and could be directly observed and instructed on correct exercise technique, which reduces the risk of injury and may also improve adherence. Home-based activity might increase adherence to PA because it is cost-effective for participants and PA can be incorporated in to daily routines (26). Men in the control condition were not referred to an exercise program and received usual care, which typically does not include recommendations for PA.

Random Assignment

Clinicians were invited to participate in the study and were randomly allocated using an online random number generator to either the intervention or control condition.

Measures

Demographic and clinical characteristics were assessed at baseline. Data presented in this analysis are based on PA behavior and the social cognitive determinants assessed at baseline (T1), post-intervention (12 weeks, T2), and at follow-up, three months after the completion of the intervention (6 months, T3).

Demographic and clinical characteristics. Date of birth, level of education and type of treatment (surgery, radiotherapy and hormone therapy) were collected through self-report. Weeks since treatment completion and cancer stage were collected through medical records.

Primary outcome. An adapted version of the Leisure-Time Exercise Questionnaire (27) was used to measure PA participation. In the Leisure-Time Exercise Questionnaire, participants report the average weekly frequency of strenuous, moderate, and light exercise over the past month. We asked participants to report the average duration of time they spend exercising at each intensity, in addition to the frequency during an average week in the past month (15, 27) and we also and removed examples of physical activities that were not common in Australia. The Leisure-Time Exercise Questionnaire has been used extensively

with cancer survivor groups (27, 28). In the current analyses, we used data on minutes per week of strenuous PA as our outcome (i.e. VPA).

Mediators.

Outcome expectations. Outcome expectations were measured using the Multidimensional Outcome Expectations for Exercise Scale (MOEES) (29). This scale was designed for use in older adults and comprises 15 items that represent three sub-scales: physical (e.g., exercise will strengthen my bones), social (e.g., exercise will improve my social standing), and self-evaluative (e.g., exercise will give me a sense of personal accomplishment) outcome expectations. Participants respond to each item on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). The instrument's construct validity has been demonstrated through confirmatory factor analysis and significant correlations with other constructs consistent with the predictions inherent in SCT (29, 30). We used the total outcome expectations scale as well as the three subscales in our analyses. In the current sample, Cronbach's alpha for the total MOEES scale and subscales were high: total outcome expectations (0.92), physical (0.87), social (0.84), and self-evaluative (0.87).

Self-efficacy. Both task and barrier self-efficacy were measured using methods Bandura (24, 31) suggested. *Task self-efficacy* was assessed using 9 items, asking participants to rate how confident they are, ranging from 0% (not at all confident) to 100% (extremely confident), that they can perform three different types of PA (walking fast; running, fast swimming or cycling hard; and doing exercises with weights) for three time durations (10, 20, and 30 minutes). Similar items have been included in previous PA and cancer research in which task self-efficacy was measured (32). Higher scores indicate higher levels of task-self-efficacy. In the current sample, Cronbach's alpha for the task self-efficacy items was high (0.92). *Barrier self efficacy* was assessed using 25 items, asking participants to rate how

confident they are, ranging from 0% (not at all confident) to 100% (extremely confident), that they can perform PA when faced with specific barriers. Examples of barriers included, ‘when I am feeling tired’ and ‘when there are other interesting things to do’. The items were based on Bandura's (31) self-efficacy to regulate exercise instrument, with supplementary items from research on PA for prostate cancer survivors (25) and cancer patients (32). Higher scores indicate higher levels of barrier self-efficacy. In the current sample, Cronbach’s alpha for the barrier self-efficacy items were high (0.95).

Socio-structural factors. Social-structural factors facilitating (operationalised as motivation) or impeding (operationalised as barriers) participation in PA were measured using guidelines for the development of scales to assess barriers to PA for cancer patients (33). The content of these scales was based on previous research on the perceived benefits and barriers to PA for prostate cancer survivors (25). Participants are asked their perceptions of the frequency with which motivations (10 items) and barriers (12 items) occur using a 5-point Likert scale anchored with 0 (never) and 4 (always). Examples of motivation items include ‘socialising with other people’ and ‘increasing my energy levels’. Examples of barrier items include ‘injuries (e.g. muscular and joint problems)’ and ‘lacking time to do exercise’. In the current sample, Cronbach's alphas for the barrier and motivation items were high (0.83 and 0.92, respectively).

Goals. Goals were measured based on items from previous PA research that assessed SCT constructs (34). Participants are asked to report the number of days per week they intended to perform at least 30 minutes of exercise at a light, moderate or vigorous intensity and were asked about current goals and their 12-week exercise goals (2 items).

Statistical Approach

We used STATA version 14 to analyse data. There was minimal missing data for the variables included in this analysis (overall < 2% values missing). We calculated the mean

score for MOEES, exercise motivation, exercise barriers, task self-efficacy and barrier self-efficacy if at least 70% of the items were answered. Two items measured exercise goals; a score was calculated if at least one of these was answered. When less than 70% of responses were available for a scale, or where all items were reported as 'not applicable', data were treated as missing. For longitudinal analyses, we accounted for missing data using the generalised estimating equations (GEE) approach and we eliminated missing data from other analyses (35).

Our process for testing the possible mediation of the intervention effect on PA was guided by Baron and Kenny's (36) principles. As others have argued (37), however, the structural equation modelling (SEM) approach is more appropriate than Baron and Kenny's (36) approach because it estimates all paths simultaneously instead of assuming that equations 1 to 3 are independent. As such, the SEM approach was used for examining mediation. We only tested social cognitive determinants as possible mediators if they were affected by the intervention (i.e., condition assignment) and associated with follow-up VPA. We assessed the impact of the intervention on social cognitive determinants between baseline and post-intervention (12 weeks) and baseline and follow up (6 months) using time-by-treatment interactions in a repeated measures split-plot in time ANOVA model for continuous outcomes. We estimated model parameters using GEE with an exchangeable working correlation matrix to take account of the repeated measures for each participant. We also conducted post-hoc contrasts to determine follow-up-by-intervention impact. We calculated effect sizes (follow-up by intervention effect) using Cohen's *d*. We conducted a series of regression analyses using change scores to investigate the extent to which changes in the social cognitive determinants of behavior post-intervention (12 weeks) and follow-up (6 months) explained the increased VPA at follow-up (6 months). We adjusted for baseline

VPA and the baseline data of the SCT determinants for each analysis. We also reported eta-squared effect sizes for these analyses.

Finally, we used path regression analyses using the SEM approach to test for possible mediation of the intervention effect on VPA. We controlled for both baseline social cognitive determinants and VPA in the path analysis. That is, we considered the baseline data of potential mediators (i.e. social cognitive determinants) effect modifiers for post-intervention and follow-up mediator data as well as baseline and follow-up VPA. We also considered baseline VPA as an effect modifier for follow-up VPA. The autoregressive SEM model (38) was used for this purpose. We report standardized coefficients to aid in the interpretation of the mediation effects. Mediation is present when the proposed mediator maintains a significant relationship with the outcome, whereas condition does not. We also reported the controlled direct effect and natural indirect effect of mediators. We did not adjust for multiple comparisons because our mediation analyses was performed by implementing SEMs where all pathways, including the mediation effects, were assessed simultaneously. As this study was a cluster randomized controlled trial, we examined the effect of clustering by clinician for the social cognitive determinants and VPA by calculating the intra-cluster correlation coefficient (ICC) for the mean difference between each social cognitive determinant. Each ICC was less than 0.05, except task self-efficacy (ICC = 0.198) and follow-up VPA (ICC = 0.31). Therefore, we evaluated the clustering effect of clinician in the path analysis in a sensitivity analysis by including clinician as a fixed effect modifier factor.

Results

Study Flow and Participant Characteristics

The flow of participants and a detailed description of the demographic and clinical characteristics of the sample have been reported previously (19). Overall, 147 (46%; 54 intervention and 93 control) eligible patients consented to participate in the study.

Participants ranged in age from 39 to 84 years ($M = 65.6$; $SD = 8.5$); 27.2% had a university degree; the majority had stage I or II disease (82.8%); and 43.5% were treated with surgery only, with 21.1% treated with surgery and radiotherapy.

We obtained post-intervention (T2) data from 88.4% of participants ($n = 130$; 47 intervention, 83 control). There was no significant difference in attrition rates between the intervention and control conditions (control, 11%; intervention, 13%; $P = .70$). We obtained 6 month follow-up (T3) data from 121 (83.3%; 43 intervention, 78 control) participants. There was no significant difference in attrition rates between the intervention and control groups at T3 (control, 16.3%; intervention, 20.5%; $P = .23$).

As previously reported (19), 85% of participants adhered to at least 18 of the 24 supervised sessions. For participants who returned their home exercise diary (74%), 81% completed at least 9 of the 12 of the prescribed home-based weekly sessions.

Effect of the Exercise Intervention on Social Cognitive Determinants Post-Intervention (T2, 12 weeks)

Descriptive statistics and social cognitive determinant change scores immediately post-intervention (12 weeks) across the two conditions are presented in Table 1. Compared to the control condition, participants in the intervention condition had significantly higher task self-efficacy with a large effect size ($+16.23$; 95% CI = $+9.19$ to $+23.31$, $d = 0.85$, $P < .001$). There were no significant differences between the intervention and control conditions for any other social cognitive determinant and effect sizes were small (all less than $d = 0.30$).

Effect of the Exercise Intervention on Social Cognitive Determinants at Follow-up (T3, 6 months)

Descriptive statistics and social cognitive determinant change scores at follow-up (6 months) across the two conditions are presented in Table 2. Compared to the control condition, participants in the intervention condition had higher task self-efficacy at follow-up,

with a moderate effect size (+12.58; 95% CI = +4.45 to +20.71, $d = 0.50$; $P = 0.002$). There were no significant differences between the two conditions for any other social cognitive determinants at follow-up.

Association between Social Cognitive Determinants and Follow-up Vigorous Physical Activity

Associations between social cognitive determinants at post-intervention (T2, 12 weeks) and VPA at follow-up (T3, 6 months) showed that increases in barrier self-efficacy ($B = 1.61$, 95% CI = +0.57 to +2.65, $\eta^2 = 0.08$, $P = 0.003$) and reductions in motivation ($B = -21.19$, 95% CI = -41.60 to -0.78, $\eta^2 = 0.04$, $P = 0.04$) predicted improved participation in follow-up VPA (Table 3).

Associations between social cognitive determinants at follow-up (T3, 6 months) and VPA at follow-up (T3, 6 months) showed that increases in outcome expectations-social ($B = 39.92$, 95% CI = + 8.99 to +70.86, $\eta^2 = 0.06$, $P = 0.01$), task self-efficacy ($B = 1.48$, 95% CI = +0.45 to +2.50, $\eta^2 = 0.07$, $P = 0.005$), barrier self-efficacy ($B = 1.72$, 95% CI = +0.79 to +2.66, $\eta^2 = 0.11$, $P = < 0.001$), and goal setting ($B = 11.29$, 95% CI = +1.45 to +21.13, $\eta^2 = 0.05$, $P = 0.03$) predicted improved participation in follow-up VPA.

Mediation Analysis

The intervention had a positive effect on task self-efficacy at follow-up, and task self-efficacy at follow-up was associated with VPA at follow-up. Task self-efficacy was the only social cognitive determinant that met the criteria for the mediation analysis. The path analysis is shown in Figure 1. The association between the exercise intervention (condition) and follow-up VPA was only slightly reduced from $\beta = 0.25$ ($P = 0.001$) to $\beta = 0.18$ ($P = 0.01$) and was still significant after adjusting for follow-up task self-efficacy. The path from follow-up task self-efficacy remained significantly associated with follow-up VPA ($\beta = 0.35$, $P = < 0.001$). Follow-up task self-efficacy was a partial mediator of the effect of the exercise

intervention on follow-up VPA, as demonstrated through a significant indirect effect on VPA (natural indirect effect: $B = 19.90$; 95% CI 1.56 to 38.25, $P = 0.03$), with the intervention continuing to have a controlled direct effect ($B = 54.12$, 95% CI 9.64 to 98.60, $P = 0.02$).

Discussion

Our study is one of the few exercise interventions to focus on PA behavior change for prostate cancer survivors and also addressed several limitations of previous SCT-based exercise interventions for cancer survivors (18). We examined an exercise intervention that incorporated both supervised and unsupervised exercise, changes in scores on measures representing theoretical constructs of SCT, and conducted mediation analyses to examine if changes in social cognitive determinants affected change in VPA. We found that the exercise intervention was effective in increasing task self-efficacy post-intervention, which was maintained at follow-up, and task self-efficacy partially explained the effect of the intervention on longer-term VPA.

Self-efficacy is a key determinant of SCT (13) and the intervention may have achieved a positive effect on task self-efficacy in a number of ways. Bandura (13) proposed that expectations of personal efficacy are derived from four sources of information: performance accomplishments, vicarious experience, verbal persuasion and physiological states. *Performance accomplishments* may have been improved through participants completing the exercises and the feedback and guidance on performing strength and aerobic exercise provided by exercise trainers. During the supervised sessions, success was encouraged through starting the program at a level achievable by the participants and building the intensity throughout the program. *Vicarious experience* may have been improved through observations of other gym members participating in exercise at the community-based gyms in which exercise sessions were located. *Verbal persuasion* was likely to be influential through the clinician's referral to the exercise program and the ongoing encouragement by

exercise trainers. Finally, through participation in the exercise program, men may have learned to interpret *physiological states* that accompany exercise such as increased heart rate, sweating and muscle fatigue as signs that their body was responding normally to the exercise, rather than as a negative sign of inability to exercise or as a reason to discontinue activity. Future research could generate a better understanding of the relative importance of each of these information sources.

Direct comparisons with other interventions are limited because we could not find any other research that focused only on prostate cancer survivors which examined change in self-efficacy. Home-based PA interventions that have included prostate cancer survivors (along with breast cancer survivors) have shown mixed findings on their effectiveness in improving self-efficacy (17, 39). For example, a home-based diet and PA intervention for older breast and prostate cancer survivors (43% prostate cancer), which included telephone counselling and mailed materials had a positive effect on self-efficacy for PA. However, this intervention did not improve PA participation (39). Conversely, a mailed print intervention to improve dietary and PA practices among newly diagnosed breast and prostate cancer survivors (44% prostate cancer) had no effect on self-efficacy for PA (17). Although each of these studies used different measures of self-efficacy, the findings are comparable in that task self-efficacy, rather than barrier self-efficacy, was assessed. Studies of other cancer population groups, which have assessed the impact of PA interventions on self-efficacy, also resulted in conflicting findings (40, 41). A recent systematic review found that although PA interventions improve self-efficacy among healthy older adults, the use of self-regulatory techniques were associated with *reduced* self-efficacy (42). Drawing conclusions about the factors that may lead to an increase of self-efficacy among prostate cancer survivors is hampered by the limited amount of research in this area; our results suggest that a combined supervised and home-based intervention can enhance task-self-efficacy for this group.

We found that task self-efficacy was a partial mediator of the effect of the exercise intervention on longer term VPA. Previous research focusing on men (43) and older adults (44) have shown that self-efficacy is a key determinant of PA participation. Examination of the mediators of PA interventions has usually focused on self-efficacy and, as previously discussed, studies that have included prostate cancer survivors either did not improve self-efficacy (17) or did not increase PA participation (39). Several researchers have examined mediators of PA behavior change for cancer survivors using the theory of planned behavior (28, 45, 46) and showed that perceived behavioral control (28, 45), and planning and intention (46) were partial mediators of the effect of the intervention on PA behavior. Taken collectively, it appears that theoretical constructs in both SCT and theory of planned behavior only partially explain PA behavior change in cancer survivors, suggesting that other, unmeasured factors may explain the effect of such interventions on PA behavior change.

Contrary to our expectations, apart from a positive effect on task self-efficacy, the exercise intervention did not significantly improve the other social cognitive determinants assessed in our study. This is in contrast with a recent intervention aimed at increasing PA among cancer survivors and their carers that had a positive impact on behavioral goal setting and outcome expectations. This intervention included intensive sessions on goal setting and weekly monitoring of goals using a pedometer and diary (47). Thus, it may be that more intensive sessions that are focused on goal setting and monitoring is required to elicit changes..

There are also several other possible explanations for why our intervention did not have an impact on other social cognitive determinants. First, several of the social cognitive determinants in our study demonstrated high (or low) scores at baseline and might have demonstrated ceiling and floor effects. For example, the mean score for outcome expectations was close to 4 (possible range 1-5) and barriers was less than 0.7 (possible range 0-4).

Second, response shift theory (48) posits that, as a consequence of an intervention, the participants' awareness and understanding of the variable being measured changes and alters each participant's perspective in his or her self-evaluation. For example, men who participated in the exercise program may have found that the physical outcomes that they expected to achieve from exercise may have changed from what they expected prior to taking up regular exercise. Vallance et al. (46) noted that response shift theory may provide an explanation for why researchers find changes in PA behavior whereas cognitive variables remain relatively stable.

We found that increased social expectations of PA participation, barrier self-efficacy, and goal setting at follow-up predicted increased participation in VPA which provides support for SCT. Increased barrier self-efficacy and reduced exercise motivation at post-intervention also predicted improved VPA. Interventions that successfully improve perceptions of social outcomes of exercise, increase beliefs that one can overcome barriers to PA participation, and promote goal setting are likely to lead to improvements in VPA. In particular, barrier self-efficacy seems to be an important factor as it was associated with longer-term VPA at both post-intervention and follow-up, with large effect sizes. Furthermore, in a recent systematic review, goal setting has been identified as a significant predictor of PA behaviour across a range of population groups (49) and should also be considered an important component of PA interventions. Future interventions should focus on these factors to improve participation in VPA among prostate cancer survivors.

Our study had a number of strengths. The randomized controlled study design provided the necessary causal relationships for examining mediation and its prospective design minimized the potential for overestimation of associations that can occur when PA predictors are examined in cross-sectional studies (50). Our examination of the mediators of follow-up VPA is also important to assess the factors that influence longer-term behavior

change. The limitations of this study must also be considered when interpreting our results. The intervention did not have a sustained impact on minutes of moderate-vigorous PA or meeting guidelines for PA, so we instead focused only on VPA. We used a self-report measure of PA, which can introduce measurement error. Finally, although we followed guidelines for the development of measures of SCT determinants, some of our measures have not been validated in previous research.

Summary

Clinician referral to a combined supervised and home-based exercise program improved task self-efficacy and this increase partially explained longer-term engagement in VPA. Future PA behavior change interventions should focus on improving task self-efficacy, as well as social outcome expectations, goal setting and barrier self-efficacy to improve VPA among men with prostate cancer. Furthermore, future research should examine the mediators of PA behavior for prostate cancer survivors so that the important mechanisms of behavior change can be identified and targeted.

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Table 1: Effects of the Intervention on Social Cognitive Determinants at Post-Intervention (T2; N127)

	Baseline	Post-Intervention	Mean Change	Between-group comparison	<i>d</i>	<i>P</i>
	M (SD)	M (SD)	M (95% CI)	M (95% CI)		
<i>Outcome Expectations (range 1-5)</i>						
Int	4.02 (0.46)	4.00 (0.45)	-0.02 (-0.17 to 0.08)	+0.01 (-0.14 to +0.16)	0.02	0.89
Cont	3.87 (0.60)	3.83 (0.62)	-0.03 (-0.13 to 0.06)			
<i>Outcome Expectations-Physical (range 1-5)</i>						
Int	4.43 (0.39)	4.45 (0.42)	+0.02 (-0.10 to +0.15)	+0.01 (-0.15 to +0.17)	0.02	0.91
Cont	4.33 (0.58)	4.34 (0.55)	+0.02 (-0.09 to +0.12)			
<i>Outcome Expectations-Social (range 1-5)</i>						
Int	3.27 (0.77)	3.21 (0.70)	-0.06 (-0.21 to +0.09)	+0.06 (-0.16 to +0.30)	0.10	0.59
Cont	3.06 (0.87)	2.94 (0.90)	-0.12 (-0.27 to +0.02)			
<i>Outcome Expectations-Self-Evaluative (range 1-5)</i>						
Int	4.13 (0.54)	4.09 (0.535)	-0.05 (-0.18 to +0.08)	-0.03 (-0.23 to +0.18)	-0.06	0.78
Cont	3.97 (0.67)	3.94 (0.81)	-0.02 (-0.15 to +0.11)			
<i>Task Self-Efficacy (range 0-100)</i>						
Int	53.00 (28.07)	72.31 (25.60)	+18.17 (+11.50 to +24.84)	+16.23 (+9.19 to +23.31)	0.85	<0.001
Cont	56.81 (25.41)	59.15(26.86)	+1.70 (-2.04 to +5.44)			
<i>Barrier Self-Efficacy (range 0-100)</i>						
Int	63.81 (19.25)	70.22 (19.41)	+7.09 (+1.29 to +12.90)	+5.33 (-2.17 to +12.82)	0.25	0.16
Cont	58.16 (23.84)	58.96 (26.23)	+2.10 (-2.51 to +6.71)			
<i>Barriers (range 0-4)</i>						
Int	0.46 (0.43)	0.44 (0.43)	-0.03 (-0.17 to +0.12)	+0.05 (-0.13 to +0.23)	0.08	0.61
Cont	0.63 (0.585)	0.55 (0.57)	-0.07 (-0.18 to +0.03)			
<i>Motivation (range 0-4)</i>						
Int	2.44 (1.19)	2.11 (1.24)	-0.33 (-0.66 to 0.00)	-0.01 (-0.41 to -0.39)	-0.08	0.98
Cont	2.06 (1.00)	1.66 (1.09)	-0.32 (-0.56 to -0.09)			
<i>Goals (range 1-9)</i>						
Int	6.21 (1.72)	6.26 (1.83)	+0.04 (-0.54 to +0.61)	+0.38 (-0.34 to +1.10)	0.17	0.30
Cont	5.72 (2.48)	5.32 (2.56)	-0.34 (-0.77 to +0.09)			

Notes: Int = Intervention condition; Cont = Control condition; M mean; SD standard deviation; CI confidence interval; *d* = cohen's d effect size; Baseline and post-intervention means and standard deviations are raw data; Higher scores for each variable represent higher levels of that variable; Mean change and between-group comparison are based on model parameters using generalized estimating equations (GEE); At T2, 130 questionnaires were received with baseline data missing for three participants. The GEE approach was used for between-group comparisons to account for baseline missing data

Table 2: Effects of the Intervention on Social Cognitive Determinants at Follow-Up (T3; N = 118)

	Baseline	Follow-up	Mean Change	Between-group comparison	d	P
	M (SD)	M (SD)	M (95% CI)	M (95% CI)		
<i>Outcome Expectations (range 1-5)</i>						
Int	4.03 (0.45)	4.08 (0.44)	+0.03 (-0.03 to +0.08)	+0.02 (-0.16 to +0.19)	0.06	0.86
Cont	3.85 (0.56)	3.89 (0.61)	+0.02 (-0.04 to +0.08)			
<i>Outcome Expectations-Physical (range 1-5)</i>						
Int	4.45 (0.40)	4.50 (0.40)	+0.02 (-0.04 to +0.09)	+0.03 (-0.16 to +0.21)	0.04	0.78
Cont	4.33 (0.54)	4.36 (0.53)	+0.01 (-0.05 to +0.07)			
<i>Outcome Expectations-Social (range 1-5)</i>						
Int	3.24 (0.71)	3.33 (0.64)	+0.04 (-0.035 to +0.12)	+0.02 (-0.25 to +0.28)	0.02	0.91
Cont	3.01 (0.87)	3.06 (0.95)	+0.03 (-0.06 to +0.12)			
<i>Outcome Expectations-Self-Evaluative (range 1-5)</i>						
Int	4.16 (0.54)	4.20 (0.57)	+0.02 (-0.05 to +0.09)	0.00 (-0.20 to +0.21)	-0.07	0.97
Cont	3.95 (0.67)	3.99 (0.75)	+0.02 (-0.05 to +0.09)			
<i>Task Self-Efficacy (range 0-100)</i>						
Int	53.75 (27.56)	71.27 (28.51)	+8.31 (+4.41 to +12.22)	+12.58 (+4.45 to +20.71)	0.50	0.002
Cont	56.95 (27.24)	60.63 (25.36)	+1.95 (-0.16 to +4.06)			
<i>Barrier Self-Efficacy (range 0-100)</i>						
Int	63.57 (19.16)	71.08 (21.49)	+3.72 (+0.40 to +7.03)	+4.39 (-3.77 to +12.55)	0.13	0.29
Cont	57.75 (24.17)	61.29 (26.77)	+1.48 (-0.96 to +3.91)			
<i>Barriers (range 0-4)</i>						
Int	0.44 (0.43)	0.41 (0.55)	-0.02 (-0.10 to +0.07)	+0.03 (-0.20 to +0.25)	0.01	0.82
Cont	0.63 (0.60)	0.56 (0.63)	-0.03 (-0.10 to +0.04)			
<i>Motivation (range 0-4)</i>						
Int	2.49 (1.17)	2.26 (1.33)	-0.12 (-0.27 to +0.04)	-0.06 (-0.47 to +0.36)	-0.08	0.79
Cont	2.02 (1.00)	1.84 (1.06)	-0.09 (-0.22 to +0.04)			
<i>Goals (range 1-9)</i>						
Int	6.16 (1.70)	6.51 (1.73)	+0.17 (-0.13 to +0.48)	+0.42 (-0.45 to +1.28)	0.17	0.35
Cont	5.65 (2.42)	5.56 (2.59)	-0.03 (-0.31 to +0.24)			

Notes: Int = Intervention condition; Cont = Control condition; M mean; SD standard deviation; CI confidence interval; *d* = cohen's d effect size; Baseline and post-intervention means and standard deviations are raw data; Higher scores for each variable represent high levels of that variable; Mean change and between-group comparison are based on model parameters using generalized estimating equations (GEE); At T3, 121 questionnaires were received with baseline data missing for three participants. The GEE approach was used for between-group comparisons to account for baseline missing data

Table 3: Associations between Social Cognitive Determinants and Follow-up VPA

	B	95% CI	η^2	P
Post-intervention (12 weeks)				
Outcome Expectations	6.29	-46.07 to +58.65	0.00	0.81
Outcome Expectations-Physical	-20.14	-67.34 to +27.05	0.01	0.40
Outcome Expectations-Social	23.31	-10.69 to 57.31	0.02	0.18
Outcome Expectations-Self-Evaluative	-0.94	-39.67 to +37.78	0.00	0.96
Task Self-Efficacy	0.95	-0.21 to +2.11	0.02	0.11
Barrier Self-Efficacy	1.61	+0.57 to +2.65	0.08	0.003
Barriers	32.20	-12.67 to +77.07	0.02	0.16
Motivation	-21.19	-41.60 to -0.78	0.04	0.04
Goals	-9.67	-21.09 to +1.76	0.03	0.10
Follow-Up (6 months)				
Outcome Expectations	25.50	-21.86 to +72.86	0.01	0.29
Outcome Expectations-Physical	-9.50	-53.09 to +34.08	0.00	0.67
Outcome Expectations-Social	39.92	+8.99 to +70.86	0.06	0.01
Outcome Expectations-Self-Evaluative	13.01	-26.45 to +52.46	0.00	0.52
Task Self-Efficacy	1.48	+0.45 to +2.50	0.07	0.005
Barrier Self-Efficacy	1.72	+0.79 to +2.66	0.11	<0.001
Barriers	-12.16	-49.30 to +24.98	0.00	0.52
Motivation	5.20	-15.27 to +25.67	0.00	0.62
Goals	11.29	+1.45 to +21.13	0.05	0.03

Notes: Analyses were adjusted for baseline VPA and baseline of the social cognitive determinant

Figure 1. Path model testing follow-up task self-efficacy as a mediator of the effects of the exercise intervention on follow-up VPA. Model adjusted for baseline value of task self-efficacy and baseline VPA. Parentheses indicate the path from the exercise intervention to follow-up VPA without task self-efficacy in the model