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Abstract

Objective. To compare the effects of a group-mediated cognitive behavioral (GMCB) exercise and dietary (EX+D) intervention with those of standard-of-care (SC) treatment on select social cognitive outcomes in prostate cancer (PCa) patients undergoing androgen deprivation therapy (ADT). **Methods.** In the single-blind, 2-arm, randomized controlled Individualized Diet and Exercise Adherence–Pilot (IDEA-P) trial, 32 PCa patients (mean age = 66.2 years; SD = 7.8) undergoing ADT were randomly assigned to a 12-week EX+D intervention (n = 16) or SC treatment (n = 16). The exercise component of the personalized EX+D intervention integrated a combination of supervised resistance and aerobic exercise performed twice per week. The dietary component involved counseling and education to modify dietary intake and composition. Blinded assessments of social cognitive outcomes were obtained at baseline and 2-month and 3-month follow-up. **Results.** Intent-to-treat analysis of covariance demonstrated that the EX+D intervention resulted in significantly greater improvements in scheduling ($P < .05$), coping ($P < .01$), and exercise self-efficacy ($P < .05$), and satisfaction with function ($P < .01$) at 3 months relative to SC. Results of partial correlation analysis also demonstrated that select social cognitive outcomes were significantly correlated with primary trial outcomes of mobility performance and exercise participation ($P < .05$) at 3-month follow-up. **Conclusions:** The GMCB lifestyle intervention yielded more favorable improvements in relevant social cognitive outcomes relative to SC among PCa patients undergoing ADT. Additionally, more favorable social cognitive outcomes were associated with superior mobility performance and exercise participation following the independent maintenance phase of the EX+D intervention.

Keywords

oncology, physical activity, patient-reported outcomes, physical function

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Introduction

The therapeutic benefits of androgen deprivation therapy (ADT) in the treatment of prostate cancer (PCa) patients is well established.¹ As advances in PCa treatment develop, patients often experience many years of treatment on ADT. Unfortunately, despite the efficacy of androgen suppression for PCa control, the constellation of adverse effects accompanying prolonged ADT, such as loss of muscle mass and strength, increased fat mass, and reductions in bone mineral

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density, place PCa patients at heightened risk for sarcopenic obesity, functional decline, cardiovascular disease, and metabolic syndrome.²⁻⁹ As ADT is now becoming increasingly employed in the adjuvant and neoadjuvant treatment of PCa, it is critical to identify efficacious supportive care interventions that can offset the deleterious effects of ADT and attenuate the heightened chronic disease risk among PCa patients.^{2,5,9-17}

Emerging evidence demonstrates the benefits of lifestyle interventions for attenuating and/or reversing the well-documented adverse effects of ADT.¹⁰⁻¹³ Findings from multiple recent small-scale trials revealed that lifestyle interventions combining exercise and dietary intake components resulted in clinically meaningful improvements in mobility performance, muscular strength, and fat mass while concomitantly attenuating the loss of lean body mass shown to accompany ADT.¹³⁻¹⁷

Although these findings support the potential utility of integrating lifestyle EX+D interventions in the supportive care of PCa patients undergoing ADT, adoption and maintenance of regular exercise participation and change in dietary intake involve complex, multifaceted behavioral processes. Accordingly, insufficient motivation or incentive to adopt health behavioral change and lack of the self-regulatory skills necessary to successfully maintain desired changes in exercise participation and dietary intake can pose meaningful challenges to adherence that can, in turn, subsequently undermine the efficacy of implementing lifestyle interventions in the treatment of PCa patients.^{11,13}

Social cognitive models of behavior¹⁸⁻²⁰ provide a well-established theoretical framework for delineating the potential role of key self-regulatory and motivational factors involved in exercise and dietary behavior change that has consistently been implemented in the design and delivery of lifestyle interventions. Within the context of social cognitive theory, behavior-specific self-efficacy (SE) judgments, including mobility-related and self-regulatory SE beliefs, are identified as key aspects of one's agency to pursue goal-directed actions that are integral to successful adoption and maintenance of lifestyle behavior change.¹⁹⁻²¹ Outcome expectations, the anticipated outcomes that will result from engaging in a given behavior, partially determine one's decision to engage in behavior change efforts. Thus, outcome expectations also reflect an important agency aspect of social cognitive models of behavior serving as an incentive to engage in behaviors that one believes will yield positive outcomes, which may interact with one's SE and self-regulatory capacities to influence the behavior change process.²¹⁻²⁴ Contemporary findings from the behavioral weight management literature research consistently demonstrate that complex interactions among multiple social cognitive variables serve as potential mechanisms in exercise and dietary behavior change processes.²⁵⁻²⁸ Therefore, within social cognitive perspectives, the interplay between

SE beliefs, outcomes expectations, and self-regulatory processes is a relevant determinant of health behavior change, and ultimately contributes to the efficacy of lifestyle interventions. Within this conceptual context, SE beliefs may serve as direct determinants of exercise and dietary behavior or indirectly influence exercise and dietary intake through their interaction with other social cognitive constructs including one's self-regulatory abilities and relevant expectations regarding both the behavioral processes and desired outcomes resulting from volitional change in exercise and dietary behavior.^{16,21,29,30}

Although it is well established that implementing conceptual frameworks, such as social cognitive theory, to guide the design and delivery of EX+D interventions enhances the efficacy of these approaches,³¹⁻³⁷ few lifestyle interventions targeting PCa patients have been based on behavioral theory or targeted social cognitive factors associated with change in exercise participation and dietary intake.^{13,32} Indeed, the majority of prior lifestyle research in PCa patients implemented interventions that can be characterized as theory-informed rather than theory-based.^{13,16,32,34-37} Hence, determining the extent to which theory-driven EX+D interventions result in change in key social cognitive outcomes is important in both guiding the design and delivery of lifestyle weight management interventions and establishing the utility of integrating these approaches in the supportive care of PCa patients undergoing ADT.

In this regard, findings from analysis of the primary outcomes from our recently completed Individualized Diet and Exercise Adherence–Pilot (IDEA-P) trial demonstrate that an EX+D intervention, delivered using a group-mediated cognitive behavioral (GMCB) approach, yielded significant, clinically meaningful improvements in an array of outcomes relative to standard-of-care (SC) treatment in PCa patients on ADT.¹⁶ Additionally, the GMCB intervention, based on social cognitive theory¹⁸ and the group dynamics literature,^{38,39} has also recently produced meaningful adherence to exercise and dietary behavior change and also yielded significant improvements in a variety of clinically relevant outcomes for PCa patients in randomized trials targeting a variety of chronic disease patients at heightened risk of functional decline.^{40,41} A key component of this EX+D intervention is the use of the GMCB counseling approach to promote the development and practice of the key behavioral self-regulatory skills required to successfully plan, execute, and self-manage goal-directed EX+D behaviors, harness the social dynamics of small groups to incentivize and support motivation for behavior change, and personalize the EX+D prescription to each patient's individual capacity and preference to improve adoption, adherence, and intervention efficacy. Given the theoretical foundation of the IDEA-P trial provides a unique opportunity to evaluate the utility of this lifestyle intervention for promoting change in key social cognitive constructs that are associated with successful

Table 1. Select Baseline Patient Characteristics.

| Measure | Intervention Arms, n (%) | |
|------------------------------------|--------------------------|---------------|
| | EX+D | SC |
| Age, mean (SD) | 69.4 (9.0) | 64.5 (8.6) |
| Ethnicity | | |
| White | 12 (75) | 15 (93.8) |
| African American | 3 (18.8) | 0 (0) |
| Mixed | 0 (0) | 1 (6.2) |
| Not reported | 1 (6.2) | 0 (0) |
| Education | | |
| High school or less | 0 (0) | 0 (0) |
| More than high school | 14 (87.5) | 15 (93.8) |
| Income, US\$ | | |
| <\$15 000 | 0 (0) | 0 (0) |
| \$15 000-35 000 | 1 (6.3) | 2 (12.5) |
| \$35 000-50 000 | 3 (18.8) | 1 (6.3) |
| >\$50 000 | 11 (68.8) | 12 (75) |
| BMI, kg/m ² , mean (SD) | 28.5 (9.05) | 31.5 (6.23) |
| BMI classification | | |
| Underweight | 0 (0) | 0 (0) |
| Normal | 3 (18.8) | 0 (0) |
| Overweight/obese | 12 (75) | 16 (100) |
| Gleason, mean (SD) | 7.77 (1.0) | 7.64 (1.39) |
| Time on ADT (months), mean (SD) | 32.18 (27.28) | 15.31 (19.39) |
| MVPA (minutes), mean (SD) | 59.70 (92.67) | 57.70 (88.14) |

Abbreviations: EX+D, exercise and dietary; SC, standard of care; ADT, androgen deprivation therapy; MVPA, moderate-to-vigorous physical activity.

health behavior change and also to explore the relationship of these constructs with clinically relevant behavioral and functional outcomes in PCa patients undergoing ADT. Therefore, the primary objective of the present investigation is to conduct ancillary analysis of IDEA-P secondary outcomes to examine changes in select social cognitive outcomes following the EX+D and SC interventions. As noted previously, findings from the primary outcomes of the IDEA-P trial demonstrated that the lifestyle intervention yielded superior improvements in mobility performance and select measures of physical activity, exercise, and dietary intake relative to the SC.¹⁶ Consequently, a secondary objective is to explore the extent to which these social cognitive variables are related to exercise behavior and mobility performance. It was hypothesized that the EX+D intervention would result in greater improvements in social cognitive outcomes relative to SC and that more favorable social cognitive beliefs would be associated with superior exercise participation and mobility performance.

Methods

Participants

IDEA-P is a single-blind, 2-arm randomized controlled pilot trial. A total of 32 PCa patients (80% of originally

project accrual of 40 total patients) on ADT (mean age = 66.2 years [SD = 7.8]; 84% Caucasian, 16% African American) were recruited to participate in the trial. Select baseline characteristics of the sample are provided in Table 1. Based on recent recommendations for estimating sample size in pilot, randomized trials,⁴² the IDEA-P sample size was adequate to obtain effect size estimates necessary to accurately set parameters for a subsequent, optimally powered randomized controlled lifestyle intervention trial. Primary eligibility criteria included the following: (1) histologically defined diagnosis of PCa based on pathology reports and staging studies; (2) current ADT with a planned course of at least 3 months of continuous therapy; (3) <60 minutes of structured exercise participation per week during the past 6 months; (4) lack of poorly controlled medical conditions that precluded safe participation in an exercise program, such as uncontrolled coronary artery disease, hypertension, peripheral vascular disease, cerebral ischemia, congestive heart failure, chronic obstructive pulmonary disease, insulin-dependent diabetes, psychiatric disease, renal failure, liver failure, other active cancers, or anemia; and (5) consent to participate from the treating oncologist and primary care physician. The trial was approved by the Ohio State University Institutional Review Board (Protocol # 2012C0008), and all participants completed informed consent prior to participation.

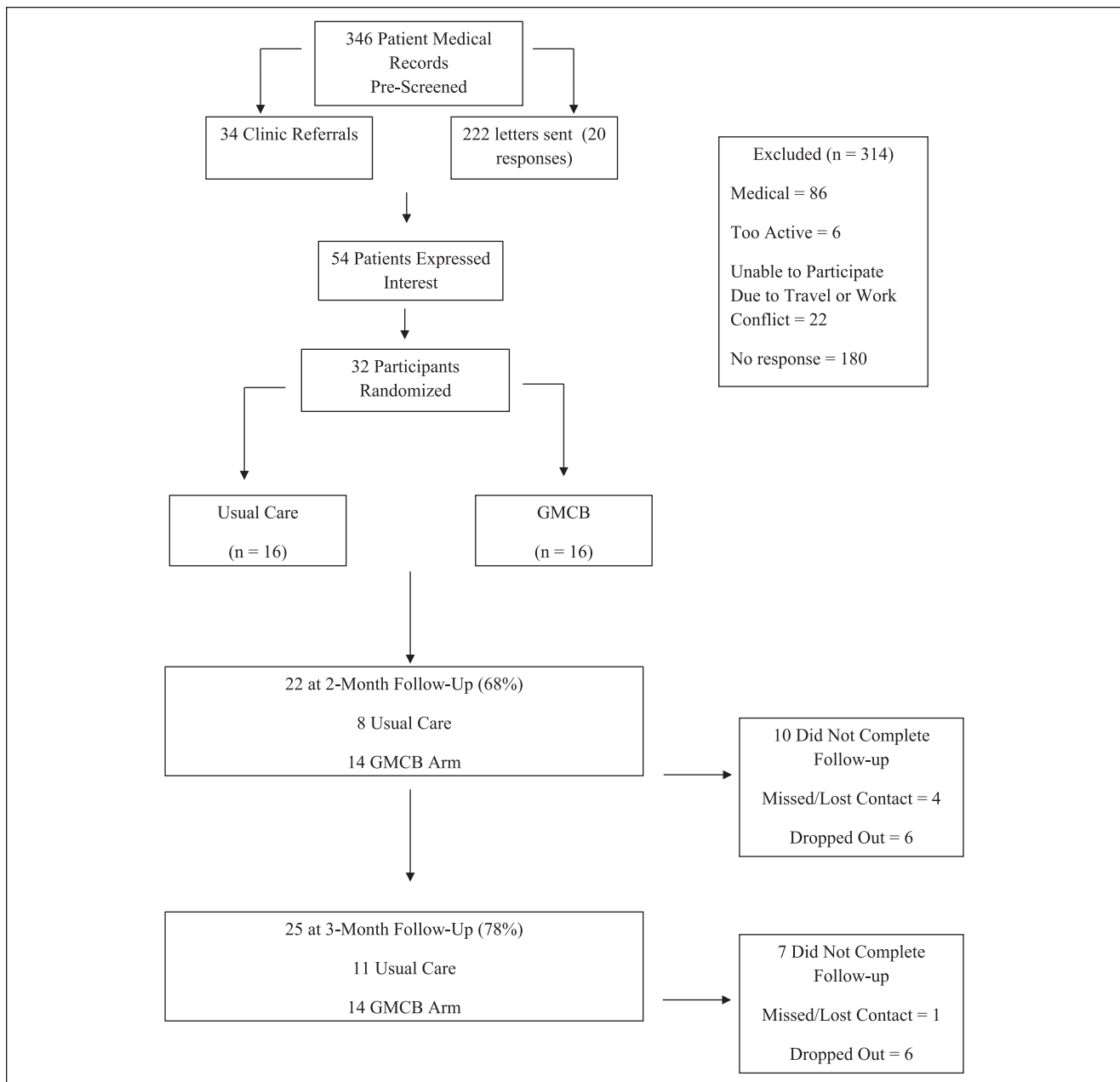


Figure 1. Consolidated Standards of Reporting Trials (CONSORT) diagram for the Individualized Diet and Exercise Adherence–Pilot (IDEA-P) trial.

Procedures

Detailed descriptions of the IDEA-P trial design and methods have been published previously.^{16,43} However, a thorough description of the trial procedures, interventions, and measures is also provided here. Volunteers interested in participating in the study were referred to study investigators from oncologists at the Genitourinary Oncology Clinics of the James Cancer Hospital at the Ohio State University. Men completed a telephone or in-clinic eligibility screening, and

those determined to be eligible were scheduled for the baseline assessment visit. The Consolidated Standards of Reporting Trials (CONSORT) diagram illustrating the recruitment and retention of PCa patients through the trial is summarized in Figure 1.

At the baseline screening visit, inclusion criteria were verified, institutional review board–approved informed consent and HIPAA forms were completed, and assessments of all trial outcomes, including all the social cognitive measures, were obtained. The 32 PCa patients who

participated in the trial were randomly assigned with equal probability to either the EX+D (n = 16) or SC (n = 16) treatment arms in a 1:1 ratio using a computer-generated randomization allocation sequence following the completion of the baseline screening visit. The computer-generated randomization allocation was sequentially numbered and sealed in opaque envelopes. The randomization allocation sequence was also concealed from the study staff responsible for conducting baseline assessments. At 2-month and 3-month follow-up visits, assessments of all outcomes were obtained using the same procedures by study staff blinded to participants' treatment group assignments.

Interventions

GMCB Exercise and Dietary Intervention. The EX+D intervention involved a multicomponent approach designed to facilitate exercise and dietary behavior change and promote adherence, independent of study staff, to these changes in lifestyle behavior across the 12-week intervention. The GMCB counseling component, based on social cognitive theory¹⁸ and the social dynamics literature,^{38,39} was integrated to facilitate the development, practice, and mastery of self-regulatory skills necessary to adopt and maintain change in exercise and dietary behavior. This approach is designed to create a supportive group learning environment in which patients use the group to facilitate the learning, development, and practice of self-regulatory skills, not only from the intervention facilitator but from the group members themselves. The GMCB approach to harnessing group dynamics to actively promote self-regulatory skill development is unique from traditional group interventions in which patients passively receive education and counseling from the intervention leader. The promotion of group identity, to provide a common motivational base, and exchange between group members facilitated by the intervention leader are structured to develop a consistent group focus on learning self-regulatory skills. Ultimately, this approach is structured to create a progressive, systematic group counseling effect that supports self-regulatory skill development for lifestyle behavior change.

Group-mediated cognitive behavioral counseling was delivered via small group (group size = 4-8 patients) sessions lasting 30 minutes in duration conducted immediately following center-based exercise sessions during months 1 to 2. Group sessions structure included the following: welcome/sharing of progress; presentation of topic of the day (physical activity/exercise-focused topics covered by BCF, the principal investigator; dietary/nutrition-focused covered by EG, the study's project's registered dietitian); facilitate group discussion; and summary/takeaways. The GMCB sessions were co-led by the principal investigator (BCF) and project registered dietitian (EG) who both have considerable prior experience in leading group and individualized

lifestyle counseling in research and applied contexts. Additionally, periodic fidelity checks (at least 1 per wave) were conducted to ensure the planned physical activity/exercise and dietary focused topics were addressed. In addition to the group sessions, participants also received 2 individualized phone-based dietary counseling sessions. The small group-mediated counseling sessions focused on development of group identity and social norms for activity, group problem solving, sharing of peer-initiated barrier solutions, and fostering social support. Additionally, consistent with the SE and agency aspect of social cognitive theory, counseling addresses a systematic group focus on the learning, development, and practice of self-regulatory skills including self-monitoring, goal setting, anticipating challenges and problem-solving barriers to exercise participation and healthier dietary intake/eating habits, reducing sedentary time, and action planning for increased physical activity, exercise, and healthier dietary intake were focal aspects of the GMCB approach. This approach uses the group as an agent of behavioral change, helping increase motivation and develop these behavioral self-regulatory skills to support increasing frequency of independent exercise and healthier dietary intake. A basic principle underlying these contacts and their sequencing is one of progressively weaning of participants from the dependency on staff and the group program toward independent self-regulation of exercise and dietary intake. This process was one of a phased increase in the ratio of personal responsibility in conjunction with a phased decrease in staff, group, and clinic dependency. More detailed descriptions of the GMCB intervention approach are provided in multiple prior publications,^{16,44,45} and the session content, topics, and behavior change techniques used within the lifestyle intervention are provided in the online supplemental materials accompanying this article.

The exercise component of the lifestyle intervention integrated 1-hour exercise sessions performed twice per week and involving a combination of resistance and aerobic exercise. The exercise prescription was personalized to each participant's exercise tolerance and gradually increased across the intervention to progress across the targeted prescription ranges. Resistance exercise involved performing 1 to 3 sets at each individual's 8 to 12 repetition maximum (8RM-12RM) at a rating of perceived exertion ranging from 3 (Moderate) to 6 (Hard) for 9 different exercises (leg extension, leg curl, chest press, lat pull-down, overhead press, triceps extension, bicep curl, calf raises, and abdominal crunch). A 1- to 2-minute rest interval was maintained between each set and exercise. The resistance exercise stimulus was personalized to each individual's abilities and exercise tolerance and capacity. Consequently, the targeted prescription and progression of load, volume, and volume load was implemented in a symptom-limited manner, guided by participant's functional capacity, exercise tolerance, and perceived exertion remaining in the target range.

Load progression was systematically implemented using the 2 for 2 approach by which when participants could successfully complete 2 additional repetitions on 2 consecutive sets with a given training load, the weight was increased for subsequent sets and/or training sessions.

The aerobic exercise stimulus consists of 10 to 20 minutes of exercise performed at a rating of perceived exertion ranging from 2 (Fairly Light) to 4 (Somewhat Hard) on the participant's choice of a treadmill, stationary cycle, or elliptical trainer. Participants were also encouraged to gradually increase independent, home-based exercise participation and purposeful activity and decrease sedentary time in order to progress toward accruing a total weekly volume of physical activity consistent with national guidelines for health and well-being (>150 minutes of moderate-vigorous physical activity).^{46,47}

The dietary component was designed to be consistent with the nutritional objectives recommended by the 2010 to 2015 Dietary Guidelines for Americans,⁴⁸ the American Heart Association/American College of Cardiology, and the World Cancer Research Fund/American Institute of Cancer Research (WCRF/AICR),^{49,50} and aimed to provide basic nutrition education/counseling to all participants, address contemporary topics in nutrition and cancer, and personalize guidance toward adopting changes in dietary intake characterized by shifts toward a diet rich in whole grains, vegetables, and fruits; limited consumption of processed high-fat, low-nutrient dense foods; reduced intake of red and processed meats; and overall caloric intake levels that promote achieving/maintaining a healthy body weight and avoiding weight gain. The GMCB counseling in the dietary component of the lifestyle intervention focused on harnessing the group dynamics to foster commitment, practice, and mastery of the self-regulatory skills and peer-initiated problem-solving approach to address dietary intake changes to portion control and dietary composition.

Standard of Care Intervention. Men randomized to the SC intervention received standard disease management education, as well as complementary literature describing the WCRF/AICR dietary and physical activity guidelines. To equate contact between treatment arms to levels consistent with similar contemporary lifestyle intervention trials,^{13,51} 20-minute phone contacts delivered by study staff focusing on routine aspects of PCa self-management were conducted biweekly with men in the control arm.

Measures

Self-Efficacy. Multiple measures were used to assess participants' relevant SE beliefs. The Exercise Self-Efficacy Scale (EXSE)⁵² assesses one's belief in the ability to successfully engage in incrementally more demanding volumes of

moderate intensity exercise. Internal consistency for EXSE was excellent in the present study ranging from 0.98 to 0.99. The Multidimensional Self-Efficacy for Exercise Scale (MSES) evaluates one's belief in their ability to successfully complete 3 behavioral subdomains of exercise-related SE, based on subscales for task (belief in the ability to complete the elemental aspects of exercise), coping (belief in the ability to complete exercise in the face of challenges), and scheduling SE (belief in the ability to schedule exercise in the face of challenges). Rodgers et al⁵³ have previously demonstrated evidence supporting the multidimensional factor structure, validity and reliability of this measure, and the internal consistency of the subscales was strong in the present study, ranging from 0.80 to 0.99. Mobility-Related Self-Efficacy (MRSE) assesses one's belief in their ability to successfully complete more challenging increments of walking during the 400-m walk task was measured using an 8-item scale constructed consistent with Bandura's recommendations involving hierarchically organized items assessing beliefs in successfully completing incrementally more challenging aspects of the walking behavior.⁴³ Prior research supports the construct, convergent, and divergent validity of the MRSE measure,^{54,55} and the internal consistency in the present study was excellent, ranging from 0.86 to 0.96. Additionally, each of these measures has been previously demonstrated to be sensitive to change in prior randomized controlled lifestyle interventions.^{21,30,43,44,51,56,57}

Satisfaction With Physical Function (SWF) and Appearance (SWA). The 9-item measure assessed patients' SWF and SWA on a 7-point scale ranging from -3 (Very Dissatisfied) to +3 (Very Satisfied). This measure has previously demonstrated appropriate psychometric properties,⁵⁸ had strong internal consistency in the present study ranging from 0.89 to 0.95, and has been used as an assessment of satisfaction and function/appearance-related outcome expectancies in prior lifestyle intervention trials in older adults.^{21,30,43,51}

Mobility Performance and Exercise Participation. Changes in the primary outcomes of mobility performance, assessed using the 400-m Walk Test, and objectively measured (LIFECORDER Plus accelerometer; Suzuken Kenz Inc Limited, Japan) and self-reported exercise participation (Godin Leisure-Time Exercise Questionnaire) in the IDEA-P trial have been reported previously with findings demonstrating that the lifestyle intervention resulted in superior improvements in these outcomes relative to SC treatment.¹⁶ Both measures have well-established validity and reliability and have been used in prior lifestyle intervention trials.^{21,30,43,51} The exercise and mobility measures were included in the present study to evaluate the extent to which the select social cognitive measures are related to these important primary outcomes in IDEA-P trial.

Statistical Analysis

The effects of the EX+D and SC interventions on changes in the social cognitive outcomes were analyzed using separate 2 (Treatment: EX+D and SC) \times 2 (Time: 2 months and 3 months) analysis of covariance (ANCOVA). Baseline-adjusted changes in each social cognitive measure were used as the outcomes with time on ADT (in months) and baseline values of each measure included in the models as covariates. ANCOVA analyses were conducted using the intention-to-treat principle with the last value carried forward approach used to account for missing data. Fisher's least significant difference post hoc tests were performed to determine the location of significant mean differences. Effect sizes (Cohen's d) and their accompanying confidence interval (CI) were calculated by taking the mean difference and dividing by the pooled standard deviation to determine the magnitude of differences observed for the adjusted means of each outcome. Finally, given the GMCB EX+D intervention was designed to promote independent maintenance of behavior change and mobility across the trial, partial correlation analyses controlling for time on ADT were conducted to examine the relationship between the social cognitive outcomes and mobility performance and exercise participation at the 3-month follow-up assessment.

Results

The CONSORT diagram summarizing flow of participants through the IDEA-P trial is provided in Figure 1. In the IDEA-P trial, there was 68% retention at 2-month follow-up (EX+D = 88%; SC control = 50%) and 78% retention at 3-month follow-up (EX+D = 88%; SC control = 69%). Collectively, 25 of 32 (78%) patients completed the baseline and at least 1 follow-up assessment. In the EX+D intervention, adherence to exercise sessions and dietary counseling sessions was 88% and 84%, respectively.

Self-Efficacy Outcomes

The unadjusted descriptive statistics for the SE outcomes are provided in Table 2. ANCOVA analysis of change in EXSE yielded a significant treatment main effect ($P < .05$). The EX+D intervention resulted in superior increases in EXSE at 2 months ($d = 0.61$; CI = -0.09 to 1.32) and 3 months ($d = 0.66$; CI = -0.04 to 1.38) relative to SC. However, results of the ANCOVA analysis of change in MRSE revealed no significant treatment main effect. Consequently, change in MRSE did not significantly differ between EX+D and SC at 2-month ($d = 0.27$; CI = -0.42 to 0.97) or 3-month ($d = 0.01$; CI = -0.70 to 0.68) follow-up.

ANCOVA analysis of change in the MSES coping SE subscale revealed significant treatment main effect ($P < .01$). The EX+D intervention resulted in greater increases

in coping SE at 2 months ($d = 0.71$; CI = 0.01 to 1.43) and 3 months ($d = 0.63$; CI = 0.24 to 1.71) relative to SC (see Figure 2). Similarly, ANCOVA analysis of change in the MSES scheduling SE subscale revealed significant treatment main effect ($P < .05$). The EX+D intervention resulted in greater increases in scheduling SE at 2 months ($d = 0.62$; CI = -0.09 to 1.32) and 3 months ($d = 0.62$; CI = 0.12 to 1.57) when compared with SC (see Figure 3). In contrast to the other MSES subscales, ANCOVA analysis of change in the task SE subscale revealed the treatment effect was nonsignificant ($P = .09$). Although this analysis did not reach conventional levels of significance, inspection of the effect sizes demonstrate that the EX+D intervention resulted in more favorable improvements in task SE at 2 months ($d = 0.44$; CI = -0.26 to 1.14) and 3 months ($d = 0.75$; CI = 0.03 to 1.47) relative to SC.

SWF and SWA

ANCOVA analysis of change in SWF yielded a significant treatment main effect ($P < .01$). The EX+D intervention resulted in greater increases in SWF at 2 months ($d = 0.60$; CI = 0.10 to 1.31) and 3 months ($d = 1.33$; CI = 0.57 to 2.10) relative to the SC intervention (see Figure 4). Results of the ANCOVA analysis of change in SWA revealed that the treatment main effect was nonsignificant. Although this analysis did not reach conventional levels of significance, inspection of the effect sizes demonstrate that the EX+D intervention resulted in more favorable improvements in SWA at 2 months ($d = 0.32$; CI = -0.38 to 1.01) and 3 months ($d = 0.63$; CI = -0.07 to 1.35) relative to SC. The unadjusted descriptive statistics for SWF and SWA are summarized in Table 2.

Correlation Analyses

Partial correlation analyses controlling for time on ADT were conducted to examine the relationships between the social cognitive outcomes and key trial outcomes of mobility performance and exercise participation at 3 months. Results revealed that coping SE ($r = -.52$; $P < .01$), scheduling SE ($r = -.37$; $P < .05$), and SWF ($r = -.55$; $P < .01$) were significantly correlated with improved mobility performance at 3 months. Additionally, coping SE ($r = .41$; $P < .05$) and scheduling SE ($r = .44$; $P < .01$) were significantly correlated with higher volume of objectively determined aerobic exercise and SWF ($r = .59$; $P < .01$) and SWA ($r = .58$; $P < .05$) were significantly correlated with higher volume of self-reported resistance exercise participation. Collectively, the partial correlation analyses suggest that social cognitive outcomes were associated with more favorable levels in exercise participation and mobility performance at the 3-month follow-up, which represents the

Table 2. Unadjusted Means (SD) for the Social Cognitive Outcomes.

| Variable | Intervention Arms | |
|--|-------------------|---------------|
| | EX+D | SC |
| Exercise self-efficacy | | |
| Baseline | 81.64 (19.33) | 80.41 (23.81) |
| 2 months | 88.13 (15.43) | 75.47 (33.17) |
| 3 months | 81.33 (24.12) | 63.67 (36.62) |
| Mobility-related self-efficacy | | |
| Baseline | 91.98 (22.59) | 89.79 (14.74) |
| 2 months | 97.40 (5.51) | 94.90 (8.11) |
| 3 months | 96.77 (8.46) | 96.04 (7.38) |
| Task self-efficacy | | |
| Baseline | 7.85 (2.03) | 7.85 (1.97) |
| 2 months | 8.19 (1.84) | 7.90 (1.98) |
| 3 months | 8.27 (1.72) | 7.40 (1.48) |
| Coping self-efficacy | | |
| Baseline | 6.38 (1.86) | 5.67 (2.23) |
| 2 months | 6.56 (2.09) | 5.42 (2.05) |
| 3 months | 7.15 (1.26) | 5.63 (2.18) |
| Scheduling self-efficacy | | |
| Baseline | 7.08 (2.65) | 6.96 (2.32) |
| 2 months | 7.60 (2.11) | 6.77 (2.60) |
| 3 months | 7.83 (2.21) | 6.31 (2.50) |
| Satisfaction with physical function | | |
| Baseline | 1.25 (1.13) | 0.54 (1.53) |
| 2 months | 1.92 (0.55) | 1.03 (1.28) |
| 3 months | 2.04 (0.50) | 0.85 (1.02) |
| Satisfaction with physical appearance | | |
| Baseline | 0.58 (1.31) | -0.48 (1.21) |
| 2 months | 1.25 (1.25) | 0.17 (1.17) |
| 3 months | 1.15 (1.22) | -0.27 (1.14) |

Abbreviations: EX+D, exercise and dietary; SC, standard of care.

independent maintenance phase of behavior change in the IDEA-P trial.

Discussion

Findings from the IDEA-P trial revealed that a GMCB lifestyle intervention integrating personalized exercise and dietary prescription with group-mediated self-regulatory skills counseling to promote independent, self-directed adherence to the desired behavior changes resulted in significant improvements in social cognitive outcomes when compared with SC treatment. Additionally, select social cognitive outcomes were associated with more favorable levels of exercise participation and mobility performance following the independent maintenance phase of the trial at 3-month follow-up. Consequently, the improvements in social cognitive outcomes accompanying the EX+D intervention in IDEA-P are consistent with findings observed in

prior GMCB lifestyle intervention trials and extend these findings to PCa patients undergoing ADT.^{21,30,51}

It is well established within social cognitive models of motivation that SE beliefs are integral throughout successful behavior change processes.^{18,20} However, the extent to which specific SE beliefs serve as determinants of exercise participation and dietary intake may vary meaningfully during volitional behavior change processes, in part, due to the unique barriers and challenges individuals experience across the motivation, volitional action, and maintenance phases accompanying health behavior change.^{20,21,25-27} Emerging evidence addressing the social cognitive mechanisms of health behavior suggest change in exercise and dietary behavior are determined through a constellation of complex interaction sequences among SE and self-regulatory processes.²⁵⁻²⁸ An integral feature of the EX+D intervention in the IDEA-P trial was integration of a group-mediated counseling component designed to enhance SE and promote

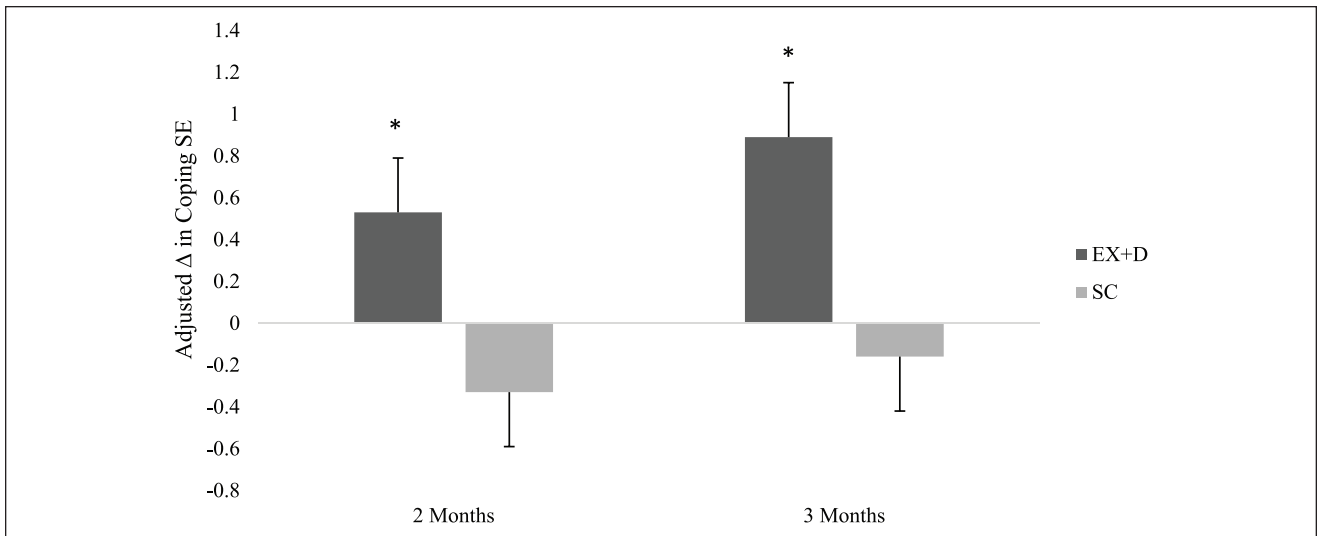


Figure 2. Adjusted change in coping self-efficacy.

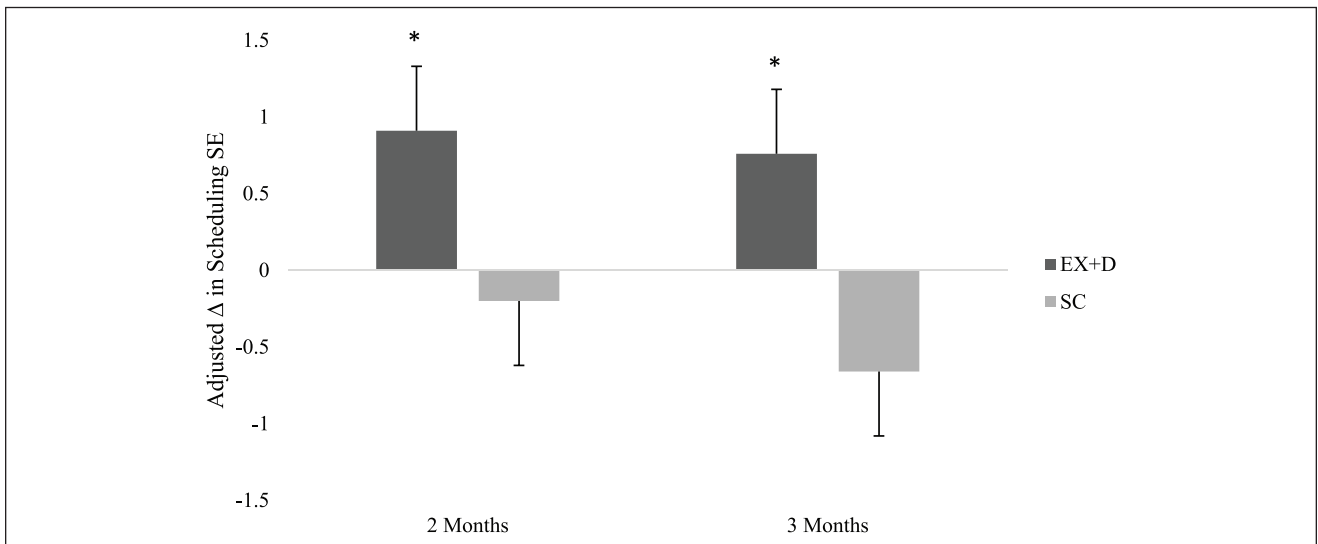


Figure 3. Adjusted change in scheduling self-efficacy.

the development, practice, and mastery of behavioral self-regulatory abilities required to facilitate independent maintenance of desired exercise and dietary behavior changes.^{16,41,43,44} Consistent with this objective, the GMCB intervention yielded meaningful improvements in exercise participation and self-reported dietary intake.⁴⁵ Therefore, the comparable improvements in task, scheduling, and coping SE observed following both the supervised adoption and independence maintenance phases of the GMCB lifestyle intervention are promising findings that could have meaningful implications for promoting the exercise and dietary behavior changes in the supportive care of PCa patients. For example, improvements in task-related SE may be

particularly important in motivating one's initial efforts to set goals and adopt changes in exercise participation and dietary intake.^{21,27,28} Similarly, more favorable levels of scheduling and coping SE are linked with superior action control and planning ability that subsequently may facilitate enhanced ability to translate goals into desired changes in exercise and dietary behavior.^{20,26,28} In light of these findings and the relevance of self-regulation in promoting successful adherence to exercise and dietary behavior, delineating the patterns of change in key SE outcomes within the context of longer duration lifestyle interventions among PCa patients undergoing ADT warrants further investigation. It is important to acknowledge that the significant treatment difference

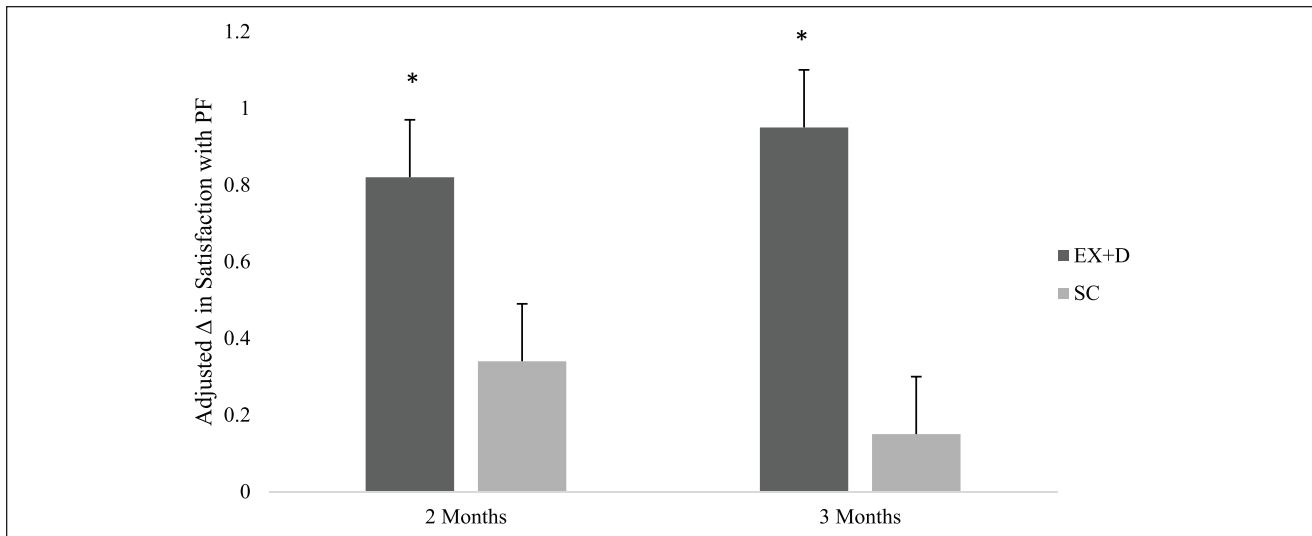


Figure 4. Adjusted change in satisfaction with physical function.

in exercise SE observed at 3 months was primarily driven by modest change in the lifestyle intervention combined with a meaningful decline with SC treatment. The factors that contributed to this trajectory of change in exercise SE cannot be determined from the present data. However, the exercise SE measure assesses efficacy for engaging in incrementally more demanding volumes of moderate intensity exercise across an incrementally increasing number of weeks. As noted in prior analysis of the exercise outcomes from the primary outcome article,¹⁶ the observed increases in objectively determined aerobic exercise were not maintained and returned to baseline at 3-month follow-up. Therefore, that pattern of change observed for exercise SE within the lifestyle intervention arm closely aligns with the trajectory of change in aerobic exercise, and this may account, in part, for the modest change in exercise SE observed at 3 months.

As prolonged ADT consistently results in functional decline,²⁻⁹ positive outcomes expectancies, such as anticipation that lifestyle changes will yield meaningful improvements in physical function, may be integral to PCa patients' incentive to adopt and maintain changes in exercise participation and dietary intake. Accordingly, the observed improvement in SWF, a well-established measure of satisfaction and functional outcome expectations, is a novel finding that may have important behavioral and clinical implications for the utility of EX+D interventions in preserving physical function and mobility among PCa patients undergoing ADT. SWF is a key social cognitive construct that has previously been shown to serve as an independent mediator of the effects of lifestyle interventions on physical function among older adults.^{21,56} It is also notable that the observed improvements in SE beliefs and SWF are conceptually proposed to have a synergistic effect that may contribute to enhanced exercise behavior and physical

function.^{21,29,30,51,56} Taken collectively, the favorable changes in SE and outcome expectations observed in the IDEA-P trial support the position that the GMCB EX+D intervention results in meaningful improvements in social cognitive outcomes that are vital to promoting exercise and dietary behavior change and preserving physical function. The present results are among the first to extend these findings to PCa patients undergoing ADT.

A secondary purpose of the present investigation was to explore the extent to which the social cognitive outcomes were associated with the primary trial outcomes of mobility performance and exercise participation. Findings of the partial correlation analyses revealed multiple significant relationships between the social cognitive, mobility performance, and exercise outcomes that are relevant for guiding the design and delivery of future lifestyle interventions for PCa patients. These findings demonstrate that more favorable levels of exercise self-regulatory beliefs, shown to be predictive of successful behavioral action planning and control, are linked with superior exercise participation and physical function performance. Similarly, function-related outcome expectancies, which are proposed to serve as a key incentive to adopting and sustaining behavior change, were also associated with more favorable amounts of exercise participation and mobility performance. These findings are consistent with conceptual predictions of social cognitive models and further underscore the importance that promoting systematic development and mastery of self-regulatory skills within lifestyle interventions may have in the supportive care of PCa patients undergoing ADT. Nonetheless, while the present findings suggest meaningful associations between relevant social cognitive, behavioral, and mobility outcomes, the role these social cognitive and self-regulatory factors may have in determining adherence to health behavior change or enhanced

mobility performance in PCa patients has yet to be systematically investigated. In this regard, there is mounting interest in delineating the extent to which interactions between key social cognitive constructs may serve as psychological mechanisms of change in exercise and dietary behavior and clinically relevant outcomes among PCa patient undergoing ADT, and these relationship warrant future inquiry relationships in lifestyle interventions targeting PCa patients.^{13,16}

Although the present findings are promising and contribute to a more comprehensive understanding of the effect of lifestyle interventions on social cognitive outcomes among PCa patients, there are select limitations that should be considered when interpreting the results. For example, this is a single-center pilot trial with a sample size that did not provide optimal statistical power to detect differences in all outcomes or allow for analysis to explore the extent potential mechanistic sequences among the social cognitive, behavioral, and mobility outcomes accompanying the EX+D intervention.¹⁶ While an intention-to-treat analysis was conducted, the last value carried forward approach has well-established limitations and is a conservative approach to the imputation of missing data. However, given the small sample size, amount of missing data, the assumptions regarding the random nature of the missing data, and the analytic approach used in the present trial, the gain in accuracy of alternative, less biased multiple imputation methods are likely to yield incremental gains in accuracy of the imputed missing values. Consequently, future larger scale trials incorporating valid, more sophisticated maximum likelihood imputation methods are warranted. It is also important to acknowledge that while the EX+D intervention yielded significant improvements in multiple SE outcomes, in contrast to prior findings, no meaningful changes in mobility-related SE accompanied the EX+D intervention in IDEA-P.^{21,30,51,56} Although the mechanisms underlying the absence of change in mobility-related efficacy beliefs are unclear, it is possible that the relatively high baseline values observed may have attenuated the opportunity to capture significant improvements in mobility-related SE in the present study. It should also be noted that the SE measures included in the present trial focused exclusively on physical activity/exercise. Accordingly, it is particularly important that future lifestyle intervention trials targeting PC patients expanded the assessment approach to include measures of dietary-related social cognitions. Finally, since IDEA-P was designed to compare the effects of an EX+D intervention with those of SC treatment, future comparative efficacy trials examining the benefits of EX+D with other active treatment interventions on social cognitive outcomes are warranted.

Conclusions

In summary, the result of the IDEA-P trial demonstrated that a lifestyle EX+D intervention integrating personalized exercise and dietary intake prescription and GMCB

self-regulatory counseling resulted in meaningful improvements in social cognitive outcomes that were related to more favorable levels of exercise participation and mobility performance in PCa patients undergoing ADT. These findings underscore the potentially synergistic benefits of lifestyle interventions integrating personalized exercise and dietary prescription and group-mediated self-regulatory skills among PCa patients undergoing ADT. Additional inquiry designed to replicate and extend the present findings through large-scale randomized controlled lifestyle intervention trials are among the future directions required to determine the efficacy and translational capacity of the GMCB lifestyle intervention in the supportive care of PCa patients undergoing ADT.

Declaration of Conflicting Interests

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Trial Registration

NCT02050906 Registered; January 24, 2014.

Ethical Approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed Consent

Informed consent was obtained from all individual participants included in the study.

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Supplemental Material

Supplemental material for this article is available online.

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