Social Cognitive Constructs did not mediate the BEAT Cancer Intervention Effects on Objective Physical Activity Behavior based on Multivariable Path Analysis

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Abstract

Background—Most breast cancer survivors do not meet physical activity recommendations. Understanding mediators of physical activity behavior change can improve interventions designed to increase physical activity in this at-risk population.

Purpose—Study aims were to determine the 3-month BEAT Cancer behavior change intervention effects on social cognitive theory constructs and the mediating role of any changes on the increase in accelerometer-measured physical activity previously reported.

Methods—Post-treatment breast cancer survivors (N=222) were randomized to BEAT Cancer or usual care. Assessments occurred at baseline, 3 months (M3), and 6 months (M6). Adjusted linear mixed model analysis of variance determined intervention effects on walking self-efficacy, outcome expectations, goal setting, and perceived barriers interference at M3. Path analysis determined mediation of intervention effects on physical activity at M6 by changes in social cognitive constructs during the intervention (i.e., baseline to M3).

Results—BEAT Cancer significantly improved self-efficacy, goals, negative outcome expectations, and barriers. Total path analysis model explained 24% of the variance in M6 physical activity. There were significant paths from randomized intervention group to self-efficacy ($\beta = .15$, $p < .05$) and barriers ($\beta = −.22$, $p < .01$). Barriers demonstrated a borderline significant association with M6 physical activity ($\beta = −.24$, $p = .05$). No statistically significant indirect effects were found.

Conclusions—Although BEAT Cancer significantly improved social cognitive constructs, no significant indirect effects on physical activity improvements 3 months post-intervention were observed (NCT00929617).

Keywords

Oncology; Compliance; Mechanism; Health promotion; Social cognitive theory

Introduction

Regular physical activity after breast cancer diagnosis can improve recovery and reduce risk of cancer and all-cause mortality [1, 2]. Moreover, breast cancer survivors are more likely to die from a chronic medical condition such as cardiovascular disease rather than breast cancer [3], a comorbidity risk exacerbated by cancer treatment-related increases in body weight and reductions in physical activity [4]. Given that only 37% of breast cancer survivors meet the current recommendations to engage in at least 150 weekly minutes of moderate intensity physical activity [5], helping breast cancer survivors adopt and maintain regular physical activity is a significant clinical and health behavior problem. To that end, efforts to better understand mechanisms of physical activity behavior change are needed. This is optimally done in randomized controlled trials due to the required temporal sequence, yet such studies have rarely reported mechanisms of observed behavior change for any cancer type [6].

For prior research not limited to cancer survivors, social cognitive factors accounted for 31% of the variance in physical activity [7]. Also, interventions infrequently change theoretical mediators and fewer still have tested potential mediating relationships [8, 9]. Only 4 of the 107 theory-based health behavior interventions reviewed by Prestwich et al. [9] reported statistically significant mediation of intervention effects and only 3 were able to make suggestions regarding theory refinement [9]. Clearly, further research is needed.

Our physical activity behavior change intervention [Better Exercise Adherence after Treatment for Cancer (BEAT Cancer)] has proven efficacious among breast cancer survivors, eliciting significant improvements in physical activity behavior immediately post-intervention and 3 months later (i.e., at 6 months) [10]. The BEAT Cancer intervention was

designed using social cognitive theory which is based on dynamic interactions among multiple behavioral, personal, and environmental factors [11, 12]. The present study had two objectives. The first was to compare the effects of BEAT Cancer with usual care on self-efficacy, outcome expectations, goal setting, and perceived barriers interference immediately post-intervention (i.e., month 3). The second objective was to examine whether these effects mediated the previously reported improvements in objectively-measured physical activity behavior change resulting from the intervention 3 months post-intervention (i.e., month 6) [10, 12]. We hypothesized that BEAT Cancer, when compared with usual care, would result in significant improvements in self-efficacy, outcome expectations, goal setting, and perceived barriers interference. We also hypothesized that the effect of BEAT Cancer on physical activity at month 6 would be mediated by changes in the social cognitive theory constructs from baseline to month 3.

Methods

Setting, participants, and study design

This multicenter randomized controlled trial has been previously described [12]. In brief, participants were enrolled at three U.S. academic sites using the following inclusion criteria: 1) adult women up to age 70, 2) history of stage IIIA breast cancer no longer on primary cancer treatment, 3) English speaking, 4) received medical clearance for participation, and 5) engaging in 30 minutes of vigorous or 60 minutes moderate intensity physical activity on average per week over the past 6 months. Exclusion criteria were as follows: 1) dementia, 2) disorders preventing full participation in all intervention activities, 3) physical activity contraindicated, 4) recurrent or metastatic breast cancer, 5) unable to ambulate, 6) surgery or lengthy travel outside of local area anticipated during intervention period, and 7) participating in another exercise trial. Enrolled participants were randomized (in blocks of 4 within each recruiting site) to receive the BEAT Cancer intervention or usual care. Outcomes were assessed at baseline (prior to randomization), immediately post-intervention (3 months), and 3 months post-intervention (6 months).

Interventions

The 3-month *Better Exercise Adherence after Treatment for Cancer (BEAT Cancer) physical activity behavior change intervention*, previously described in detail [12], included 12 supervised exercise sessions tapered to unsupervised exercise (e.g., home-base), 6 discussion group sessions, and 3 biweekly face-to-face update counseling sessions (once supervised sessions were completed mid-intervention). Self-efficacy was targeted in the supervised exercise sessions (setting realistic goals, reviewing progress toward goal, and facilitating successful progress), update counseling sessions (facilitated increased awareness of successful achievement of exercise goals), exercising on their own (increased awareness of being able to meet exercise goals), and discussion group sessions (review of progress and watching other breast cancer survivors succeed). Outcome expectations were addressed during the exercise sessions (personal benefits reviewed, fears about increased blood pressure or injury addressed, etc.), update counseling sessions (personal benefits), and group sessions (e.g., listed and discussed benefits, asked participants to consider benefits of most importance to them personally when designing behavioral modification plan, journaling

benefits experienced, etc.). Goal setting was an integral part of the exercise log, including review of goals at every exercise, counseling, and discussion group session. Strategies for overcoming exercise barriers were discussed during each supervised exercise session and update counseling session with a special emphasis placed on dealing with barriers during the third discussion group session and the process of creating a personal behavioral modification plan. Both the BEAT Cancer and usual care participants received publically available print materials from the American Cancer Society describing physical activity recommendations for cancer survivors [10, 12].

Measures

Demographic and medical variables were self-reported. Weekly minutes of moderate intensity physical activity was measured by 7-day waist-worn MTI/ActiGraph accelerometer monitoring (GT1M and GT3X models; protocol previously published) [10, 12]. Weekly minutes of vigorous activity (cut point 5,725) were doubled before adding to minutes of moderate activity (cut point 1,952 – 5,724) [13]. A walking task self-efficacy scale assessed confidence in ability to walk at a moderately fast pace for increasing time periods ranging from 5 to 30 minutes in 5 minute increments [14]. Cronbach's alpha in our sample was 0.97. Likert scales for the self-efficacy measure ranged from 0% (not at all confident) to 100% (extremely confident) with score calculated as a mean of the responses. We tested task self-efficacy (confidence in ability to physically perform a behavior) because it may be a stronger predictor of physical activity in cancer and other chronic disease populations when compared to barriers self-efficacy (confidence in ability to overcome barriers) [15–19]. Outcome expectations were assessed with 17 items listing 14 potential exercise benefits (e.g., less depressed) and 3 potential risks (e.g., more joint pain) [20]. Participants were asked to rank their agreement with the statement that exercise would result in the benefit or risk (5-point Likert scale of 1 (*strongly disagree*) to 5 (*strongly agree*)). The items related to benefits were summed for positive outcome expectations with risk items summed for negative outcome expectations [20]. Cronbach's alphas in our sample were .79 (positive outcome expectations) and .70 (negative outcome expectations). Goal setting was assessed by asking participants to indicate their exercise goal for the next 3 months on a Likert type scale (i.e., 0 = *do not have a specific exercise goal*1 = *not exercise*2 = *exercise 1 to 2 days a week for 30 or more minutes a day*3 = *exercise 3 to 4 days a week for 30 or more minutes a day*4 = *exercise 5 to 6 days a week for 30 or more minutes a day*5 = *exercise 7 days a week for 30 or more minutes a day*) [21]. A perceived barriers interference scale [22, 23] asked participants to indicate how often 21 different barriers interfered with exercise on a 5-point Likert scale (1 = *never* to 5 = *very often*). Responses were summed for the perceived barriers interference score. Cronbach's alpha in our sample was 0.84.

Data analytic strategy

To determine the intervention effects on the social cognitive theory constructs at month 3, adjusted linear mixed model analysis of variance incorporating an unstructured covariance matrix was carried out using SAS® statistical software (Cary, NC). Two-sided p value < 0.05 was used to determine statistical significance. Analyses were adjusted for previously identified covariates (i.e., baseline value of the outcome, study site due to stratification before randomization, hormonal therapy (none versus 1 year versus > 1 year), breast

cancer stage, history of chemotherapy, history of radiation, comorbidities, and marital status) [10].

To test the hypothesized path model, data were analyzed using *Mplus 6.0* 24] with a full information maximum likelihood estimator (FIML) [25–27]. Preliminary analyses [28] of the data confirmed our assumption that our data were missing completely at random [χ^2 = 252.76 (229), p = .14] and thereby justified our use of FIML estimation. Goodness of fit tests included the chi-square statistic, Root Mean Square Error of Approximation (RMSEA), Comparative Fit Index (CFI), and Standardized Root Mean Square Residual (SRMR). Chi square p values at or above .05, RMSEA below .08, CFI above .95, and SRMR below .08 are indicative of good model-data fit [29]. We tested a path model that hypothesized the effects of BEAT Cancer on physical activity at six months would be mediated by changes in social cognitive constructs across the three month intervention (baseline to month 3; hypothesized mediating effects were tested in a parallel fashion). Residualized change scores were calculated for each of the social cognitive constructs used in the path model. Mediation effects were tested using bootstrapping procedures and indirect effects were based upon 10,000 sample draws. The model was tested using all variables in manifest form. Consistent with previous analyses [10], study site, cancer stage, history of chemotherapy and radiation, comorbidities, hormonal therapy, marital status, and baseline physical activity were included as covariates associated with physical activity at 6 months.

Results

As previously described (including published CONSORT flow sheet), 222 participants were randomized with 97% retained at 3 months (96% in BEAT Cancer; 98% in usual care) and 96% retained at 6 months (95% BEAT Cancer; 96% usual care) [10]. Adherence was 98% for supervised exercise sessions, 96% for update sessions, and 91% for group sessions [10]. Mean participant age was 54.4 ± 8.5 and education was 15.5 ± 2.6 years. The majority (83.8%) were White and 71.2% married or living with significant other. For breast cancer stage, 11.3% had DCIS, 42.9% had stage I, 35.1% had stage II, and 11.7% had stage III. Mean months since diagnosis was 54.0 ± 54.5 with 57.7% reporting history of chemotherapy and 69% reporting history of radiation therapy. About half (51.3%) were not currently on hormonal therapy while 23.9% had been taking hormonal therapy for 1 year and 24.8% for > 1 year [10].

There were modest increases in self-efficacy and goals across the three month intervention and reductions in barriers and negative outcome expectations (Table 1). Table 2 shows correlations among these variables (change from baseline to 3 months), group and physical activity at 6 months. Given the lack of intervention effect on positive outcome expectations, the mediation model did not include this construct. The hypothesized model provided an excellent fit to the data [χ^2 = 29.60 (29), p = .44, CFI = .99, RMSEA = .01 (90% CI = .00 to .06), SRMR=.03]. There was a significant path from randomized intervention group to self-efficacy (β = .15, p < .05) and barriers (β = −.22, p <.01) but not to negative outcome expectations (β = .03, p = .71) or goals (β = .11, p = .11). There was a borderline significant effect of reductions in barriers being associated with greater physical activity at six months (β = − .24, p = .05). Relative to the covariates, having a lower breast cancer stage (β = −.20,

$p = .02$) and higher baseline physical activity ($\beta = .37$, $p = .002$) were associated with more physical activity at six months. The tests of the indirect effects of the intervention on physical activity at 6 months through social cognitive variables were all nonsignificant. The indirect effect of BEAT Cancer on physical activity at 6 months through reductions in barriers was the strongest indirect effect ($\beta = .05$, $p = .11$). The total model explained 24% of the variance in M6 physical activity.

Discussion

BEAT Cancer led to increased self-efficacy and decreased barriers with a decrease in barriers directly effecting physical activity at 6 months. No statistically significant indirect effects were noted for the tested theory constructs. With regard to scientific replicability, the model predicted 24% of the variance in physical activity which is similar to a recent meta-analysis reporting that social cognitive theory predicted 31% of physical activity [7]. Also, barriers mediated BEAT Cancer effect on behavior when simple mediation models were run for the constructs individually in this sample (data not shown) and during pilot testing [30], yet the mediation effect is attenuated when tested with multivariable mediation path analysis. The lack of mediation by self-efficacy in our study is similar to that reported by Vallance et al. [31] in breast cancer survivors and during pilot testing of the intervention [30].

The hypothesized non-significant effects warrant discussion. Although it is possible for mediation to be suppressed when an intervention improves some social cognitive theory constructs while worsening others [32], this was not the case for the constructs included in our model. It is more likely that these pathways are not sufficiently strong for detection with our sample size given that significant indirect effects by social cognitive theory constructs are not frequently reported and large samples sizes may be required for detecting small mediation effect sizes [7, 32]. Also, the lack of goal setting effects is possibly due to measurement error caused by using a scale that assessed whether the participant had a goal rather than assessing the goal setting process. Moreover, there are likely other constructs (not tested here) that account for the behavior change (e.g., social support and enjoyment) or our model may have failed to capture factors that may mediate the effects of the constructs on behavior occurring between month 3 and 6 (e.g., recovery self-efficacy related to resuming physical activity after relapse [33]). Further research is needed to better understand the role of social cognitive constructs within multivariate models.

This is one of only a few randomized controlled trials in cancer survivors testing theoretically-based mediation of intervention effects on physical activity and the first to do so using an objective physical activity measure and social cognitive theory. Our study strengths also include its excellent retention and adherence rates, use of bootstrapping methods [32], and the examination of the temporal relationship between mediator change from baseline to 3 months and physical activity measured at 6 months. Importantly, the absence of several of these characteristics was identified by a recent meta-analysis as a serious knowledge gap in the field [6].

Our use of a multivariable mediation model is a strength. Although complex and infrequently reported for cancer survivorship physical activity behavior change interventions, such an approach allows testing of mediation effects independent of other mediators and more closely approximates the true effect of interventions because multiple mediators are usually present [32, 34]. Testing moderators of mediation effects, reporting mediation effect estimates in the units of the outcome measure, and measuring the mediators/outcomes at the point of theorized change (rather than points of convenience) would advance the field as the use of such models increases [32, 34].

It is recommended that action and conceptual theories be used to apply mediation results to intervention refinement. Our multivariable model indicates that the intervention changed self-efficacy and barriers (action theory test) while the only promising conceptual theory test was the borderline relationship between barriers and physical activity at 6 months [32]. This suggests several strategies for improving intervention and future trial design. First, from an action theory standpoint, including qualitative data (e.g., as part of a mixed methods approach) may be useful in better understanding the specific intervention components responsible for the changes in self-efficacy and barriers [34]. This should be planned before trial initiation and can then be used to enhance intervention focus on active components while potentially improving dissemination and implementation through cost-effective intervention refinement and adaptation. Similarly, mixed methods data may be useful for elucidating the reasons for the association (or lack thereof) between the social cognitive theory construct and physical activity (i.e., why our conceptual theory was not supported in the model) [34].

The complex interrelationships among the social cognitive constructs, intervention, and behavior over time warrant continued research. Studies should carefully choose construct measures (e.g., alternate goal setting scale), collect longitudinal data, apply multivariable mediation modeling, and test replicability in populations underrepresented in our sample (e.g., non-White, less educated, etc.). Furthermore, future research should determine reciprocal relationships among constructs, identify intermediary factors linking constructs with behavior, test moderators of mediation effects, and refine the theoretical paradigms to better reflect the mediators most responsible for intervention effects. Such research will advance our ability to increase physical activity among breast cancer survivors and, in so doing, increase the number of breast cancer survivors experiencing physical activity benefits and reduced disease risk.

Acknowledgments

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Table 1

Effects of the BEAT Cancer intervention on self-efficacy, outcome expectations, goal setting, and perceived barriers interference immediately post-intervention (i.e., 3 months)

	Unadjusted means		Adjusted[a] between-group differences
			Estimated least square mean with (95% CI[b]); *p* value
Outcome	Baseline mean (SD[c])	Month 3 mean (SD)	BEAT Cancer vs usual care at month 3 (post-intervention)
Walking self-efficacy			19.5 (13.4 – 25.6); <.001
Intervention	72.4 (25.7)	86.0 (22.2)	
Usual care	70.4 (25.1)	66.0 (30.6)	
Positive outcome expectations			1.2 (−0.3 – 2.7); .12
Intervention	57.3 (6.0)	57.1 (6.9)	
Usual care	58.2 (6.0)	56.7 (5.9)	
Negative outcome expectations			−0.9 (−1.5 – −0.3); .004
Intervention	8.1 (2.7)	7.2 (2.4)	
Usual care	7.9 (2.7)	7.8 (2.8)	
Exercise goal for the next 3 months			0.8 (0.5 – 1.0); <.001
Intervention	2.9 (1.1)	3.6 (0.7)	
Usual care	2.8 (1.2)	2.9 (1.1)	
Perceived barriers interference			−12.0 (−15.2 – −8.9); <.001
Intervention	60.5 (12.5)	44.6 (13.0)	
Usual care	58.8 (12.2)	55.4 (12.9)	

[a]Adjusted for baseline value, study site, breast cancer stage, history of chemotherapy, history of radiation therapy, current hormonal therapy, comorbidities, and marital status

[b]Confidence intervals

[c]Standard deviation

Table 2

Correlations among moderate intensity accelerometer-measured physical activity at 6 months, changes in social cognitive variables across the 3-month intervention, and treatment conditions

	1	2	3	4	5	6
1. Moderate intensity physical activity	-					
2. Self-efficacy	.13	-				
3. Negative outcomes expectations	−.01	−.13	-			
4. Perceived barriers interference	−.09	−.27	.32	-		
5. Goals	.07	.29	.03	−.15	-	
6. Study group allocation	.11	.38	−.14	−.45	.30	-