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Effects of the BEAT Cancer physical activity behavior change intervention on physical activity, aerobic fitness, and quality of life in breast cancer survivors: a multicenter randomized controlled trial

Laura Q. Rogers,

Department of Nutrition Sciences, University of Alabama at Birmingham, Webb 222, 1720 2nd Avenue South, Birmingham, AL 35294-3360

Kerry S. Courneya,

Faculty of Physical Education and Recreation, University of Alberta, Edmonton, AB, Canada

Philip M. Anton,

Department of Kinesiology, Southern Illinois University Carbondale, Carbondale, IL, USA

Patricia Hopkins-Price,

Department of Medicine, Southern Illinois University School of Medicine, Springfield, IL, USA

Steven Verhulst,

Statistics and Research Informatics Core, Center for Clinical Research, Southern Illinois University School of Medicine, Springfield, IL, USA

Sandra K. Vicari,

Department of Psychiatry, Southern Illinois University School of Medicine, Springfield, IL, USA

Randall S. Robbs,

Statistics and Research Informatics Core, Center for Clinical Research, Southern Illinois University School of Medicine, Springfield, IL, USA

Robert Mocharnuk, and

Department of Medicine, Southern Illinois University School of Medicine, Springfield, IL, USA

Edward McAuley

Department of Kinesiology and Community Health, University of Illinois at Urbana-Champaign, Urbana, IL, USA

Abstract

Most breast cancer survivors (BCS) are not meeting recommended physical activity guidelines. Here, we report the effects of the Better Exercise Adherence after Treatment for Cancer (BEAT Cancer) behavior change intervention on physical activity, aerobic fitness, and quality of life

(QoL). We randomized 222 post-primary treatment BCS to the 3-month intervention (BEAT Cancer) or usual care (UC). BEAT Cancer combined supervised exercise, face-to-face counseling, and group discussions with tapering to home-based exercise. Assessments at baseline, immediately post-intervention (month 3; M3), and 3 months post-intervention (month 6; M6) included accelerometer and self-reported physical activity, submaximal treadmill test, and QoL [Functional Assessment of Cancer Therapy (FACT)-Breast scale]. Adjusted linear mixed-model analyses demonstrated significant effects of BEAT Cancer compared to UC on weekly minutes of moderate intensity physical activity at M3 by accelerometer [mean between group difference (M) = +41; 95 % confidence interval (CI) = 10–73; p = 0.010] and self-report (M = +93; CI = 62–123; p < 0.001). Statistical significance remained at M6 for self-reported physical activity (M = +74; CI = 43–105; p < 0.001). BEAT Cancer participants were significantly more likely to meet physical activity recommendations at both time points [accelerometer M3 adjusted odds ratio (OR) = 2.2; CI = 1.0–4.8 and M6 adjusted OR = 2.4; CI = 1.1–5.3; self-report M3 adjusted OR = 5.2; CI = 2.6–10.4 and M6 adjusted OR = 4.8; CI = 2.3–10.0]. BEAT Cancer significantly improved fitness at M6 (M = +1.8 ml/kg/min; CI = 0.8–2.8; p = 0.001) and QoL at M3 and M6 (M = +6.4; CI = 3.1–9.7; p < 0.001 and M = +3.8; CI = 0.5–7.2; p = 0.025, respectively). The BEAT Cancer intervention significantly improved physical activity, fitness, and QoL with benefits continuing 3 months post-intervention.

Keywords

Oncology; Survivorship; Compliance; Adherence; Exercise

Introduction

Physical activity improves fitness, manages symptoms, enhances quality of life, and may improve cancer outcomes in breast cancer survivors (BCS) [1, 2]. The American Cancer Society and National Comprehensive Cancer Network (NCCN) survivorship guidelines recommend that cancer survivors engage in at least 150 min per week of moderate intensity physical activity [3, 4]. As the majority of BCS are not meeting these aerobic physical activity guidelines [5], behavior change interventions aimed at increasing physical activity in this population are warranted.

Physical activity behavior change trials differ from exercise efficacy studies because their primary aim is to change behavior rather than determine exercise effects [6]. Several physical activity behavior change interventions for BCS have been tested in randomized controlled trials with physical activity as the primary outcome [7–17], but progress in the field is limited by the fact that only two [10, 18] demonstrated significant improvements in self-reported physical activity months after intervention completion and only one confirmed improvements with an objective measure (i.e., BEAT Cancer intervention pilot study [18]). Therefore, further research is needed to design and test interventions with potentially greater efficacy.

Therefore, the primary aim of the present study was to extend our earlier pilot work [11, 18] to compare the effects of the Better Exercise Adherence after Treatment for Cancer (BEAT

Cancer) physical activity behavior change intervention to usual care (UC) on physical activity in BCS in a larger multicenter trial. We hypothesize that BEAT Cancer, when compared with UC, would result in significant increases in physical activity immediately post-intervention (month 3; M3) and 3 months post-intervention (month 6; M6). A secondary aim was to compare the effects of BEAT Cancer to UC on aerobic fitness and quality of life. We hypothesized that, when compared to UC, BEAT Cancer would result in significant improvements in these health-related outcomes.

Methods

Setting and participants

The study was conducted at Southern Illinois University School of Medicine (SIUSOM), University of Illinois at Urbana-Champaign, and University of Alabama at Birmingham (UAB). Participants were recruited from January 2010 to September 2013 through physician referrals, direct mailings, tumor board, local cancer support groups, newsletters, Army of Women®, media releases, television news interviews, newspaper advertisements, and flyers (e.g., clinical waiting rooms, beauty salons, laundry mats, etc.). Inclusion criteria included: (1) women ages 18 to 70 years with history of ductal carcinoma in situ (DCIS) or Stage I-IIIa breast cancer who were not currently receiving or planning to receive chemotherapy or radiation therapy, (2) 8 weeks post-surgical procedure; (3) English speaking; (4) medical clearance for participation provided by physician; and (5) participating, on average, in 30 min of vigorous physical activity or 60 min of moderate activity per week during the past 6 months. Exclusion criteria included: (1) dementia or organic brain syndrome; (2) disorders that would interfere with ability to fully participate in assessments and BEAT Cancer activities (e.g., psychosis, schizophrenia, etc.); (3) contraindication to participation in regular physical activity; (4) metastatic or recurrent breast cancer; (5) inability to ambulate; (6) elective surgery anticipated during the intervention which would interfere with participation (e.g., breast reconstructive surgery); (7) travel plans interfering with the scheduled study sessions; and (8) participating in another exercise study. All recruiting study sites obtained institutional review board (IRB) approval and all participants provided written informed consent before initiating study procedures.

Study design and random assignment to groups

The study protocol for this randomized controlled trial has been previously described [19]. Potential participants who contacted the study office were screened by trained research staff using an IRB approved telephone script. If eligible and interested, potential participants were scheduled for an orientation visit during which written informed consent was obtained and baseline assessments initiated. Enrollment occurred in waves (or cohorts) due to the discussion session component of the intervention (described below). Randomization to one of the two study group conditions was completed using computer-generated numbers in blocks of 4 within each recruiting site to facilitate an even distribution between study conditions during each recruitment wave. Random assignment was kept in sealed, opaque envelopes which were opened in the order in which participants completed baseline testing. Research staff members were unaware of the assignment until the envelope was opened.

Better Exercise Adherence after Treatment for Cancer (BEAT Cancer) intervention

The BEAT Cancer behavior change intervention is based on social cognitive theory [20] and needs assessments carried out with BCS [21–26]. A detailed intervention description has been published [19]. In brief, the 3-month BEAT Cancer intervention included 12 supervised exercise sessions with a trained exercise specialist, which were tapered over the first 6 weeks to an exclusively home exercise program. During the second 6 weeks of the intervention, participants attended a face-to-face update counseling session with the exercise specialist every 2 weeks. Participants were gradually advanced from three weekly exercise sessions in week 1 [duration of 15–25 min; 40–59 % of heart rate reserve; 10-point rating of perceived exertion (RPE) = 1.5–3] to 150 weekly minutes of moderate intensity physical activity by week 7 [i.e., 3 weekly sessions (duration of 30–50 min; 40–59 % of heart rate reserve; 10-point RPE = 3.5–5.5)] [19]. Participants also attended six discussion group sessions led by trained facilitators during the first 9 weeks of the intervention. Counseling provided by the exercise specialists and group sessions focused on self-efficacy, exercise barriers, behavioral capability, goal setting with self-monitoring, behavioral modification strategies, time management, stress management, safety, cognitive reframing, relapse prevention, and role models (see previously published details [19]). BEAT Cancer participants received a participant education notebook provided as part of the group sessions curriculum and a personal heart rate monitor. Quality control to ensure fidelity was completed as previously described [19].

Usual care (UC)

Usual care participants received printed American Cancer Society materials describing physical activity recommendations for cancer survivors (e.g., Living Smart: The American Cancer Society's guide to eating healthy and being active). No additional instructions regarding physical activity were given with the materials.

Measures

Outcomes were assessed at baseline, M3 (immediately post-intervention) and M6 (3 months after intervention completion). The following descriptive characteristics were self-reported: age, ethnicity, race, years of education, annual household income, employment status, marital status, cancer stage, months since breast cancer diagnosis, history of chemotherapy, history of radiation therapy, current hormonal therapy, months on hormonal therapy, current use of beta blocker, number of comorbidities [27], menopausal status, smoking, alcohol, and prior exercise advice from oncologist.

The primary outcome was weekly minutes of moderate intensity physical activity assessed by the MTI/Acti-Graph accelerometer (models GT1M and GT3X; protocol previously published [19]). Cutpoints were 1,952–5,724 for moderate activity and 5,725 for vigorous intensity activity [28]. We also included the Godin Leisure-Time Exercise Questionnaire which assesses volitional, leisure-time physical activity [29–31]. Participants reported the frequency and average duration of exercise bouts per week over the past month at light, moderate, and vigorous intensity. Minutes of moderate intensity physical activity were calculated. For accelerometer and self-report, vigorous minutes were multiplied by two and added to moderate minutes as suggested in the physical activity guidelines [32]. Using this

variable, participants were defined as meeting aerobic physical activity recommendations if 150 min/week of moderate intensity physical activity was achieved.

Aerobic fitness was measured using a submaximal treadmill test and modified Naughton protocol [33, 34]. Quality of life (QoL) was measured using the Functional Assessment of Cancer Therapy (FACT)—Breast which uses 37 items (5-point Likert scale; higher score indicates better quality of life) to assess five subscales (physical well-being, social well-being, emotional well-being, functional well-being, and breast additional concerns), FACT-General (sum of all but additional concerns subscale), FACT-Breast (sum of FACT-General plus additional concerns), and trial outcome index (sum of physical well-being, functional well-being, and breast additional concerns subscales) [35].

Sample size calculation and statistical analyses

Our retention goal was 194 participants (or 97 per group) which allowed detection of a small to medium effect size = 0.40 ($p < 0.05$, power of 0.80). This goal was sufficient for achieving similar effects in the pilot study while also detecting smaller effect size improvements in the secondary outcomes [18, 19].

For our primary analyses, we used adjusted linear mixed models incorporating an unstructured covariance matrix to test BEAT Cancer effects on primary and secondary outcomes at M3 and M6. SAS[®] statistical software (Cary, NC) was used and statistical significance was determined by two-sided p value < 0.05 . These analyses adjusted for the baseline value of the outcome and site (stratification variable for randomization), as well as covariates associated with the primary outcome of M6 physical activity [i.e., breast cancer stage, history of chemotherapy, history of radiation, hormonal therapy (none versus on hormonal therapy for 1 year versus on hormonal therapy for 1 year), and marital status (i.e., married or living with significant other versus other)]. Age, race (Caucasian versus other), years of education, income, number of comorbidities, and months since diagnosis were not statistically significant covariates. Odds ratios (ORs) with 95 % confidence intervals (CIs) were calculated for the dichotomous outcome of meeting recommendations using generalized linear mixed model adjusting for baseline and covariates. All analyses were intention-to-treat with all data available being used.

Results

Participant flow, retention, and adverse events

Of the 610 women responding to our recruitment efforts, 453 were within our target population based on age and history of breast cancer diagnosis. Participant flow through the study is provided in Fig. 1. Enrollment occurred from 2010 to 2013. We enrolled 241 instead of our proposed 256 because of a higher than anticipated retention rate. Of randomized participants, retention was 97 % at M3 overall (96 % BEAT Cancer and 98 % UC) and 96 % at M6 (95 % BEAT Cancer and 96 % UC). Baseline characteristics are provided in Table 1. The study groups were balanced with regard to all characteristics except that a greater percentage of participants in the UC group had been on hormonal therapy for 1 year ($p = 0.02$).

Adherence to planned BEAT Cancer components was 98 % for supervised exercise sessions, 96 % for update sessions, and 91 % for discussion group sessions. Only five BEAT Cancer participants did not receive the allocated intervention (i.e., did not complete 75 % of all intervention components combined; Fig. 1). All UC participants received the written materials according to protocol. Only one related serious adverse event occurred (intervention group; pelvic stress fracture). Related expected adverse events in the BEAT Cancer group included back or lower extremity musculoskeletal pain or injury ($n = 14$), heart rate monitor rash ($n = 1$), fall while walking ($n = 1$), breast reconstruction ($n = 3$), and chest pain during treadmill fitness test ($n = 1$). Related adverse events in the UC group included arm tingling ($n = 1$) during the tread-mill test and knee tendonitis ($n = 1$).

Changes in physical activity behavior at month 3 (M3) and month 6 (M6)

BEAT Cancer significantly increased weekly minutes of moderate intensity physical activity (accelerometer $p = 0.022$ and self-report $p < 0.001$ for model study group effect). Mean between group differences in physical activity was statistically significant at M3 (accelerometer = +41; CI = 10–73; $p = 0.010$ and self-report = +93; CI = 62–123; $p < 0.001$) and remained statistically significant at M6 for self-reported physical activity (mean between group difference of +74 weekly minutes; CI = 43–105; $p < 0.001$) (Table 2; Fig. 2). BEAT Cancer participants were significantly more likely to meet aerobic physical activity recommendations at M3 and M6 when measured by accelerometer (M3 adjusted OR = 2.2; CI = 1.0–4.8 and M6 adjusted OR = 2.4; CI = 1.1–5.3) and self-report (M3 adjusted OR = 5.2; CI = 2.6–10.4 and M6 adjusted OR = 4.8; CI = 2.3–10.0) (Table 3). Using accelerometer, the percent of BEAT Cancer participants meeting recommendations increased from 50 % at baseline to 72 % at M3 and 67 % at M6, while the percent of UC participants meeting recommendations was 50 % at baseline, 58 % at M3, and 54 % at M6. Using self-report, the percent meeting recommendations in the BEAT Cancer group increased from 9 % at baseline to 54 % at M3 and 46 % at M6, and the UC group increased from 3 % at baseline to 22 % at M3 and 18 % at M6.

Changes in health outcomes and quality of life

When compared with UC, BEAT Cancer significantly improved aerobic fitness (model study group effect $p = 0.003$; M6 between group difference = + 1.8 ml/kg/min; CI = 0.8–2.8; $p = .001$) (Table 2; Fig. 3). When compared with UC, BEAT Cancer significantly improved FACT-Breast (study group effect $p = 0.001$) at M3 (between group difference = + 6.4; CI = 3.1–9.7; $p < 0.001$) and M6 (between group difference = + 3.8; CI = 0.5–7.2; $p = 0.025$) (Table 2; Fig. 4). With regard to subscales, BEAT Cancer intervention compared to UC significantly improved physical well-being (study group effect $p = 0.003$), emotional well-being ($p = 0.008$), functional well-being ($p < 0.001$), FACT-General ($p < 0.001$), and trial outcome index ($p = 0.001$) (Table 2) with between group differences remaining statistically significant at M6 for physical well-being and FACT-General (Table 2; Fig. 4).

Discussion

To our knowledge, the BEAT Cancer intervention is the only physical activity behavior change intervention for BCS reporting a statistically significant improvement in an objective

physical activity outcome, months after intervention completion (i.e., the percent meeting recommendations based on accelerometer reported here). One other physical activity behavior change intervention for BCS has reported intervention benefits on physical activity behavior months after intervention completion, but this was not confirmed with objective monitoring [10, 15]. Given the 27 % reduction in all-cause mortality and 25 % reduction in breast cancer mortality reported for BCS who engage in at least 10 MET-hours/week (equivalent to 150 weekly minutes of moderate intensity physical activity) [36], our intervention effect of more than doubling the odds of achieving these recommendations immediately and 3 months post-intervention completion suggests considerable clinical value. Moreover, our improvements in physical activity were sufficient for eliciting a statistically significant improvement in aerobic fitness at M6. Although two behavior change interventions for BCS have demonstrated improvements in the 6-minute walk immediately post-intervention [7, 17], only one has reported continued improvements in fitness (measured by Rockport 1-mile test) months after a behavior change intervention [10, 37].

Also of clinical relevance, the BEAT Cancer intervention achieved the minimally important difference (MID) for FACT-General (MID = 3–7) and functional well-being (MID = 2–3) [38]. FACT-Breast and trial outcome index did not reach a MID due, in part, to the lack of intervention effect on the additional concerns subscale. Several physical activity behavior change interventions have significantly improved the QoL immediately post-intervention [7, 12, 15, 17] but none have reported continued significant benefits several months after intervention completion [15, 39]. The fact that our relatively short-term behavior change intervention was able to significantly improve QoL several months after intervention completion is an important and worthwhile finding.

The average minutes of moderate intensity physical activity measured by accelerometer are higher than that reported for population-based sampling of cancer survivors [40]. Possible contributing factors include enrollment of relatively healthy and motivated individuals and use of a stricter definition of non-wear time (i.e., 20 min of consecutive zeros) which was decided a priori [19]. Also, accelerometers measure all types of physical activity (volitional such as leisure-time and non-volitional such as occupational). Therefore, average accelerometer weekly minutes of moderate intensity activity measured at baseline was higher than self-reported leisure-time physical activity. Also, study exclusion was based on self-reported physical activity level at time of screening with some participants increasing their physical activity between screening and baseline questionnaire completion. It is not surprising that the self-report measure indicated a larger between group difference than the accelerometer because our intervention focused on increasing volitional physical activity during leisure time and accelerometers are unable to measure the movement and/or intensity of certain activities (e.g., stationary bicycle, inclines, swimming, elliptical, etc.).

Generalizability of our study results is improved by our enrollment at three study sites in two U.S. states and lack of association between study site and primary outcome (data not reported). Although the amount of BEAT Cancer-participant interaction could be a barrier to dissemination and implementation, it is this interaction that most probably contributed to the magnitude of our BEAT Cancer intervention benefits. Indeed, the odds of meeting recommendations reported herein is more than double that reported by any previous physical

activity behavior change intervention for BCS, all of which have been delivered by mail, single in-person encounters, and/or telephone. Only our BEAT Cancer intervention combines supervised exercise sessions tapering to a home-based approach augmented by face-to-face counseling. Furthermore, our intervention is the first to provide a methodology that may be appropriate for enhancing behavior change in cancer survivors needing referral to an exercise specialist as stated in the National Comprehensive Cancer Network survivorship guidelines (NCCN) [4]. Budgetary constraints prevented a cost-effectiveness assessment, but future study is warranted to determine if the benefits achieved outweigh the resource investment. Similarly, additional research identifying the core intervention components for changing behavior and moderators of intervention response is needed.

We acknowledge several limitations with this study. First, we focused on aerobic physical activity, as resistance training was not specified in the recommendations at study inception. However, we have reported that resistance training can be easily integrated [41]. Although our study did not examine whether our intervention is well tolerated in BCS at higher exercise risk (as defined by the NCCN guidelines [4]), recovering from recent surgery, or currently on primary treatment, the close supervision and expertise of exercise staff [19] support adapting and testing the BEAT Cancer intervention in such populations.

Conclusions

As hypothesized, the BEAT Cancer physical activity behavior change intervention for BCS significantly improved physical activity, aerobic fitness, and quality of life. Statistically significant between group differences for BEAT Cancer versus UC group continued 3 months post-BEAT Cancer intervention completion for total weekly minutes of physical activity (self-report), percent meeting recommendations (accelerometer and self-report), fitness, physical well-being, FACT-General, and FACT-Breast. The BEAT Cancer intervention is an efficacious program for increasing physical activity, aerobic fitness, and QoL in BCS. Additional research is needed to improve maintenance of benefits, determine cost-effectiveness, enhance dissemination and implementation potential, and test intervention effects when enrolling higher risk patients and survivors as described by the NCCN survivorship guidelines [4].

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Fig. 1.
Participants' flow through the study (note: more than one reason for ineligibility possible)

Fig. 2.

BEAT Cancer intervention effects on physical activity immediately post-intervention (month 3) and 3 months later. Legend: 3 months = immediately post-intervention, 6 months = 3 months after intervention completion; minutes of vigorous activity doubled before adding to minutes of moderate intensity; adjusted least square means with standard error bars provided for month 3 and month 6 only because baseline used as covariate in the model (see text for list of all covariates); **a** accelerometer measuring free-living physical activity and **b** self-report measuring leisure-time physical activity only

Fig. 3. BEAT Cancer intervention effects on cardiorespiratory fitness immediately post-intervention (month 3) and 3 months later. Legend: 3 months = immediately post-intervention, 6 months = 3 months after intervention completion; adjusted least square means with standard error bars provided for month 3 and month 6 only because baseline used as covariate in the model (see text for list of all covariates)

Fig. 4. BEAT Cancer intervention effects on quality of life immediately post-intervention (month 3) and 3 months later. Legend: 3 months = immediately post-intervention, 6 months = 3 months after intervention completion; adjusted least square means with standard error bars provided for month 3 and month 6 only because baseline used as covariate in the model (see text for list of all covariates); **a** Functional Assessment of Cancer Therapy (FACT)-Breast and **b** FACT physical well-being subscale

Table 1

Baseline participant characteristics overall and by study group

Variable	Overall (<i>n</i> = 222)	BEAT Cancer (<i>n</i> = 110)	Usual care (<i>n</i> = 112)	<i>p</i> value
Age (years) [mean ± SD (range)]	54.4 ± 8.5 (21-70)	54.9 ± 9.3 (21-70)	53.9 ± 7.7 (32-70)	0.35
Ethnicity [no. (%)]				
Hispanic	4 (1.8 %)	3 (2.7 %)	1 (0.9 %)	0.37
Non-Hispanic	218 (98.2 %)	107 (97.3 %)	111 (99.1 %)	
Race [no. (%)]				
White	186 (83.8 %)	92 (83.6 %)	94 (83.9 %)	0.55
African-American	25 (11.3 %)	11 (10.0 %)	14 (12.5 %)	
Other	11 (4.9 %)	7 (6.4 %)	4 (3.6 %)	
Education, years [mean ± SD (range)]	15.5 ± 2.6 (9-21)	15.7 ± 2.7 (10-21)	15.3 ± 2.5 (9-20)	0.21
Income [no. (%)]				
<\$10 K	7 (3.2 %)	4 (3.7 %)	3 (2.7 %)	0.68
\$10 K to \$20 K	10 (4.6 %)	5 (4.6 %)	5 (4.5 %)	
\$20 K to \$35 K	20 (9.1 %)	12 (11.0 %)	8 (7.2 %)	
\$35 K to \$50 K	26 (11.8 %)	10 (9.2 %)	16 (14.4 %)	
\$50 K	157 (71.4 %)	78 (71.6 %)	79 (71.2 %)	
Employed (yes) [no. (%)]	157 (70.7 %)	76 (69.1 %)	81 (72.3 %)	0.60
Marital status [no. (%)]				
Married or living with sig other	158 (71.2 %)	75 (68.2 %)	83 (74.1 %)	0.33
Other	64 (28.8 %)	35 (31.8 %)	29 (25.9 %)	
Cancer stage [no. (%)]				
DCIS ^a	25 (11.3 %)	13 (11.8 %)	12 (10.7 %)	0.97
1	93 (41.9 %)	47 (42.7 %)	46 (41.1 %)	
2	78 (35.1 %)	37 (33.6 %)	41 (36.6 %)	
3	26 (11.7 %)	13 (11.8 %)	13 (11.6 %)	
Months since breast cancer diagnosis [mean ± SD (range)]	54.0 ± 54.5 (2-276)	57.3 ± 54.4 (2-237)	50.8 ± 54.6 (2-276)	0.38
History of chemotherapy (yes) [no. (%)]	128 (57.7 %)	59 (53.6 %)	69 (61.6 %)	0.23
History of radiation (yes) [no. (%)]	151 (68.0 %)	79 (71.8 %)	72 (64.3 %)	0.23
Current hormonal therapy [no. (%)]				
None	114 (51.3 %)	56 (50.9 %)	58 (51.8 %)	0.02
On hormonal therapy 1 year	53 (23.9 %)	19 (17.3 %)	34 (30.4 %)	
On hormonal therapy >1 year	55 (24.8 %)	35 (31.8 %)	20 (17.9 %)	
Hormonal therapy (type) ^b [no. (%)]				
Estrogen receptor modulator (yes)	54 (50.0 %)	25 (46.3 %)	29 (53.7 %)	0.44
Aromatase inhibitor (yes)	54 (50.0 %)	29 (53.7 %)	25 (46.3 %)	
Beta blocker (yes)	24 (10.8 %)	13 (11.8 %)	11 (9.8 %)	0.63
Comorbidity score [mean ± SD (range)]	2.2 ± 1.9 (0-7)	2.3 ± 1.9 (0-7)	2.1 ± 1.9 (0-7)	0.52
Menopause [no. (%)]				

Variable	Overall (n = 222)	BEAT Cancer (n = 110)	Usual care (n = 112)	p value
Pre-menopausal	29 (13.1 %)	9 (8.2 %)	20 (17.9 %)	0.100
Unsure	16 (7.2 %)	8 (7.3 %)	8 (7.1 %)	
Post-menopausal	177 (79.7 %)	93 (84.6 %)	84 (75.0 %)	
Smoker [no. (%)]				0.82
Never	155 (69.8 %)	75 (68.2 %)	80 (71.4 %)	
Ex-smoker	62 (27.9 %)	32 (29.1 %)	30 (26.8 %)	
Current smoker	5 (2.3 %)	3 (2.7 %)	2 (1.8 %)	
Alcohol (yes) [no. (%)]	128 (57.7 %)	68 (61.8 %)	60 (53.6 %)	0.21
Oncologist ever advised to exercise (yes) [no. (%)]	115 (51.8 %)	60 (54.6 %)	55 (49.1 %)	0.42

^c For all subjects (0 months = subjects not on hormonal therapy)

^a DCIS = Ductal carcinoma in situ

^b Both study groups had 54 subjects for an overall n of 108 (subjects on hormonal therapy)

Table 2

Effects of the BEAT Cancer intervention on physical activity, aerobic fitness, and quality of life at post-intervention (month 3) and 3 months after intervention completion (month 6) in breast cancer survivors

Outcome	Unadjusted means			Adjusted ^a between-group differences Estimated least square mean with (95 % CI ^b); <i>p</i> value	
	Baseline mean (SD) ^c	Month 3 mean (SD)	Month 6 mean (SD)	BEAT Cancer versus usual care at month 3 (post-intervention)	BEAT Cancer versus usual care at month 6 (3 months post-intervention)
Accelerometer physical activity, weekly minutes, moderate intensity ^d				41 (10 to 73); 0.010	20 (−12 to 52); 0.212
BEAT Cancer	178 (124)	246 (153)	216 (131)		
Usual care	168 (88)	197 (138)	192 (136)		
Self-report leisure-time physical activity, weekly minutes, moderate intensity ^d				93 (62 to 123); <0.001	74 (43 to 105); <0.001
BEAT Cancer	40 (68)	169 (119)	137 (137)		
Usual care	21 (43)	74 (107)	63 (95)		
Aerobic fitness ^e				1.0 (0.0 to 2.0); 0.058	1.8 (0.8 to 2.8); 0.001
BEAT Cancer	21.0 (5.1)	23.6 (4.8)	23.7 (5.2)		
Usual care	20.7 (4.9)	22.7 (5.3)	21.8 (4.9)		
Physical well-being				1.5 (0.5 to 2.4); 0.002	1.0 (0.1 to 2.0); 0.030
BEAT Cancer	22.9 (4.0)	24.1 (3.5)	23.9 (3.9)		
Usual care	22.5 (4.4)	22.5 (5.0)	22.7 (5.1)		
Social well-being				0.9 (−0.2 to 2.1); 0.120	1.1 (−0.1 to 2.3); 0.071
BEAT Cancer	20.7 (5.2)	21.0 (5.7)	21.0 (5.9)		
Usual care	21.4 (5.4)	20.7 (5.8)	20.5 (5.4)		
Emotional well-being				0.9 (0.3 to 1.5); 0.003	0.5 (−0.1 to 1.1); 0.102
BEAT Cancer	19.9 (3.4)	20.6 (2.9)	20.5 (3.5)		
Usual care	19.8 (3.5)	19.7 (3.2)	20.0 (3.2)		
Functional well-being				2.3 (1.3 to 3.3); <.001	1.0 (−0.1 to 2.0); .063
BEAT Cancer	20.8 (4.6)	22.3 (4.5)	21.4 (5.1)		
Usual care	20.7 (5.7)	20.3 (5.5)	20.5 (5.7)		
Additional concerns				0.9 (−0.2 to 1.9); .099	0.4 (−0.7 to 1.5); .453
BEAT Cancer	26.5 (6.0)	27.8 (6.2)	28.2 (5.7)		
Usual care	25.4 (6.4)	26.2 (6.3)	27.0 (6.1)		
FACT-General				5.6 (2.9 to 8.3); <0.001	3.5 (0.8 to 6.3); 0.011
BEAT Cancer	84.3 (13.2)	88.1 (12.4)	86.9 (14.5)		
Usual care	84.5 (14.9)	83.2 (15.5)	83.6 (15.8)		
FACT ^f -Breast				6.4 (3.1 to 9.7); <0.001	3.8 (0.5 to 7.2); 0.025
BEAT Cancer	110.8 (17.8)	115.9 (17.2)	115.1 (18.8)		
Usual care	110.0 (19.7)	109.4 (20.4)	110.6 (20.2)		

Outcome	Unadjusted means			Adjusted ^a between-group differences Estimated least square mean with (95 % CI ^b); <u>p value</u>	
	Baseline mean (SD) ^c	Month 3 mean (SD)	Month 6 mean (SD)	BEAT Cancer versus usual care at month 3 (post-intervention)	BEAT Cancer versus usual care at month 6 (3 months post- intervention)
Trial outcome index				4.6 (2.3 to 6.9); <0.001	2.3 (0.0 to 4.7); 0.050
BEAT Cancer	70.2 (12.6)	74.2 (11.9)	73.6 (12.4)		
Usual care	68.6 (14.1)	69.0 (14.5)	70.0 (14.3)		

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

^b Confidence intervals

^c Standard deviation

^d Minutes of vigorous activity doubled when calculating weekly minutes

^e ml/kg/min

^f Functional Assessment of Cancer Therapy

Table 3

Odds of meeting physical activity recommendations immediately post-intervention (month 3) and 3 months after intervention completion (month 6) in breast cancer survivors receiving the BEAT Cancer intervention compared with usual care^a

Outcome	Unadjusted % meeting recommendations			Adjusted ^a Odds Ratio with (95 % CI ^b); <i>p</i> value	
	Baseline	Month 3	Month 6	BEAT Cancer versus usual care; month 3	Beat Cancer versus usual care; month 6
Meet recommendations (accelerometer) ^c				2.2 (1.0 to 4.8); 0.042	2.4 (1.1 to 5.3); 0.024
BEAT Cancer	49.8	71.7	67.4		
Usual care	49.8	57.8	53.6		
Meet recommendations (self-report) ^c				5.2 (2.6 to 10.4); <0.001	4.8 (2.3 to 10.0); <0.001
BEAT Cancer	8.7	54.3	45.6		
Usual care	2.8	21.8	17.7		

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

^b Confidence intervals

^c Minutes of vigorous activity doubled when calculating meeting recommendations