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ORIGINAL REPORT

Randomized Controlled Trial of the Effects of Print Materials and Step Pedometers on Physical Activity and Quality of Life in Breast Cancer Survivors

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ABSTRACT

Purpose
To determine the effects of breast cancer–specific print materials and step pedometers on physical activity (PA) and quality of life (QoL) in breast cancer survivors.

Patients and Methods
Breast cancer survivors (N = 377) were randomly assigned to receive one of the following: a standard public health recommendation for PA, previously developed breast cancer–specific PA print materials, a step pedometer, or a combination of breast cancer–specific print materials and step pedometers. The primary outcome was self-reported moderate/vigorous PA minutes per week. Secondary outcomes were QoL (Functional Assessment of Cancer Therapy–Breast), fatigue, self-reported brisk walking, and objective step counts. Assessments were conducted at baseline and postintervention (12 weeks).

Results
Attrition was 10.3% (39 of 377). On the basis of linear mixed-model analyses, PA increased by 30 minutes/week in the standard recommendation group compared with 70 minutes/week in the print material group (mean difference, 39 minutes/week; 95% CI = −10 to 89; $d = 0.25$; $P = .117$), 89 minutes/week in the pedometer group (mean difference, 59 minutes/week; 95% CI, 11 to 108; $d = 0.38$; $P = .017$), and 87 minutes/week in the combined group (mean difference, 57 minutes/week; 95% CI, 8 to 106; $d = 0.37$; $P = .022$). For brisk walking minutes/week, all three intervention groups reported significantly greater increases than the standard recommendation group. The combined group also reported significantly improved QoL (mean difference, 5.8; 95% CI, 2.0 to 9.6; $d = 0.33$; $P = .003$) and reduced fatigue (mean difference, 2.3; 95% CI, 0.0 to 4.7; $d = 0.25$; $P = .052$) compared with the standard recommendation group.

Conclusion
Breast cancer–specific PA print materials and pedometers may be effective strategies for increasing PA and QoL in breast cancer survivors. A combined approach appears to be optimal.

Clinical Trial Registration
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INTRODUCTION

Breast cancer and its treatments are often associated with negative adverse effects that affect quality of life (QoL)[1,2] and may persist even years after treatment(s).[3-5] One intervention that has been found to enhance psychosocial and physical outcomes in breast cancer survivors is physical activity (PA).[6-9] A recent prospective cohort study of almost 3,000 breast cancer survivors reported that higher levels of PA were associated with reduced risks of breast cancer death and breast cancer recurrence.[10] Despite the benefits of PA, the majority of breast cancer survivors are not meeting public health guidelines.[11-14] Given these findings, interventions to increase PA in breast cancer survivors are warranted.

Here, we report results from the Activity Promotion trial. The Activity Promotion trial was a randomized controlled trial designed to determine the effects of breast cancer–specific PA print materials (PM), a step pedometer (PED), or their combination (COM), on self-reported PA and QoL in breast cancer survivors. The primary outcome was change in self-reported moderate/vigorous PA between baseline and postintervention (ie, 12 weeks). Secondary outcomes were changes in self-reported QoL, fatigue, brisk walking, and objective step

counts. We hypothesized that survivors in the PM, PED, and COM groups would report greater increases in self-reported PA and QoL compared with survivors receiving a standard PA recommendation (SR), and that survivors in the COM group would report the greatest increases.

PATIENTS AND METHODS

Setting and Participants

The trial was conducted at the University of Alberta (Edmonton, Canada). Ethical clearance was received from the Alberta Cancer Board and the University of Alberta. Eligibility criteria included histologically confirmed stage I to IIIa breast cancer, physician approval, freedom from chronic medical and orthopedic conditions that would preclude PA (eg, congestive heart failure, or recent knee or hip replacement), English as spoken language, completion of adjuvant therapy except hormone therapy, and absence of current breast cancer.

Design and Recruitment

The Alberta Cancer Registry was used to identify breast cancer survivors residing in Northern Alberta, Canada, diagnosed between January 2000 and December 2003. The trial was conducted between July and October 2005. Each survivor's physician was required to approve participation in the study. Each approved survivor was sent a letter of invitation. Interested and eligible survivors were then mailed a baseline assessment package that contained a cover letter, consent forms, baseline questionnaire, pedometer, 7-day step log, and a postage-paid business reply envelope. Before random assignment, survivors were required to complete and submit the baseline questionnaire and a 7-day pedometer step test, which consisted of wearing a pedometer for 7 days and recording their daily step totals.

Random Assignment to Groups

Survivors were randomly assigned to one of four groups using a computer-generated random numbers list (GraphPad Software, San Diego, CA). A research assistant generated the group assignments in sequentially numbered and sealed opaque envelopes. Survivors were notified via telephone of their group allocation.

Intervention Groups

All groups received a standard recommendation to perform 30 minutes of moderate/vigorous PA on 5 days of the week. Survivors meeting PA guidelines at baseline were encouraged to increase their PA minutes per day and/or days per week. The SR group received no additional intervention materials. The PM group received a copy of *Exercise for Health: An Exercise Guide for Breast Cancer Survivors*.[15] A description of the guidebook is published elsewhere.[15] The PED group received a Digi-Walker SW-200 pedometer (New Lifestyles Inc, Lee's Summit, MO) and a 12-week step calendar. The COM group received both interventions (ie, PM and PED). Survivors randomly assigned to the COM and PED groups were instructed to wear the pedometer everyday for the 12-week duration of the study (ie, 84 days) and record the daily step totals at the end of each day. The SR and PM groups only wore the pedometer for baseline and postintervention assessments. Survivors were not instructed to achieve a step target (eg, 10,000 steps).

Measures

Demographic and medical characteristics assessed included age, marital status, education, family income, employment status, height, weight, comorbidities, body mass index (BMI), and menopausal status. Medical data were extracted from the Alberta Cancer Registry and included tumor stage and grade, treatment(s) received, and time since diagnosis.

Adherence to the guidebook was assessed by asking survivors how many times they read the entire guidebook and how long they spent reading the guidebook. Survivors that received a guidebook and completed the trial (ie, n = 163) were asked if they found the guidebook helpful, if the information about PA was informative, if the guidebook helped to overcome barriers, and whether setting goals was effective in helping increase PA. Survivors indicated their responses on a 5-point Likert scale ranging from 1 ("not at all") to 5 ("very much"). We report the average response for the entire sample as well as the percentage of survivors that indicated a score of at least 3 ("somewhat") on the Likert scale.

Self-report PA was assessed by the leisure score index (LSI) of the Godin Leisure-Time Exercise Questionnaire.[16] The LSI contains three questions that assess the average frequency of mild, moderate, and strenuous exercise during free time in a typical week in the last month. We modified the LSI so that average duration was also provided. For the present study, we calculated the total minutes of moderate plus strenuous exercise for each of the two time periods (ie, baseline and postintervention). An independent evaluation of the Godin Leisure-Time Exercise Questionnaire found its reliability to compare favorably to nine other self-report measures of exercise based on various criteria including test-retest scores, objective activity monitors, and fitness indices. The LSI demonstrated a 1-month test-retest reliability of 0.62 and concurrent validity coefficients of 0.32 with another objective indicator (ie, accelerometer), 0.56 maximum oxygen consumption (as measured by expired gases), and −0.43 with percent body fat (as measured by hydrostatic weighing).[17]

We also collected self-report data on brisk walking using the LSI format. The item assessed the average frequency and duration of brisk walking (defined as "walking like you were late for an appointment") during a typical week in the last month. Objective walking behavior was assessed via a 7-day step test using the Digi-Walker pedometer. Survivors completed this assessment at baseline and once again at 12 weeks (ie, postintervention). During the 7 days, survivors recorded their daily step counts at the end of the day, and reset the pedometer to zero each morning.

QoL was assessed by the Functional Assessment of Cancer Therapy–Breast (FACT-B) scale.[18,19] Fatigue was assessed using the Fatigue Scale[20] from the FACT measurement system. On the QoL and fatigue scales, higher scores represent better QoL/fatigue or less severe symptoms.

Sample Size Calculation and Statistical Analyses

To detect a medium standardized effect ($d = 0.50$) on our primary outcome (ie, self-reported PA) with a power of 0.80 and a two-tailed α less than .05, we needed 63 survivors per group. Baseline comparisons were performed using univariate analysis of variance for continuous variables and χ^2 analyses for categoric variables. For all analyses, we used the intention-to-treat approach.[21] Linear mixed-model analyses[22] were used to assess differences in group changes from baseline to postintervention. Linear mixed models use all available data and provide a valid analysis when data are missing at random. As a sensitivity analysis, we also analyzed the data using the last observation carried forward and for completers only. There were no substantive differences among the three analytic approaches and the conclusions drawn from each analysis did not differ. Therefore, we present the results from the mixed-model analyses. For all self-reported PA data, outliers (ie, z score > 3.29) remained in the data but were adjusted to be one unit less than the next most extreme score.[23] The primary hypothesized comparisons were the three intervention groups (ie, PM, PED, COM) compared with SR. Secondary hypothesized comparisons were the COM group versus PM and PED. Effect sizes (d) for all analyses were computed based on the mixed-model fits and are interpreted as $d = 0.20$ (small), $d = 0.50$ (medium), and $d = 0.80$ (large).[24] No corrections were made for multiple comparisons. Therefore, care must be exercised in the interpretation of statistical significance because of the potential false-positive findings.

RESULTS

Flow of Participants Through the Trial

Figure 1 shows the flow of participants through the trial. Because of the high level of interest, we randomly assigned 377 participants instead of our planned 252. Retention for this study was 89.7% (338 of 377) and did not differ among groups ($P = .39$).

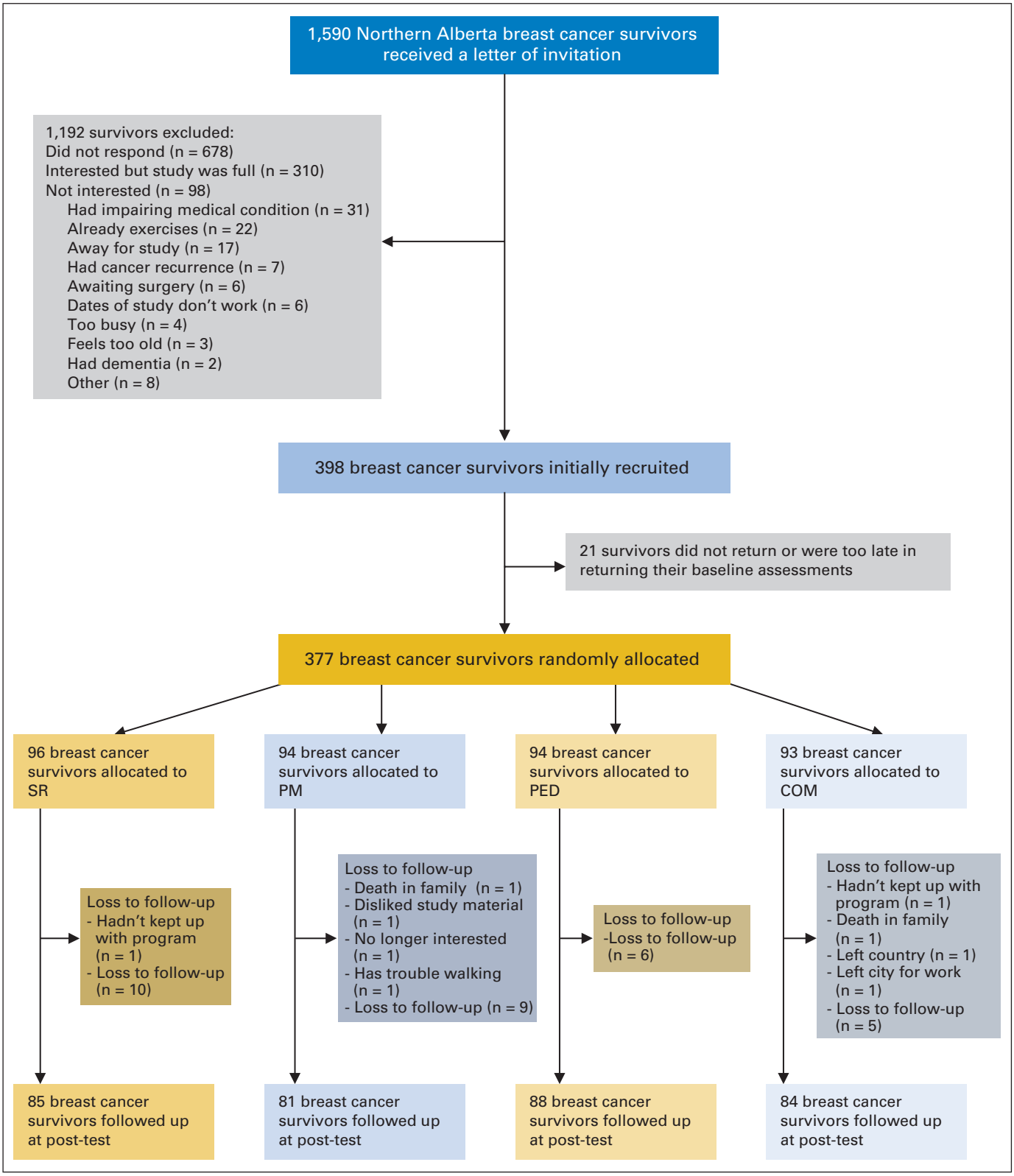

Fig 1. Flow of participants through the study. SR, standard recommendation; PM, printed materials; PED, step pedometer; COM, combination PM and PED.

Baseline Characteristics and Sample Generalizability

Baseline characteristics for all randomly assigned survivors are listed in Table 1. The groups were balanced on all study measures except the PED group had a higher proportion of postmenopausal survivors ($P = .017$). To examine the representativeness of our sample, we compared our sample of survivors (n = 377)

Table 1. Baseline Demographic, Medical, and Behavioral Profile of Participants Overall and by Group Assignment

Variable	Overall (N = 377)		SR (n = 96)		PM (n = 94)		PED (n = 94)		COM (n = 93)	
	No. of Participants	%	No. of Participants	%	No. of Participants	%	No. of Participants	%	No. of Participants	%
Demographic profile										
Age, years										
Mean	58		57		57		58		58	
Range	30-90		37-90		31-88		34-75		38-86	
≥ 60	134	35.5	35	36.5	28	29.8	34	36.2	37	39.8
Married	272	72.1	70	72.9	62	66.0	71	75.5	69	74.2
Completed university	112	29.7	37	38.5	35	37.2	40	42.6	38	40.9
Income > $80,000/year*	99	26.3	28	29.2	19	20.2	24	25.5	28	30.1
Full-time employed	114	30.2	32	33.3	29	30.9	29	30.9	24	25.8
Canadian ethnicity	160	42.4	36	37.5	39	41.5	39	41.5	46	49.5
European ethnicity	85	22.6	21	21.9	20	21.3	18	19.2	26	28.0
Rural resident	112	29.7	31	32.3	25	26.6	30	31.9	26	28.0
Medical profile										
Weight, kg										
Mean	74.7		76.4		74.5		74.1		73.5	
SD	15.8		17.8		16.4		15.6		13.4	
BMI, kg/m^2										
Mean	27.7		28.2		27.9		27.4		27.2	
SD	5.6		6.7		5.5		5.3		4.6	
Overweight	141	37.4	34	35.4	31	33.0	31	33.0	45	48.4
Obese	111	29.4	31	32.2	31	33.0	29	30.9	20	21.5
Obese class I†	77	20.4	17	17.7	23	24.4	23	24.4	14	15.1
Obese class II‡	17	4.5	9	9.4	3	3.2	2	2.1	3	3.2
Obese class III§	17	4.5	5	5.2	5	5.3	4	4.3	3	3.2
Postmenopausal	232	62.0	55	57.3	50	53.2	70	74.5	57	61.3
Months postdiagnosis										
Mean	39.0		39.9		38.9		38.5		38.7	
SD	11.3		11.2		10.7		11.5		11.6	
Disease stage										
I (T1N0)	194	51.5	48	50	53	56.4	38	40.4	55	59.1
IIa (T1N1, T2N0)	111	29.4	27	28.1	26	27.7	35	37.2	23	24.7
IIb (T2N1, T3N0)	50	13.3	13	13.5	11	11.8	15	16.0	11	11.8
IIIa (T1N2, T2N2, T3N1-2)	22	5.8	8	12.0	4	4.3	6	6.4	4	4.3
Treatment										
Surgery	377	100	96	100	94	100	94	100	93	100
Chemotherapy	203	53.9	52	54.2	47	54	56	59.6	48	51.6
Radiation	261	69.2	65	67.8	62	66.0	75	79.8	59	63.4
Hormones	252	66.8	65	67.7	66	70.2	63	67.0	58	62.4
Current hormone therapy										
Tamoxifen	182	48.3	47	49.0	37	39.4	51	54.3	47	50.0
Aromatase inhibitor	42	11.1	12	12.5	13	13.8	11	11.7	6	6.5
Comorbidities										
Diabetes	41	10.9	10	10.4	8	11.8	12	12.8	11	11.8
Hypertension	122	32.4	31	32.3	27	28.7	32	34.0	32	34.4
High cholesterol	100	26.5	22	22.9	27	28.7	26	27.7	25	26.9
Behavioral profile										
Current exerciser	127	33.7	35	36.5	32	34.0	32	34.0	28	30.1
Exercise limitation‖	117	31	27	28.1	31	33.0	28	28.8	31	33.3

Abbreviations: SR, standard recommendation; PM, print material; PED, step pedometer; COM, PM and PED combined; SD, standard deviation; BMI, body mass index.
*n = 356.
†BMI 30.0-34.9.
‡Obese class II, BMI 35.0-39.9.
§Obese class III, BMI ≥ 40.
‖Denotes survivors who indicated that a health condition limited their exercise participation either a little, somewhat, quite a lot, or completely.

to nonparticipants (n = 1,213) on available medical variables (months since diagnosis, morphology, stage, and treatment[s] received). Study participants were on average 11 months more proximal to their date of diagnosis. Furthermore, a greater proportion of study participants received chemotherapy (54%) than nonparticipants (41%). We also compared survivors who completed the trial (n = 338) versus noncompleters (n = 39) on sociodemographic (ie, age, education, income, employment, ethnicity, residence) and medical variables (ie, months since diagnosis, breast cancer stage, treatment[s] received, BMI). There were no significant differences on any variable.

Adherence to the Intervention Materials

Survivors in the two groups that received PED as an intervention (ie, COM and PED; n = 187) recorded their pedometer steps on 83.3% (70 of 84) of study days. Survivors in the two groups that received PM (ie, COM and PM; n = 163) reported reading the entire PM an average of 2.1 times for an average of 113 minutes.

Evaluation of the Physical Activity Guide

Of survivors who received the PM and completed the trial (ie, n = 163), 76.5% found the guidebook helpful (overall sample mean, 3.3 of a possible 5.0), 88.3% found the information about PA informative (mean, 3.8 of a possible 5.0), 68.9% reported that setting PA goals helped them increase PA (mean, 3.1 of a possible 5.0), and 45.7% reported that the guidebook helped them overcome PA barriers (mean, 2.4 of a possible 5.0).

Changes in Self-Reported Moderate/Vigorous Physical Activity

Table 2 lists the PA data. Baseline values for PA did not differ between groups. From baseline to 12 weeks, self-reported moderate to vigorous PA increased by 30 minutes/week in the SR group compared with 70 minutes/week in the PM group (mean difference, 39 minutes/week; 95% CI = −10 to 89; $d = 0.25$; $P = .117$), 89 minutes/week in the PED group (mean difference, 59 minutes/week; 95% CI, 11 to 108; $d = 0.38$; $P = .017$), and 87 minutes/week in the COM group (mean difference, 57 minutes/week; 95% CI, 8 to 106; $d = 0.37$; $P = .022$).

Changes in Self-Reported and Objectively Measured Walking Behavior

Self-reported brisk walking minutes did not change (ie, zero change) in the SR group compared with an increase of 72 minutes/week in the PM group (mean difference, 72 minutes/week; 95% CI, 20 to 123; $d = 0.48$; $P = .006$), 93 minutes/week in the PED group (mean difference, 94 minutes/week; 95% CI, 43 to 144; $d = 0.62$; $P = .000$), and 58 minutes/week in the COM group (mean difference, 58 minutes/week; 95% CI, 6 to 109; $d = 0.39$; $P = .028$). There were no differences between any of the groups on objectively measured steps per day.

Changes in QoL

Table 3 lists the QoL data. The baseline values for the QoL outcomes did not differ between groups. QoL (FACT-B) improved by 6.9 points in the COM group compared with 1.1 points in the SR group (mean difference, 5.8; 95% CI, 2.0 to 9.6; $d = 0.33$; $P = .003$). Fatigue improved by 3.6 points in the COM group compared with 1.3 points SR group (mean difference, 2.3; 95% CI, 0.0 to 4.7; $d = 0.25$; $P = .052$). There were no significant differences between any of the groups on BMI. Changes in PA were associated with changes in fatigue ($r = .17$, $P = 002$) but not QoL ($r = .09$, $P = .087$), whereas changes in brisk walking were associated with changes in both fatigue ($r = .14$, $P = 013$) and QoL ($r = .20$, $P < .001$).

Table 2. Effects of PM and PED on PA and Walking Behavior in Breast Cancer Survivors (N = 377)

	Baseline*		Postintervention†		Mean Change‡		Between-Group Comparison		
Variable	Mean	SD	Mean	SD	Mean	95% CI	Mean	95% CI	*P*
Self-reported moderate/vigorous PA, minutes/week									
SR (n = 96)	133	144	163	121	+30	−4 to 65	COM *v* SR: +57	8 to 106	.022
PM (n = 94)	126	159	197	160	+70	34 to 105	PED *v* SR: +59	11 to 108	.017
PED (n = 94)	123	154	214	178	+89	55 to 123	PM *v* SR: +39	−10 to 89	.117
COM (n = 93)	119	163	211	169	+87	53 to 123	COM *v* PED:−2	−63 to 67	.947
							COM *v* PM: +21	−45 to 87	.532
Self-reported brisk walking, minutes/week									
SR (n = 96)	101	143	102	105	+0	−36 to 36	COM *v* SR: +58	6 to 109	.028
PM (n = 94)	77	121	153	206	+72	35 to 108	PED *v* SR: +94	43 to 144	.000
PED (n = 94)	69	118	162	221	+93	57 to 129	PM *v* SR: +72	20 to 123	.006
COM (n = 93)	64	105	121	146	+58	21 to 94	COM *v* PED: −36	−98 to 27	.260
							COM *v* PM: −18	−81 to 45	.576
7-day pedometer step count									
SR (n = 96)	7,938	3,905	8,028	3,457	+91	−1,021 to 1,203	COM *v* SR: −301	−1,887 to 1,304	.710
PM (n = 94)	8,306	3,831	8,114	3,778	−191	−1,323 to 941	PED *v* SR: −146	−1,718 to 1,425	.885
PED (n = 94)	8,476	3,248	8,420	5,226	−55	−1,166 to 1,055	PM *v* SR: −282	−1,870 to 1,304	.727
COM (n = 93)	7,993	3,559	7,783	3,048	−210	−1,341 to 921	COM *v* PED: −155	−1,740 to 1,430	.848
							COM *v* PM: −19	−1,619 to 1,581	.982

Abbreviations: PM, print material; PED, step pedometer; PA, physical activity; SD, standard deviation; SR, standard recommendation; COM, PM and PED combined.
*Data based on all study participants (N = 377).
†Data based on participants who completed the trial (n = 338).
‡Mean change scores based on mixed-model analysis; may not precisely reflect postintervention minus baseline scores given that means are mode fitted.

Table 3. Effects of PM and PED on Quality of Life and Fatigue in Breast Cancer Survivors (N = 377)

Variable	Baseline*		Postintervention†		Mean Change‡		Between-Group Comparison		
	Mean	SD	Mean	SD	Mean	95% CI	Mean	95% CI	*P*
FACT-B (0-148)									
SR (n = 96)	117.5	17.3	119.2	17.3	+1.1	−3.7 to 1.6	COM *v* SR: +5.8	2.0 to 9.6	.003
PM (n = 94)	115.3	17.9	118.3	16.2	+1.7	−1.0 to 4.4	PED *v* SR: +1.8	−1.9 to 5.5	.347
PED (n = 94)	117.4	17.2	120.5	16.1	+2.9	0.2 to 5.5	PM *v* SR: +0.6	−3.2 to 4.4	.752
COM (n = 93)	115.1	18.7	121.8	16.5	+6.9	4.2 to 9.6	COM *v* PED: +3.6	−3.6 to 10.7	.326
							COM *v* PM: +4.9	−2.2 to 12.1	.177
FS (0-52)									
SR (n = 96)	41.1	9.3	42.6	8.7	+1.3	0.4 to 2.9	COM *v* SR: +2.3	0.0 to 4.7	.052
PM (n = 94)	39.7	9.7	42.2	8.8	+1.8	0.1 to 3.5	PED *v* SR: +1.2	−1.1 to 3.5	.310
PED (n = 94)	40.3	9.9	42.8	7.6	+2.5	0.8 to 4.1	PM *v* SR: +0.5	−1.9 to 2.9	.673
COM (n = 93)	39.8	10.3	43.1	8.9	+3.6	1.9 to 5.3	COM *v* PED: +1.1	−2.7 to 4.9	.583
							COM *v* PM: +1.8	−2.0 to 5.7	.349

Abbreviations: PM, print material; PED, step pedometer; SD, standard deviation; FACT-B, functional assessment of cancer therapy–breast; SR, standard recommendation; COM, print material and pedometer combined; FS, fatigue scale.
*Baseline data based on all study participants (N = 377).
†Data based on participants that completed the trial (n = 338).
‡Data based on mixed model analysis; mean change score may not precisely reflect postintervention minus baseline scores given that means are mode fitted.

DISCUSSION

As hypothesized, we found that all three intervention groups (ie, PM, PED, and COM) reported greater increases in self-reported PA and/or brisk walking than the SR group. The COM group, however, was not significantly more active than the PM or PED groups. There were no differences in objective walking behavior across the groups. For our second hypothesis, we found that survivors in the COM group reported significantly greater improvements in QoL and fatigue than survivors in the SR group.

The strengths of our trial include that it is the first study, to the best of our knowledge, to examine the effects of PM and pedometers on self-reported PA and QoL in breast cancer survivors; the randomized controlled trial design; the use of an SR as our comparison group; the use of a theoretically based and previously evaluated PM intervention; high fidelity to the intervention materials; the large sample size; and minimal loss to follow-up. Our study was limited by the self-report of PA and the failure to blind survivors from their pedometer step count during baseline and postintervention testing. Moreover, given the 22 secondary comparisons, our study is subject to one false discovery by chance if all of these comparisons were actually null. Finally, given that our study was conducted from July to October, it is unknown if the intervention would be equally effective during the winter months.

In our study, survivors in the PM, PED, and COM intervention groups, compared with the SR group, increased their moderate to vigorous PA minutes/week by about 40 to 60 minutes/week and their brisk walking by about 60 to 90 minutes/week. In other populations, research examining print-mediated PA interventions also has provided evidence of their efficacy and efficiency.[25-28] However, few studies have focused on cancer survivors. Jones et al[29] examined the effects of an oncologist's recommendation to exercise on self-reported PA behavior in breast cancer survivors beginning adjuvant treatment. Results indicated that breast cancer survivors receiving a recommendation reported significantly higher self-reported PA (ie, approximately 30 min/wk) over a 5-week period than those not receiving a recommendation.

Most comparable to our study, Demark-Wahnefried et al[30] examined the effects of a home-based diet and exercise program delivered via telephone counseling and print materials in a mixed sample of 182 older breast and prostate cancer survivors. Results showed a significant improvement in self-reported diet quality but not in self-reported PA or QoL over a 6-month intervention period and a 6-month follow-up. Reasons for the difference in the PA findings between the two studies could be due to the use of different self-report measures of PA (the LSI versus the Community Healthy Activities Model Program for Seniors), different theoretical models to develop intervention materials (the theory of planned behavior *v* social cognitive theory and the transtheoretical model), our larger sample size (377 *v* 182), our shorter intervention period (3 *v* 6 months), our more homogeneous sample (breast cancer survivors *v* breast and prostate combined), and/or our younger sample (58 *v* 72 years old). In any case, our data suggest that simple and low-cost tools such as breast cancer–specific PM and/or objective PA monitoring devices may help breast cancer survivors increase their PA.

We found no change in objectively measured walking across all four groups. Pinto et al[31] found similar results in that their home-based PA intervention did not demonstrate significant effects on objective accelerometer data, whereas self-reported PA did increase. Pedometer-based interventions have yielded positive changes in pedometer step counts in individuals with type II diabetes[32] and those with chronic obstructive pulmonary disease[33]; however, these interventions included other behavior change strategies to complement the pedometer (eg, telephone counseling, meetings). There are at least two possible explanations for the null effect of our interventions on step counts compared with self-report brisk walking. First, survivors in our study were not advised to achieve a specific step count (ie, 10,000 steps) or to increase their number of steps per day. Given that all survivors were encouraged to engage in PA at least at a moderate intensity level, it is possible that survivors replaced light/casual walking steps with more moderate or purposeful steps to achieve the moderate intensity recommendation. Second, it is possible that our 7-day monitoring period at baseline and postintervention may not have been representative of PA during the entire 12-week intervention.

The likelihood that self-report or social desirability bias affected responses on the self-report PA questionnaires is of concern. If a response bias were present, however, we would have expected this bias across all four groups given that all groups were asked to increase PA and to provide self-report assessments of PA. Indeed, the 30-minute increase in PA we observed in the SR group (ie, control) may partly reflect this bias, which is why we selected an SR group as our comparison group. Moreover, recent research has suggested that there is minimal evidence of social desirability for the self-report exercise scale that we used.[34] Finally, poor compliance with the objective measure is also unlikely to explain this difference because we observed extremely high compliance with the 7-day baseline and postintervention objective measurements. Specifically, 97.3% (367 of 377) and 97.0% (328 of 338) of participants recorded their steps on all 7 monitoring days at baseline and postintervention, respectively.

The second main finding of our trial was that the COM intervention had a beneficial effect on QoL and fatigue compared with the SR group. The improvements in the COM group approached the minimal thresholds for clinically important differences for the FACT-B and Fatigue Scale (ie, 7.0 and 3.0 points, respectively)[35,36] and yielded standardized effect sizes in the small to moderate range. Given that our sample was on average 39 months post-treatment, it is likely that some items on the FACT-B may no longer be relevant (eg, "I have nausea"). Therefore, other QoL scales may be more sensitive to detecting changes in QoL in long-term breast cancer survivors (eg, Quality of Life in Adult Cancer Survivors[37]).

Our data suggest that PA behavior change modalities such as PM and a step pedometer may have beneficial effects on self-reported PA and QoL in breast cancer survivors. Combining PM with a pedometer showed the greatest benefits for QoL and fatigue. Additional research should determine if other distance-based strategies are effective in assisting survivors in becoming more physically active. The distance-based option is low cost (eg, print materials cost $14.00 US per participant and pedometers cost $16.00 US per participant) and may have greater generalizability and ecologic validity for long-term cancer survivors than clinic-based interventions. These programs can be implemented in most communities and may consequently benefit the greatest number of breast cancer survivors.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

The author(s) indicated no potential conflicts of interest.

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