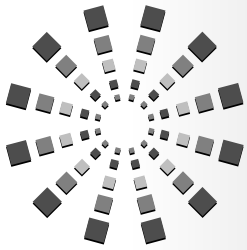

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A Brief Intervention for Fatigue Management in Breast Cancer Survivors

KEY WORDS
Breast cancer survivors
Coping
Energy level
Fatigue
Physical activity
Psycho-education
Quality of life

The purpose of this randomized control trial was to verify the effectiveness of a brief group intervention that combines stress management psycho-education and physical activity (ie, independent variable) intervention in reducing fatigue and improving energy level, quality of life (mental and physical), fitness ($VO_{2submax}$), and emotional distress (ie, dependent variables) in breast cancer survivors. This study applied Lazarus and Folkman stress-coping theoretical framework, as well as Salmon's unifying theory of physical activity. Eighty-seven French-speaking women who had completed their treatments for nonmetastatic breast cancer at a university hospital in Quebec City, Canada, were randomly assigned to either the group intervention (experimental) or the usual-care (control) condition. Data were collected at baseline, postintervention, and at 3-month follow-up. The 4-week group intervention was cofacilitated by 2 nurses. Results showed that participants in the intervention group showed greater improvement in fatigue, energy level, and emotional distress at 3-month follow-up, and physical quality of life at postintervention, compared with the participants in the control group. These results suggest that a brief psycho-educational group intervention focusing on active coping strategies and physical activity is beneficial to cancer survivors after breast cancer treatments.

Breast cancer is the most commonly occurring cancer among women in North America.[1,2] Fortunately, the survival rate has increased over the last 10 years.[1,2] Nevertheless, breast cancer treatments still have side effects that may negatively impact recovery and quality of life after initial treatments.[3] The most frequently reported side effect

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Supported by grant 03-1102-014404-104 from the "Fonds de recherche en santé du Québec" (FRSQ) and by an Investigator Award to Lise Fillion.

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Accepted for publication August 22, 2007.

of breast cancer survivors is fatigue, or low-energy level; it can persist for several months or years after the end of cancer treatments.[4–7] Indeed, more than 50% of survivors complain of persistent fatigue or low energy long after the treatments have ended.[8] This sole condition may seriously compromise survivors' quality of life.[9,10] Most patients (74%) seem to surrender to the idea that fatigue is inevitable after cancer and that it must be accepted.[8] Despite its strong prevalence and its adverse impact on quality of life,[8,9] fatigue is still generally neglected by oncology caregivers and often remains untreated.[10] This research focuses on the results of a randomized control trial aimed at alleviating fatigue and improving energy level, quality of life, fitness, and emotional distress in breast cancer survivors from a French-speaking community by providing them with a combined stress management/physical activity intervention. Before presenting our "Methods," "Results," and "Discussion" sections, the text that follows presents the theoretical frameworks on which this intervention is founded and then describes existing interventions that aim to alleviate fatigue.

Fatigue in Cancer Survivorship

Fatigue can be defined as "a subjective, unpleasant condition which incorporates total body feelings ranging from tiredness to exhaustion, creating an unrelenting overall condition which interferes with individuals' ability to function to their normal activity."[11(p524)] The National Comprehensive Cancer Network convened a panel of fatigue experts to define cancer-related fatigue as "a distressing, persistent, subjective sense of tiredness or exhaustion related to cancer or cancer treatment that is not proportional to recent activity and interferes with usual functioning."[12(pFT-1)] Others have related fatigue to perceived energy level, mental capacity, and psychological status.[13] It thus represents a multidimensional subjective phenomenon with physical, emotional, cognitive, and behavioral dimensions.[11,14,15] In the cancer literature, this phenomenon is, however, too often documented as a physical symptom associated to a pathological condition, whereas fatigue is a normal side effect of cancer treatment and is thus to be expected. To better represent the normative component of this phenomenon, often observed in the adjustment process after major events such as cancer diagnosis and treatments, an adaptation paradigm[16] is suggested. The main feature of Folkman and Moskowitz' paradigm is the inclusion of positive outcomes (eg, positive affect). Therefore, in addition to studying fatigue in breast cancer survivors, we decided to include energy level as a positive outcome.

Stress-Process Theory and Fatigue

Although little is known about the mechanisms underlying fatigue in breast cancer survivors,[8,17] the psychosocial factors associated with this phenomenon have been documented.[18,19] Several physical and psychological correlates of fatigue have been identified[2]; however, few theoretical or conceptual frameworks have been proposed to explain fatigue among cancer patients.[20] The multifactorial origin of fatigue surely contributes to this state of affairs. The first theoretical framework underlying this study is the stress-process theory[21,22] applied to fatigue.[16] From this theoretical framework, stress is the result of the appraisal of a situation or stressor that a person is experiencing. Appraisal is a cognitive process by which a person simultaneously evaluates the impact of a stressor (primary appraisal) and the capacity to cope with it (secondary appraisal). When the negative impact perceived exceeds the estimated coping capacity, stress is experienced. Fatigue can be conceptualized as a consequence of inefficient coping strategies and prolonged stress response.[23] Briefly, active coping strategies, be they emotional, behavioral, or cognitive, seem to be more efficient on both psychological and emotional outcomes than passive ones.[23–26] Incidentally, active coping strategies, such as stress management (eg, relaxation and problem solving), improving sleep hygiene (eg, planning), and physical activity (eg, active strategies), have shown to reduce fatigue and improve energy level (ie, feeling of vitality).[23,24] In contrast, passive coping strategies, such as increasing rest and sleep[27,28] and decreasing physical activity,[29] seem inefficient in relieving fatigue, in addition to creating a vicious circle of immobility and deconditioning, further contributing to more fatigue and low energy.[30]

In summary, given that passive coping strategies seem inefficient in reducing stress and that active coping has shown to relieve emotional distress, it is assumed that to alleviate cancer-related stress, one should help cancer survivors instigate active coping strategies. As a result, information on active coping strategies was selected for the stress management portion of the intervention examined in this article. (A brief description of the intervention is provided in the "Materials" subsection below.)

Unifying Theory of Physical Activity and Fatigue

Research on the effects of physical activity on healthy participants has shown an improved quality of life, stamina, and energy level.[31–34] It is therefore not surprising to find abundant numbers of studies on physical activity and fatigue. The term "physical activity" is used in this article to mean both regular, structured, leisure-time pursuit undertakings as well as domestic or occupation tasks.[35] Although fatigue and its mechanisms are yet to be thoroughly explained, research on the effects of physical activity on cancer-related fatigue has been summarized.[36,37] The American College of Sports Medicine[38] suggests the following theory: "the combined effects of cancer treatment and a decreased degree of physical activity during treatment cause a reduction in the capacity for physical performance. When patients must use greater effort and expend more energy to succeed in daily activities, fatigue levels increase."[36(p645–46)] Although this theory can contribute to the understanding of potential mechanisms, it only emphasizes the physiological dimension of fatigue and thus does not reflect the multidimensionality of the symptom.

To integrate current evidences on the effects of physical activity on biological and psychological dimensions, a unifying theory of physical activity was recently proposed by Salmon.[35] This is the second theoretical framework underlying the study. The unifying theory integrates 3 key elements: (1) physical activity can be distasteful to people, although it holds personal benefits, more likely realized when performed over long periods of time; (2) physical activity reduces depressive and anxiety-related symptoms; and (3) physical activity has shown to increase resistance to stress. According to this model, once an individual has developed some tolerance for the unpleasant aspect of the early stages of exercising, this person is more able to tolerate other stressors, such as returning to work after breast cancer treatment. In addition, the unifying theory suggests, in a simplified manner, that physical activity increases neurotransmitters' activities, thus increasing levels of serotonin, norepinephrine, and opioids. The psychological effects of these biological increments include a sense of having more energy, as well as feeling more in control and in a better mood.

Interestingly, physical activity does not invariably lead to either fitness or improved mood and anxiety. The factors that seem to be most significant in producing these beneficial effects are a level of intensity and type of physical activity that match the individual's preferences. That is to say, people are more likely to adhere to an exercise program or a regular physical activity if they like it and if they can practice it at an intensity level that corresponds to their actual abilities (for the detailed processes, please consult Salmon[35]). To summarize the unifying theory, the biological effects of physical activity partially explain the beneficial psychological effects of exercise, which, in turn, reinforce adherence and, ultimately, contribute to stress adaptation processes. It is on this evidence that the physical activity information of our intervention was established (see description of the intervention in the "Materials" subsection below).

Fatigue-Relieving Interventions

There is evidence supporting the efficacy of stress management interventions to decrease emotional distress and to improve overall quality of life including fatigue (for a review, see Ahlberg et al[20]). Stress management and psychosocial interventions (eg, relaxation training, meditation, psychoeducation, communication, and social support) conducted in a group format and over short durations (eg, 4 weeks and a weekend) seem effective in improving quality of life and fatigue in cancer patients.[39–41] In addition to quality of life and fatigue outcomes, psychosocial interventions generally documented positive impact on emotional distress, such as anxiety and depression symptoms. Similarly, and as previously mentioned, physical activity has recently provided some evidence of therapeutic benefits on fatigue, stamina, and energy level.[31,32,42] Moreover, several efficacy studies have shown that physical activity, mainly during treatments (eg, radiation therapy), also result in an improvement of fitness and quality of life[43–49] among women with breast cancer. In combining the literature from both fatigue-relieving approaches (ie, psychological and physical activity interventions), we selected the more sensitive outcomes: quality of life, fatigue, and emotional distress from psychological studies, and energy level and fitness from physical activity studies.

Despite benefits of stress management and physical activity on fatigue and quality of life among cancer treatment survivors, only one study, to our knowledge, examined the combination of both group psychotherapy and physical activity, compared with group psychotherapy alone, to reduce fatigue and improve quality of life and fitness among breast cancer survivors.[45] This pioneer study presented some limitations: the sample was heterogeneous (N = 96; mixed cancer sites, mixed disease severity, mixed treatments); it failed to control for psychosocial factors such as stress level at baseline and medical conditions that could affect the selected outcomes (eg, pain or other side effect symptoms); finally, it contained no follow-up measure to verify the long-term effects of the approach.

Therefore, to address the above-mentioned limitations, we adapted a group intervention that had proven effective in reducing stress in cancer patients and was founded on stress-coping theory.[50] The decision to offer a 4-week program rather than the regular 12-week intervention was taken for several reasons. First, it was important that the intervention be of a duration that would be manageable to individuals who were already weakened by their medical treatment and condition, thus attempting to avoid adding to their existing fatigue. Second, although research evaluating the effects of exercise on fitness recommends a minimum of 12 weeks to detect benefits,[38] our main intent was not the direct improvement of fitness per se but rather the development of an active coping behavioral strategy that is known to improve mood and lessen fatigue, that is, walking as physical activity and adherence to it. However, our design for follow-up intervention measurement integrated this 12-week component for the fitness issue. Third, increasing access to a nonpharmacological approach for breast cancer survivors has been identified as filling a need for cancer survivors.[51] Fourth, we were expecting that the "dosage" effect (combined stress management + physical activity), as evidenced in the study of Courneya et al,[45] would counteract the brevity of the intervention. That is, if we were to find long-term significant effects with a 4-week intervention, there would be no need to run a 10- or 12-week program and the efficiency criterion would be met.[52] Finally, offering a short intervention would decrease cancer center-based programs' costs and thus be more attractive to them. The 4-week psycho-education and physical activity intervention was hence facilitated by nurses and offered within or near the cancer centers where patients received their medical treatments.

Consequently, we hypothesized that a brief, nurse-lead intervention that combined information on active coping strategies and physical activity could be effective in managing this very prevalent and distressing condition that is fatigue. More specifically, it was predicted that the combined

program would reduce fatigue and improve energy level and mental and physical quality of life, and reduce emotional distress in breast cancer survivors, at both postintervention and 3 months later, as compared with patients who would receive usual care. Fitness ($VO_{2submax}$) was hypothesized to improve at 3-month follow-up for women in the experimental group as compared with participants in the control condition.

■ Methods

Study Sample and Recruitment

The study sample was constituted of women who had recently completed their radiotherapy treatments for breast cancer at a University Hospital located in the province of Quebec, Canada. The inclusion criteria were as follows: (1) being a woman diagnosed with an initial nonmetastatic breast cancer (breast cancer survivor); (2) having completed their initial breast cancer treatment no longer than 2 years before enrollment; (3) having received 1 series of adjuvant treatments of radiotherapy, or having received radiotherapy in combination with other adjuvant treatments (eg, chemotherapy or hormonal therapy); (4) understanding and speaking French; (5) passing the revised Physical Activity Readiness Medical Examination[53] to obtain the authorization of the supervising physician before performing the fitness assessment; (6) living near the cancer center and being available to take part in a series of 4 weekly sessions; and (7) accepting the randomization procedure. Excluded were participants who (1) showed clinical levels of depression symptoms, as measured by the Hospital Anxiety and Depression Scale (score higher than 10)[54,55]; (2) had insomnia, as defined by the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*[56];[a] (3) presented any symptoms of recurrence; and (4) had any known severe health problems other than cancer.

Calculations for the sample size was done by taking into account a fatigue estimate combined with a predictable attrition. Estimation of initial fatigue was based on the mean Multidimensional Fatigue Inventory (our measure of fatigue) score of 132 women with breast cancer toward the end of radiotherapy treatment,[23] which was 2.52 (SD = 0.67). Starting from this estimate, as well as an alpha error of 5% and a power of 80%, the sample size was evaluated at 30 participants per condition. Taking into account a potential attrition of 20%, the sample size was adjusted to 36 participants per condition, for a total of 72. Of the 498 patients eligible and invited to participate, 149 (30%) showed interest in participating in the study. The main reasons reported for refusal of participation were lack of time, not being tired, being already committed to other studies, or deploring that the study required too many trips to the hospital. Of the 149 participants who agreed to take part in the study for our recruitment time, 55 later declined or were excluded during the waiting period because they had no more time, had a cancer recurrence, or had a further deterioration of their physical or psychological condition. Accordingly, 94 (19%) participants met all eligibility criteria and were randomly assigned to the study conditions. Of these subjects, 7 withdrew for reasons reported on the flowchart (see Figure 1). Consequently, the data analysis was based on 87 participants. Therefore, we had the required power to test our main hypotheses.

Demographically, participants were mostly married (65.6%) and parents (71.3%), were equally distributed between levels of education (high school, 28%; college, 26%; university, 33%), lived in households in which the level of income was above $45,000, and were currently unemployed (72.4%; see Table 1 for details). Differences in patients' characteristics (see Table 2) are explicated in the results section.

Materials

INSTRUMENTS

Five outcome measures were assessed: fatigue, energy level, quality of life, fitness, and emotional distress. All measuring tools were in French and showed acceptable psychometric properties (see Table 3). Fatigue, the primary outcome, was measured with the General/Physical Fatigue subscale (7 items) of the Multidimensional Fatigue Inventory,[14,57] originally developed for use with cancer patients. The Vigor subscale (6 items) of the shortened Profile of Mood States[58,59] was used to assess energy level.

Quality of life was measured using the Medical Outcomes Study Short Form 12.[60,61] It provides 2 scores: a mental health and a physical health components. The French translation of the SF-36[62] was used to create the French version of the Medical Outcomes Study Short Form 12 by selecting the appropriate items indicated by the work of Ware et al.[61]

To measure fitness (a long-term effect outcome), the submaximal oxygen consumption ($Vo_{2submax}$) criterion measure of cardiorespiratory fitness[63] was estimated from the Single-Stage Treadmill Walking Test.[64] This submaximal treadmill walking test was adjusted according to individual fitness and age-predicted maximums.[b]

The assessment of emotional distress combines the mean scores of the anxiety and depression subscales of the Profile of Mood States.[58,59]

[a]Based on 4 (yes/no) questions adapted from the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* criteria: (1) Do you have any sleep difficulties? (2) Does it happen that you stay awake more than 30 minutes at night? (3) Does this happen 3 times or more a week? (5) Does this disrupt your daily functioning?

[b]$VO_{2submax}$ ($mL \cdot d'O_2 \cdot kg^{1} \cdot min^{1}$) = 15.1 + 21.8 (speed mph) - 0.27 (heart rate at the end of the test in bpm) - 0.263 (speed × age [year]) + 0.00504 (heart rate at the end of the test × age) + 5.48 (gender: where female = 0; male = 1).

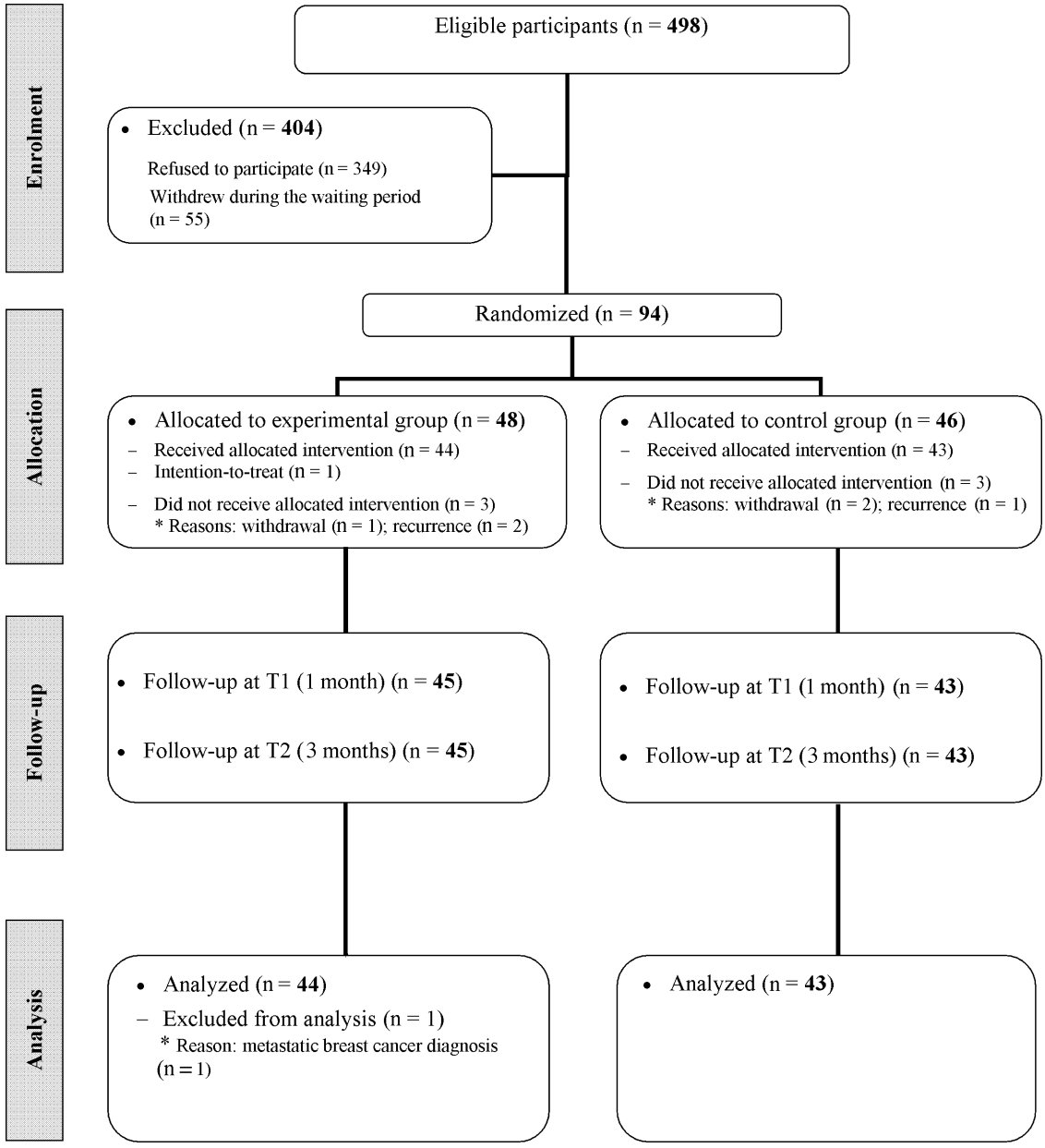

Figure 1 ■ The flow of participants through each stage of the randomized trial.

The sociodemographic and health status (ie, some potentially confounding variables), namely, age, marital status, parenthood, education, household income, employment status, hours of sleep per day, tobacco smoking, alcohol consumption, eating breakfast daily, and quality of food, were documented using a standardized questionnaire. The level of physical activity was estimated using the Actimeter,[65] a self-administered questionnaire measuring 3 physical activity categories: transportation, leisure time, and work (walking only), producing an overall score. Menopausal symptoms and pain were evaluated using 2 validated instruments: the Menopause-Specific Quality of Life Questionnaire,[66] which assesses vasomotor and physical menopausal symptoms, and the Brief Pain Inventory, which measures pain intensity.[67]

The medical data, namely, the number of days since the diagnosis and the end of treatments, body mass index, menopause stage, cancer stage, medication, affected lymph nodes, type of treatment, and type of surgery, were collected by a trained research nurse from the medical file of each participant according to a standardized grid for breast cancer.

To control for other potentially confounding variables, 3 measures of psychosocial stress were taken. First, cancer-related stressors were evaluated using the Inventory of Recent Life Experiences for Cancer patients,[68] consisting of 30 cancer-specific hassles. Second, cognitive appraisal and related symptoms of having cancer were measured using the Subjective Appraisal Rating Scale (10 items),[69] providing 2 factor-based scores (ie, perceived impact and mastery). Finally, coping

Table 1 • Patient Characteristics: Sociodemographic Variables at Baseline

Variable	Experimental Group (n = 44)		Control Group (n = 43)		*T* test or Chi-Square Test	Total Sample (N = 87)	
	M	(SD)	*M*	(SD)	*P*	*M*	(SD)
Age, y	53.09	(9.65)	51.84	(10.25)	.56	52.47	(9.91)
	n	(%)[a]	n	(%)[a]	*P*	n	(%)[a]
Marital status					.30		
Single, separated, divorced, widowed	8	(18.2)	12	(27.9)		20	(23.0)
Married	29	(65.9)	28	(65.1)		57	(65.5)
Living with other people	7	(15.9)	3	(7.0)		10	(11.5)
Parenthood	30	(68.2)	32	(74.4)	.52	62	(71.3)
Education					.82		
High school graduate	13	(29.5)	15	(34.9)		28	(32.2)
College graduate	13	(29.5)	13	(30.2)		26	(29.9)
University graduate	18	(40.9)	15	(34.9)		33	(37.9)
Household income (Canadian dollars)[b]					.23		
≤$14,999	2	(5.0)	3	(7.5)		5	(6.3)
$15,000–$29,999	1	(2.5)	6	(15.0)		7	(8.8)
$30,000–$44,999	6	(15.0)	5	(12.5)		11	(13.8)
≥$45,000	31	(77.5)	26	(65.0)		57	(71.3)
Employment status					.05[c]		
Full-time, part-time	8	(12.8)	16	(37.2)		24	(27.6)
Absence due to illness, retired, unemployed	36	(81.8)	27	(62.8)		63	(72.4)

[a]Due to rounding, percentages may not equal 100.
[b]Four participants in the experimental group and 3 participants in the control group did not answer the questions concerning income.
[c]Potentially confounding variable.

strategies were measured using the self-administered Coping With Health and Injury Problems (32 items),[61,70,71] which mainly evaluates active (instrumental and distraction) and passive (palliative and emotional preoccupation) coping.

INTERVENTION

The intervention content (in French only) has been previously published[42] and was summarized in a manual for participants. Briefly, the intervention was composed of 4 weekly group meetings of 2.5 hours and 1 short telephone "booster session" (5–15 minutes). One hour was devoted to the supervision of walking training by a kinesiologist or a trained research nurse, and 1.5 hours to the psycho-educative, fatigue management sessions, which were codirected by 2 oncology nurses. The nurses were trained in cognitive-behavioral approaches and were supervised by a health psychologist (approximately 10 hours, in addition to 6 hours of reading). The purposes of the stress/fatigue management program were (1) to acquire a broader definition of fatigue, (2) to develop relaxation skills, (3) to gain knowledge of effective coping strategies to deal with physical factors associated with fatigue (eg, circadian cycle and sleep hygiene), (4) to discover the links between thoughts, emotions, and fatigue; (5) to articulate ways to increase self-regulation techniques (eg, self-recording and goal setting) and apply them to individualized walking programs; and (6) to inform on how to further decrease passive coping strategies (eg, behavioral and social disengagement and naps). As home-based assignments for the stress/fatigue management component, participants were invited to practice relaxation and complete self-rating records of it.

The walking portion of the program included behavioral strategies and cognitive strategies. The *behavioral strategies* included (1) a personal-physical exercise program was established by the kinesiologist for each participant according to their physical condition and personal goal; (2) a written contractual agreement to try out a new strategy for a short period of time constituted the starting prescription (eg, frequency and intensity were indicated); (3) an initial training session and supervision of the exercise intensity (ie, using a Polar heart rate monitor for objective feedback) was first done at the hospital after the initial physical assessment and the contract agreement; (4) participants were encouraged to perform their home-based assignments (eg, walking program individualized in terms of intensity and frequency); (5) an ambulatory device was provided to each participant to self-monitor his or her cardiac function during home-based exercises and complete his or her personal log between sessions (ie, the Polar heart rate wristwatch); and (6) the contractual agreement was revised each week by the kinesiologist during the walking session.

The walking prescription progressed differently for each participant according to their physical condition and personal goal. The *cognitive strategies* included (1) awareness of the

Table 2 • Patient Characteristics: Health and Medical Variables at Baseline

Variable	Experimental Group (n = 44) M	(SD)	Control Group (n = 43) M	(SD)	*T* test or Chi-Square Test *P*	Total Sample (N = 87) M	(SD)
Hours of sleep per day	7.24	(1.43)	7.62	(1.79)	.27	7.43	(1.62)
Number of days since the diagnosis[a]	256.7	(101.5)	256.8	(112.7)	.99	256.7	(106.6)
Presence of pain (Brief Pain Inventory)	1.38	(1.67)	1.08	(1.85)	.43	1.23	(1.76)
Menopausal symptoms (MENQOL)							
Vasomotor symptoms	3.04	(1.85)	2.98	(1.75)	.88	3.01	(1.79)
Physical symptoms	2.04	(0.95)	1.69	(1.10)	0.12[b]	1.87	(1.04)
	n	(%)[c]	n	(%)[c]	*P*	n	(%)[c]
BMI, kg/m^2[d]					.49		
<18.5	0	(0.0)	3	(7.3)		3	(3.5)
18.5–24.9	24	(54.5)	20	(48.8)		44	(51.8)
25.0–29.9	14	(31.8)	12	(29.3)		26	(30.6)
30.0–34.9	5	(11.4)	5	(12.2)		10	(11.8)
35.0–39.9	1	(2.3)	1	(2.4)		2	(2.4)
Tobacco smoking	4	(9.1)	7	(16.3)	.31	11	(12.6)
Alcohol consumption	34	(77.3)	31	(72.1)	.58	65	(74.7)
Eating breakfast daily	41	(93.2)	38	(88.4)	.44	79	(90.8)
Quality of food					.57		
Excellent	8	(18.2)	12	(27.9)		20	(23.0)
Very good	23	(52.3)	18	(41.9)		41	(47.1)
Good	9	(20.5)	8	(18.6)		17	(19.5)
Average	3	(6.8)	5	(11.6)		8	(9.2)
Bad	1	(2.3)	0	(0.0)		1	(1.1)
Physical activity level (Actimeter)[e]					.15[b]		
Active	16	(36.4)	23	(56.1)		39	(45.9)
Moderately active	11	(25.0)	6	(14.6)		17	(20.0)
Somewhat active	12	(27.3)	11	(26.8)		23	(27.1)
Barely or not active	5	(11.4)	1	(2.4)		6	(7.1)
Menopause stage					.86		
Premenopausal	5	(11.4)	4	(9.3)		9	(10.3)
Perimenopausal	21	(47.7)	23	(53.5)		44	(50.6)
Postmenopausal	18	(40.9)	16	(37.2)		34	(39.1)
Cancer stage					0.11[b]		
0	2	(4.5)	4	(9.3)		6	(6.9)
I	21	(47.7)	17	(39.5)		38	(43.7)
II	18	(40.9)	12	(27.9)		30	(34.5)
III	3	(6.8)	10	(23.3)		13	(14.9)
Medication	37	(84.1)	40	(93.0)	.19	77	(88.5)
Affected lymph nodes	13	(29.5)	14	(32.6)	.76	27	(31.0)
Type of treatment[f]							
Chemotherapy	24	(54.5)	25	(58.1)	.74	49	(56.3)
Radiation therapy	44	(100)	43	(100)	NA	87	(100)
Hormonal therapy (tamoxifen, nolvadex, zoladex, arimidex)	29	(65.9)	35	(81.4)	.10[b]	64	(73.6)
Bone marrow transplant	0	(0.0)	0	(0.0)	NA	0	(0.0)
Surgery	43	(100)	43	(100)	NA	86	(100)
Type of surgery							
Lumpectomy (partial mastectomy)	42	(95.5)	33	(76.7)	.01[b]	75	(86.2)
Total mastectomy	2	(4.5)	10	(23.3)	.01[b]	12	(13.8)
Axillary dissection	22	(50.0)	27	(62.8)	.23	49	(56.3)

Abbreviations: BMI, Body Mass Index; MENQOL, Menopause-Specific Quality of Life Questionnaire; NA, not applicable.
[a]Information regarding the number of days since the diagnosis was not available for 1 participant in the experimental group.
[b]Potential confounding variable.
[c]Due to rounding, percentages may not equal 100.
[d]Two participants in the control group did not answer questions concerning BMI.
[e]Two participants in the control group did not answer questions concerning physical activity level.
[f]Information pertaining to surgery was not available for 1 participant in the experimental group.

Table 3 • Instruments Used in the Randomized Control Trial

Instrument	Subscale	Anchors	No. Items	Psychometric Property[a]
Outcome variables				
MFI[14,57]	General/Physical Fatigue	1 (no, that is not true) to 5 (yes, that is true)	7	α = .90
POMS[58,59]	Vigor	0 (not at all) to 4 (a lot)	6	α = .88
SF-12[61]	—	Combines: yes/no; 1 (excellent) to 5 (bad); 1 (significant limitations) to 3 (no limitations); 1 (all the time) to 5 (rarely)	12	α = .89
POMS[58,59]	Psychological Distress: Anxiety + Depression	0 (not at all) to 4 (a lot)	14	α = .92
Potentially confounding variables				
Actimeter[65]	—	1 (once a week or more) to 3 (rarely/never); 1 (1 day a week) to 7 (7 days a week)	23	κ = .75 test-retest
MENQOL[66]	Vasomotor symptoms	0 (no problem) to 6 (significant problem)	6	α = .90
	Physical symptoms	0 (no problem) to 6 (significant problem)	6	α = .84
Brief Pain Inventory[67]	—	0 (no pain) to 10 (very intense pain)	4	α = .88
IRLE-C[68]	—	1 (not at all part of my life) to 4 (very much part of my life)	30	α = .94
SARS[69]	Perceived impact	1 (not at all) to 8 (extremely)	5	α = .78
	Mastery	1 (not at all) to 8 (extremely)	5	α = .63
CHIP[61,70,71]	Active coping	1 (not at all) to 5 (very much)	16	α = .79
	Passive coping	1 (not at all) to 5 (very much)	16	α = .76

Abbreviations: CHIP, Coping With Health and Injury Problems; IRLE-C, Inventory of Recent Life Experiences for Cancer patients; MENQOL, Menopause-Specific Quality of Life Questionnaire; MFI; Multidimensional Fatigue Inventory; POMS, Profile of Mood States; SARS, Subjective Appraisal Rating Scale; SF-12, Medical Outcomes Study Short Form 12.

[a]The reported psychometric properties are those provided by the original authors.

benefits of exercise, focus on the benefits rather than the elimination of negative life circumstances (eg, exercise can be promoted as an activity that will result in more energy, rather than one that will reduce fatigue); (2) awareness of immediate outcomes from exercising (eg, enhance mood and energy, rather than long-term changes such as weight); (3) adherence techniques and focusing on the fact that one has considerable choice and control related to exercise; and (4) feedback on physical activity from nurses at each management session and support to reinforce self-efficacy, motivation, and positive outcomes. The cognitive strategies were mostly included in the psycho-education management sessions colead by nurses. Alongside the individually prescribed walking program, another behavioral active coping strategy was proposed: Participants received 20-minute, muscle-relaxation recordings and were invited to listen to them daily.

The only booster telephone session occurred midway between the end of the intervention and the follow-up measurement at 3 months, that is, between the seventh and eighth week after completing the intervention. This booster telephone session was conducted by facilitating nurse and its purpose was to verify whether the participants pursued their walking program, encourage them to do so, and identify obstacles to walking if they were not.

The stress management sessions were audiotaped in order to validate the information provided, that is, to ensure that the content was as planned. The audiotapes were listened to by 2 research assistants, and interreliability was verified.

Procedures

The randomized controlled trial included 3 measurement intervals: baseline (T0), immediately after the intervention (T1), and a 3-month follow-up (T2). The flow of participants through each stage of the trial is illustrated in Figure 2. The 4-week intervention, in addition to 1 telephone booster session, was the exposure/independent variable. Although they were waiting for their daily radiation therapy at the cancer center, a staff member invited the patients to meet a research assistant. The research assistant assessed eligibility, explained the study and the randomization procedure, and obtained informed consent for those who agreed to participate. When a sufficient number of participants was reached (4–10 per group), a cohort of randomized participants was started. The research assistant administered a first telephone interview (T0) to schedule an appointment for a physical fitness evaluation. The kinesiologist then administered an electronic version of the Actimeter, performed an evaluation of body composition and physical fitness, and randomly assigned each participant to either the control or experimental group using sealed envelopes, which were concealed to both kinesiologist and patient until then. The sequence of randomization was computer generated, after a preliminary stratification, according to the adjuvant treatments received (ie, radiotherapy only or both radiotherapy and chemotherapy). The women from both conditions (experimental and control) received the conventional medical follow-up for

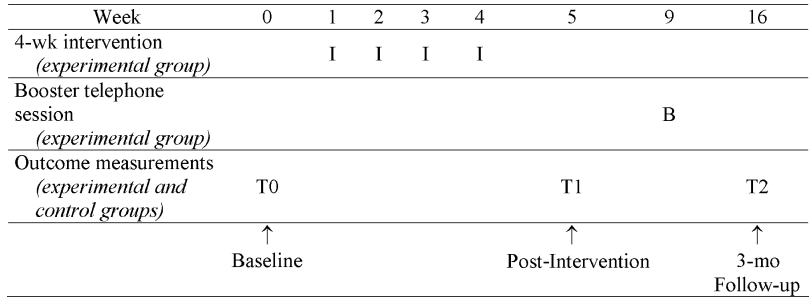

Figure 2 ■ Intervention protocol. I indicates intervention; B, booster telephone session.

breast cancer treatments. In addition to this usual care, the experimental-condition participants were invited to take part in a stress management/physical activity group intervention. Telephone interviews and fitness tests were repeated at T1 and T2 for all participants. The research protocol received approbation from the ethics board of the hospital center.

■ Results

Preliminary Analysis

Equivalence between the experimental and control groups on sociodemographic, health, medical, and psychosocial stress variables was first determined using *t* tests (2-tailed) for continuous variables and chi-square tests for discrete variables, applying a significance level of $P = .15$, thus ensuring that confounding variance be removed. Significant differences between groups were observed for the following variables: employment status, physical activity level, physical menopausal symptoms, cancer stage, hormonal therapy, and partial and total mastectomy (see Tables 1 and 2 for more detail about demographic and health variables). The association between these potentially confounding and outcome variables was further investigated using stepwise multiple regression analyses. Only "physical menopausal symptoms" was retained and then included in the main analyses as a covariate.

Both groups were equivalent on psychological stress variables (see Table 4) and showed a level of stress coherent with breast cancer survivors reported in a previous study.[23] No significant differences ($P < .05$) between the study conditions on any of the stress-related variables were found. Finally, at baseline, the participants showed a moderate intensity of fatigue and energy level (see Table 4). Physical fitness of the participants was moderate, whereas quality of life was slightly below average as compared with the general US population.[61]

The participants in the experimental group were encouraged to continue their walking program after completion; however, no monitoring of their adherence was kept. Finally, 100% of the sessions were reviewed for validation; 96% of the planned content was taught.

Main Analysis

All outcome variables, namely, fatigue, energy level, quality of life, fitness, and emotional distress were analyzed similarly on an intention-to-treat basis (ie, all participants with complete interview sets—3 times) according to their assigned conditions regardless of adherence. Mixed-model analyses of covariance (ANCOVA) were used to assess the effects of the intervention on each outcome variable, after adjusting for the baseline scores and potential covariates. The between-subject independent variable is the intervention (experimental and control groups), whereas the within-subject variable is time (ie, baseline, postintervention, and 3-month follow-up). Significance was established at $\alpha = .05$ level of probability. Effect sizes are reported as Cohen *d* in tables. Version 11.5 of SPSS was used for statistical analysis.

Marginal Group × Time interaction effects (ANCOVA; see Figures 2 and 3) emerged for fatigue (see Figure 3) and physical quality of life (see Figure 4), and significant Group and Time main effects were obtained for both fatigue and physical quality of life. Simple effect contrasts revealed a significant Group difference at T2 for fatigue and at T1 for physical quality of life. That is, women who received the intervention showed a significantly higher level of physical quality of life immediately after the intervention (T1) and a lower level of fatigue at follow-up, compared with women in the control group (see Table 4 for means and standard deviations and Tables 5 and 6 for F, *P*, and Cohen *d* values). The same analyses conducted on mental quality of life showed no interaction or main effects, thus demonstrating that both conditions improved in a similar manner on mental quality of life overtime ($P > .05$). However, an ad hoc simple effect contrast revealed a significant effect at follow-up, $F_{1,83} = 4.37$, $P = .04$ (see Table 5), indicating that the experimental group's mental quality of life improvement was more important than that of the control group.

As expected, a mixed-model ANCOVA revealed significant Group × Time interaction (see Table 5 and Figure 5), as well as Group and Time main effects for energy level (ie, energy level; see Table 3 for means and standard deviations and Table 5 for F, *P*, and Cohen *d* values). Simple effect contrasts indicated that improvement in energy level was marginal at T1 and significant at T2 (see Table 5). An examination of the means showed that women who received the intervention

Table 4 • Patient Characteristics: Psychosocial Stress and Outcome Variables at Baseline, Postintervention and Follow-up

	Baseline					Postintervention				Follow-up			
	Experimental Group (n = 44)		Control Group (n = 43)			Experimental Group (n = 44)		Control Group (n = 43)		Experimental Group (n = 44)		Control Group (n = 43)	
Variable	*M*	(SD)	*M*	(SD)	*P*	*M*	(SD)	*M*	(SD)	*M*	(SD)	*M*	(SD)
Psychological Stress													
Active coping (CHIP)	3.80	(0.50)	3.77	(0.54)	.77	3.79	(0.59)	3.67	(0.53)	3.97	(0.62)	3.76	(0.77)
Distraction	3.68	(0.67)	3.54	(0.64)	.32	3.66	(0.75)	3.53	(0.56)	3.87	(0.64)	3.60	(1.29)
Instrumental	3.93	(0.55)	4.01	(0.55)	.52	3.92	(0.59)	3.82	(0.63)	4.08	(0.87)	3.93	(0.49)
Passive coping (CHIP)	3.15	(0.56)	3.17	(0.46)	.82	2.98	(0.52)	2.94	(0.54)	2.94	(0.49)	2.93	(0.45)
Palliative	3.34	(0.54)	3.26	(0.50)	.44	3.17	(0.50)	3.10	(0.56)	3.26	(0.54)	3.07	(0.49)
Emotional preoccupation	2.95	(0.83)	3.09	(0.71)	.42	2.79	(0.74)	2.79	(0.79)	2.61	(0.68)	2.78	(0.76)
Appraisal (SARS[a])													
Perceived impact	4.69	(1.42)	5.00	(1.38)	.30	4.62	(1.17)	4.78	(1.37)	4.28	(1.26)	4.74	(1.63)
Mastery	5.22	(1.22)	5.32	(1.18)	.70	5.21	(1.36)	5.08	(1.14)	5.42	(1.41)	5.32	(1.23)
Stressors (IRLE-C)	1.65	(0.38)	1.70	(0.40)	.55	1.55	(0.40)	1.64	(0.38)	1.40	(0.32)	1.58	(0.39)
Outcomes													
Fatigue (MFI)	2.97	(0.87)	3.01	(0.95)	.83	2.65	(0.92)	2.86	(0.83)	2.40	(0.84)	2.75	(0.93)
Energy level (Vigor-POMS)	2.23	(0.76)	2.17	(0.87)	.78	2.41	(0.72)	2.14[b]	(0.87)	2.63[b]	(0.72)	2.24[b]	(0.88)
Quality of life (SF-12)													
QOL-Physical (PCS-12)	40.49	(9.50)	40.00	(9.43)	.81	45.10	(10.42)	41.76	(9.76)	46.76	(9.24)	44.64	(11.05)
QOL-Mental (MCS-12)	49.05	(8.56)	45.96	(9.01)	.11	48.54	(7.91)	47.49	(9.08)	51.38	(7.57)	47.96	(9.30)
Fitness (Vo_{2max})[c]	25.51	(4.70)	25.59	(6.04)	.85	27.04	(4.39)	26.53	(5.81)	28.10	(4.74)	27.86	(5.65)
Psychological distress (POMS anxiety + depression)	11.83	(4.23)	12.70	(4.09)	.47	12.51	(4.63)	12.64	(4.02)	11.15[c]	(3.85)	13.13	(5.44)

Abbreviations: CHIP, Coping With Health Injuries and Problems; IRLE-C, Inventory of Recent Life Experiences for Cancer patients; MFI, Multidimensional Fatigue Inventory; MCS-12, SF-12 Mental Component Summary; PCS-12, SF-12 Physical Component Summary; POMS, Profile of Mood States; QOL, quality of life; SARS, Subjective Appraisal Rating Scale; SF-12, Medical Outcomes Study Short Form 12; Vo_{2max}, maximal oxygen consumption.

[a]One participant in the experimental group did not complete SARS (impact and mastery).

[b]One missing value in that group.

[c]Information relating to fitness (Vo_{2max}) was not available for 4 participants in the control group and 1 participant in the experimental group.

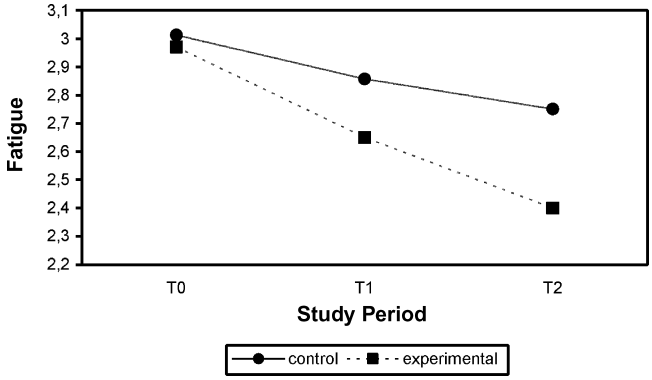

Figure 3 ■ Marginal effect of Time by Group interaction for fatigue.

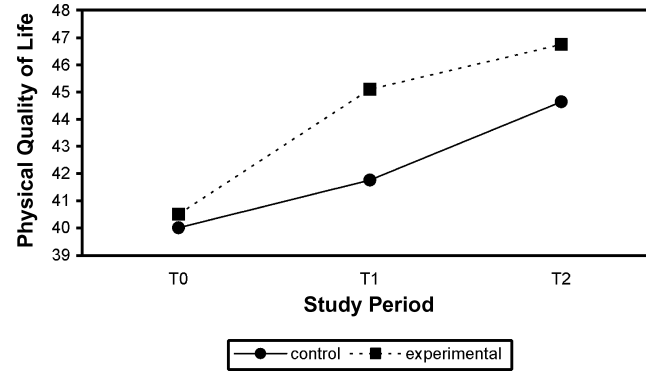

Figure 5 ■ Marginal effect of time by group interaction for physical quality of life (PCS-12).

experienced higher energy level than participants in the control group, particularly at the 3-month follow-up.

To evaluate whether the intervention affected the participants' level of fitness, a mixed-model ANCOVA was performed. The analysis demonstrated no Group × Time interaction effect and no Group and Time main effects (see Table 4 for means and standard deviations and Table 5 for F and *P* values). An examination of the means indicates that both groups improved equally on fitness.

A reduction in emotional distress (ie, combined Profile of Mood States depression/anxiety items) was predicted both immediately after the intervention and at follow-up. A mixed-model ANCOVA (adjusting for physical menopausal symptoms) on emotional distress was conducted. No interaction or Time main effects for emotional distress emerged, meaning that, overall, the participants' level of distress did not change over time (see Table 5 for F, *P*, and Cohen *d* values). However, a Group main effect was revealed (see Table 5). When examining pairwise comparisons, emotional distress significantly differed at follow-up (Control M = 13.13, SD = 5.44; Experimental M = 11.15, SD = 3.85), thus revealing that the participants exposed to the intervention experienced less distress (ie, less combined depression and anxiety symptoms) at 3-month follow-up compared with those in the control condition.

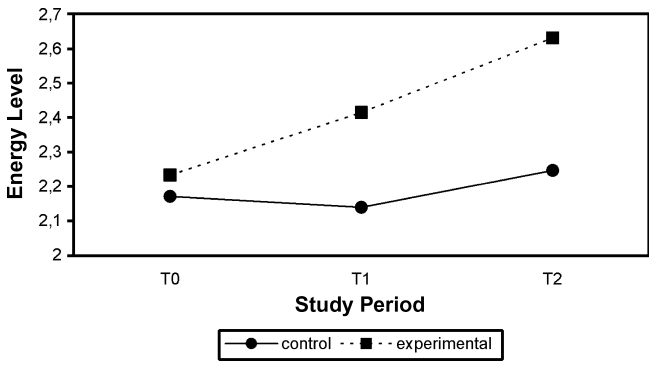

Figure 4 ■ Significant effect of Time by Group interaction for energy level.

■ Discussion

This study is the first to evaluate the effectiveness of a brief (4-week) intervention that combined stress management and physical activity to reduce fatigue and increase level of energy, quality of life (mental and physical), fitness ($Vo_{2submax}$), and emotional distress in breast cancer survivors. The ultimate objective in developing such a brief intervention to address breast cancer treatment side effects (eg, fatigue, depression, anxiety, and lowered functionality) was to provide a practical and easily applicable approach, which would become part of available, accessible, and validated survival treatments in cancer treatment centers. In other words, we were interested in providing both an effective and efficient intervention.[52] Our decision to test an intervention in which 2 approaches are combined (ie, stress management and physical activity) was 2-fold. On the one hand, stress management and psychosocial interventions, although effective, mainly address the emotional and social well-being of cancer treatment survivors,[39,40] leaving out physical and functional problems encountered in the same population. Focusing on the functional activity, physical exercise programs do quite the opposite. On the other hand, existing evidence for either approach shows that, separately, they positively affect fatigue and other relevant outcomes.[34] For all of these reasons, a brief, combined approach was put forth.

As predicted, the intervention helped improve both fatigue and energy level at 3-month follow-up. Incidentally, Cohen *d* revealed medium effect sizes of 0.48 and 0.58 for fatigue and energy level, respectively. It is hypothesized that the marginal effect in reducing fatigue and of increase in energy level immediately after the intervention could be that physical activity, as well as relaxation, requires a certain amount of time before having a positive impact on fatigue and energy level and/or that those who were exposed to active coping and exercise continued to apply their newly acquired skills and thus gain significantly more over time. It is also possible that the efforts demanded by their participation (eg, commuting and attending) affected the patients' level of fatigue and energy while participating in the intervention, a demand that

Table 5 • Interaction,[a] Main Effects, and Effect Sizes for Fatigue, Energy Level, Quality of Life, and Emotional Distress Outcomes

	Main Effects						Interaction		
	Time			Group			Group × Time		
Variable	F	*P*	*d*[b]	F	*P*	*d*	F	*P*	*d*
Fatigue (MFI)	10.00	.0001	0.69	5.03	.03	0.49	2.69	.07	0.36
Energy level (Vigor-POMS)	20.37	.0001	0.98	6.77	.01	0.56	3.71	.03	0.42
QOL (SF-12)									
PCS-12	19.33	.0001	0.95	4.30	.04	0.45	2.44	.09	0.34
MCS-12	20.64	.0001	0.99	0.65	.42		1.25	.29	
Fitness (Vo_{2max})	5.49	.006	0.51	0.09	.77		0.75	.48	
Emotional distress (POMS anxiety + depression)	0.85	.92		4.56	.04	0.46	2.26	.11	0.33

Abbreviations: MCS-12, SF-12 Mental Component Summary; MFI, Multidimensional Fatigue Inventory; PCS-12, SF-12 Physical Component Summary; POMS, Profile of Mood States; QOL, quality of life; SF-12, Medical Outcomes Study Short Form 12; Vo_{2max}, maximal oxygen consumption.
[a]Baseline value and physical menopausal symptoms as covariates.
[b]Cohen *d*, a measure of effect size.

had dissipated at follow-up. These findings are consistent with previous investigation[39,45] on the efficacy of interventions on fatigue and energy level, conducted with breast cancer survivors.

The continued decrease in fatigue after termination is considered a strength of our intervention. That is, although the intervention was brief as compared with standard psychological and exercise programs (the American College of Sports and Medicine recommends at least 12 to 15 weeks), it seems that the expected beneficial effects started taking place during the course of the intervention and became significant within a few months after the patients' exposure to it. As we are looking to put in place means that will reflect efficiency's "gold standards," our intervention would match them in several ways: the group format (ie, low cost), its brevity (ie, low cost), its accessibility (ie, same cancer center where treatment was provided), generalizability (ie, offered by oncology nurses who already practice on site, rather than psychologists or social workers), and validity (ie, effectiveness).

Regarding fitness, our findings are also consistent with a recent study[46] conducted with cancer survivors from mixed cancer sites, comparing a 10-week combined group psychotherapy plus concurrent home-based physical activity program to group psychotherapy only. Similarly to our findings, that study reported that fitness improved equally in both groups. Although no significant improvement in fitness ($Vo_{2submax}$) was found in the current investigation and in the study of Courneya et al,[46] such outcomes are rather encouraging for women with breast cancer. It suggests that in the months after the end of treatments, women improve their fitness, regardless of whether or not they received the

Table 6 • ANCOVA[a] Simple Effects Contrasts for Fatigue, Energy Level, Quality of Life, and Emotional Distress Outcomes

	Simple Effects Contrasts												
	Time Effects				Group Effects								
	T0 vs T1		T0 vs T2		T1			T2			T3		
Variable	F	*P*	F	*P*	F	*P*	*d*	F	*P*	*d*	F	*P*	*d*
Fatigue (MFI)	16.75	.001	11.08	.001	2.28	.14		4.97	.03	0.48	0.46	.50	
Energy level (Vigor-POMS)	21.21	.0001	36.80	.0001	2.74	.10	0.36	7.13	.01	0.58	0.761	.39	
QOL (SF-12)													
PCS-12	18.00	.0001	36.25	.0001	4.68	.03	0.47	2.04	.16		0.21	.65	
MCS-12	27.62	.0001	32.42	.0001	0.01	.92		1.91	.17		2.15	.15	
Fitness (Vo_{2max})	8.83	.004	10.01	.002	1.00	.32		0.02	.90		0.82	.37	
Emotional distress (POMS anxiety + depression)	0.14	.71	0.12	.72	0.75	.39		1.27	.26		4.37	.04	0.45

Abbreviations: ANCOVA, analyses of covariance; MCS-12, SF-12 Mental Component Summary; MFI, Multidimensional Fatigue Inventory; PCS-12, SF-12 Physical Component Summary; POMS, Profile of Mood States; QOL, quality of life; SF-12, Medical Outcomes Study Short Form 12; Vo_{2max}, maximal oxygen consumption.
[a]Baseline value and physical menopausal symptoms as covariates.
[b]Cohen *d*, a measure of effect size.

intervention. This improvement could also be explained by an awareness of one's physical shape triggered during the fitness evaluation itself; that is, the fitness test (ie, outcome variables measured preintervention, postintervention, and follow-up) could be a minimal intervention and, thus, a source of motivation to increase physical activity and improve fitness (ie, measurement effect).

Moreover, despite the brevity of the combination intervention, it contributed to the reduction of depression and anxiety symptoms (ie, emotional distress) over time (ie, 3 months later), which is consistent with reported effects of physical activity[35] and stress management.[16,22]

Our study adds to several recent findings and supports the hypothesis that patients may benefit from increased stress management (ie, active coping strategies) and physical activity after cancer treatment. Several self-management techniques may be taught by trained and supervised nurses and become part of routine supportive care at very low additional costs for the healthcare system. Training and supervision of nurses involves minimal time and initial investment for mental health professionals such as health psychologists who are often less available in our medical system to provide psycho-educational group interventions compared with nurses who could be assigned such tasks. In addition to the mental health professionals, our intervention required a consultation with a kinesiologist or a certified fitness appraiser for help in evaluating physical fitness, as well as designing and supervising an effective individualized walking program for cancer survivors. Indeed, the beneficial effect of physical activity in cancer patients may vary as a function of the patient's age, medical treatment, current lifestyle, and current level of physical fitness.[32] It is recommended that the intensity, duration, frequency, and type of exercise be adapted to each cancer patient.[35,72] Finally, it is hoped that a brief group intervention such as this serves as a preventive approach; that is, breast cancer patients be exposed to this intervention before and during treatment to prevent fatigue and maintain quality of life.

Although the current study is unique, study limitations must be taken into consideration when interpreting the results and planning research. First, the sample is limited in its representation of the population, which constraints the results' generalizability. Such limitation is often raised with this type of study because participants in breast cancer research tend to be resource affluent and well educated, as was the case in our sample. The low participation rate and characteristics of our sample are also reported in studies in which participation requires time or travel beyond what is required for standard medical treatment. Conversely, better participation is observed if the proposed intervention is provided as standard of care.[51] Therefore, to increase participation rate and, consequently, representation, those complementary interventions should be presented as adjuvant therapy, as suggested by Cunningham and Emonds.[41] The choice to focus on the measurement of fitness (ie, submaximal exertion and $Vo_{2submax}$) as an outcome is also a limitation. First, this measure is influenced by genetic inheritance. Second, knowing that fitness is not associated with better mood and that anaerobic and aerobic exercises are just as efficient at reducing fatigue and improving energy level and functionality,[35] a tool that would better reflect cancer patients' improvement in terms of physical functioning would a measure of functionality, that is, the patients' ability to engage in daily activities. Another limitation of our intervention, and possibly a confounding variable, would be the effects of nonspecific therapeutic processes such as engagement and social interaction. The participants in the experimental group spent more time (one-third) with the experts involved in the study, such as the facilitating nurses and the kinesiologist, encountering more social interaction than the control group. Further research aiming at disentangling the potential confounding effects of greater time and attention given to participants, as well as group cohesion,[73] is recommended. Additional limitations regard the absence of measurement of other physical activities performed (eg, vacuuming and walking upstairs/downstairs) and adherence to the planned walking program, thus limiting group comparisons and generalizability. Finally, another limitation concerns the multilevel aspect of the intervention. The intervention's benefits could not be clearly quantified for the psycho-educative versus the exercise component. Therefore, future studies should examine the impact of each component alone, as well as combined, in the same design.

In spite of these limitations, offering a brief and multidisciplinary intervention after medical cancer treatment seems a promising avenue to reduce fatigue and improve quality of life, energy level, and emotional distress among cancer survivors. Finally, it could contribute to the prevention of cases where fatigue becomes a chronic problem and a major source of morbidity and invalidity.

ACKNOWLEGMENTS

The authors thank their nursing research trainees, Sylvie Côté, Anne-Marie Gagnon, Geneviève Gosselin, Charlène Joyal, and Manon Savoie, for their participation in the recruitment and data collection. They thank their research collaborators, Jean Cleroux, Josiane Leblanc, Annick Millette, and Frank Perna, for their help in developing and implementing the walking exercise program. Finally, the authors are grateful to Marie de Serres, clinician nurse in oncology, and all the radiation oncology staff for their support in the implementation of the study in the clinical setting.

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