Randomized pilot test of a lifestyle physical activity intervention for breast cancer survivors

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Abstract

Objective: This paper will report the results of a pilot test of a 6-month, 21-session intervention to increase breast cancer survivors’ physical activity by teaching them to incorporate short periods of moderate activity into their daily routines (lifestyle intervention). The effect of the intervention on physical performance, quality of life, and physical activity are reported.

Methods: Sixty breast cancer survivors were randomized to either a lifestyle intervention or a standard care control group. Physical performance, quality of life (Medical outcomes study short form-36 [SF-36]), and physical activity (7-day recall and motivation readiness), were assessed at baseline and 6 months.

Results: The lifestyle group had significantly better performance in the 6-min walk task than the controls ($p = 0.005$) at 6 months. The intervention had positive effects on the bodily pain ($p = 0.020$) and general health ($p = 0.006$) subscales from the SF-36. The lifestyle group had a greater motivational readiness for physical activity at 6-month than standard care, but no significant differences were seen between the two in terms of number of minutes of moderate or more intense physical activity or number of days on which they did ≥30 min of moderate or more intense activity.

Conclusions: Despite the small sample size, the lifestyle intervention showed promise for improving physical functioning and quality of life and increasing physical activity, and should be tested in a larger randomized trial.

Practice Implications: If the lifestyle approach is shown to be effective in a larger trial, it represents a highly feasible intervention that can be delivered to cancer survivors by health care institutions or community organizations without dedicated exercise facilities and equipment.

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Keywords: Breast cancer; Physical activity; Adherence; Cancer survivors; Quality of life; Physical functioning

1. Introduction

Exercise improves breast cancer survivors’ physical and psychological functioning [1-4]; it may reduce the risk of cancer recurrence [5], second primary cancers and other chronic diseases [6-8], as well as prolong survival [5].

Research with cancer survivors has demonstrated that exercise increases muscle strength [9] and cardiovascular fitness [10,11], improves physical functioning [11,12], helps to control body weight [11], decrease body fat [13,14], and lower blood pressure [15]. Exercise may also alleviate symptoms that interfere with the daily life of cancer patients and survivors, such as fatigue [9,10,16-19], nausea [18], and sleep disturbance [12]. Associations between exercise and emotional well-being have been documented in observational research [20,21] and quasi-experimental [18,22] and randomized studies [10,12,15,16] involving cancer patients
and survivors, although most trials have not controlled for the possible emotional benefits of factors other than exercise, such as attention from the intervention staff.

There is emerging evidence that exercise and physical activity are beneficial for cancer survivors; the evidence is particularly compelling for breast cancer survivors [23]. Currently published clinical trials of exercise in cancer survivors have primarily prescribed uniform, structured, and often gym-based exercise programs that meet these requirements. Structured exercise interventions generally require participants to come to a center to exercise at a specified duration and frequency (e.g., 30 min four times per week). However, research in the general population indicates that structured exercise programs pose significant barriers to long-term adherence. If these barriers, which include a lack of access to facilities and equipment, lack of knowledge about appropriate exercise, and insufficient time for a regular schedule of exercise [24], interfere with adherence in healthy populations, they may be even more significant for cancer survivors or others with serious or chronic health problems. It is possible that different approaches will be needed to enhance wide scale adoption of physical activity in a cross-section of cancer survivors. The logical next step in developing physical activity interventions for cancer survivors, therefore, is to study methods to increase adherence to a physically active lifestyle by variably motivated, sedentary cancer survivors who may not have access to a gym, exercise equipment, or highly trained exercise professionals, and to test whether such interventions improve quality of life and physical functioning in cancer survivors.

According to behavioral theory and empirical research concerning the adoption and maintenance of increased physical activity by healthy populations, interventions are more effective when they aim to teach cognitive and behavioral skills, provide social support, and increase self-efficacy [25–32]. It is likely that the same holds true for cancer survivors, although interventions for this population may require some modifications in message and methods. Theory-based research on variables affecting cancer survivors’ adoption and maintenance of physical activity is limited. Courneya and colleagues have conducted most of this research using the theory of planned behavior [33] to study cancer survivors’ adherence to physical activity. Briefly, this theory states that behavior is a function of the intention to perform a behavior and the person’s perceived behavioral control over the behavior (a construct similar to self-efficacy). Intention is formed by the attitudes held toward the behavior, the subjective norm (perception of how others want the person to act), and perceived behavioral control. Studies of several cancer survivor samples demonstrate that models of exercise behavior for cancer survivors differ somewhat from those of healthy individuals [34], particularly with regard to the beliefs about outcomes that are hypothesized to create attitudes [35,36], forming the basis for behavioral intent. Overall, the studies demonstrate significant variability in the degree to which attitude, subjective norm, or self-efficacy predict the intention to exercise.

Research on the theory of planned behavior enhances our understanding of some of the factors associated with the adoption of physical activity and helps identify appropriate intervention messages for particular populations. However, it does not specify methods for changing behavior or behavioral correlates [37]. Therefore we looked to intervention approaches that have been used with healthy but sedentary populations to identify an intervention approach that would be more likely to be adopted by cancer survivors outside the setting of a clinical trial. Recognition of barriers to long-term participation in structured exercise programs, in concert with the demonstrated health benefits of even short bouts of moderate activity [38], led to development of the lifestyle approach to increasing physical activity. Participants in this type of intervention learn cognitive and behavioral skills and ways to incorporate moderate physical activity into their daily routine by: (a) accumulating short bouts of moderate to vigorous activity throughout the day; (b) integrating activity into daily routines, like performing household or occupational work at moderate intensity, walking briskly for brief periods, climbing stairs; (c) performing activities they choose, as opposed to prescribed exercise [39]. These interventions have effectively increased physical activity and decreased cardiovascular risk factors in healthy populations [26,27,28], obese women [40,41], and overweight men and women [42]. However, this approach has rarely been tested to determine whether it produces improvements in quality of life, nor has it been tested in cancer survivor populations. Therefore, we aimed to test the effect of a lifestyle physical activity intervention on quality of life and physical functioning of breast cancer survivors. Interventions using the lifestyle approach to increasing physical activity, if effective with cancer survivors, could be highly disseminable because they do not require a highly trained personnel or specialized facilities to implement. We conducted with randomized pilot test in order to determine if a large scale randomized controlled trial of a lifestyle physical activity intervention was warranted. We hypothesized that breast cancer survivors assigned to the lifestyle physical activity intervention would show greater improvements in physical performance and quality of life than survivors assigned to a standard care control group. Secondarily, we hypothesized that the lifestyle group would show greater increases in physical activity and more favorable improvements in body composition than the control group.

2. Methods

2.1. Design and sample

Participants were randomized to either the 6-month lifestyle physical activity program (Active for Life After Cancer) or to a standard care condition. They completed
baseline and 6-month assessments of physical performance, quality of life, and physical activity.

Women were eligible for the study if they were within 7 years of a breast cancer diagnosis, no longer receiving treatment for breast cancer (except hormone therapy), and not engaging in focused moderate physical activity for 30 min or more a day most days of the week. Participants received clearance from their physicians to ensure that they had no medical conditions contraindicating moderately intensive exercise. The protocol was approved by the M.D. Anderson Cancer Center Institutional Review Board, and participants provided informed consent before completing assessments.

Participants were recruited from February to August 2003 from the M.D. Anderson Cancer Center Breast Center, Kelsey-Seybold Clinic (a large, multispecialty clinic), the Houston chapter of the Sisters’ Network (a support and advocacy group for African-American breast cancer survivors), and The Rose, a community agency sponsoring support groups for breast cancer survivors. Study recruitment included mailing letters of invitation to M.D. Anderson patients who had been identified by a previous cross-sectional survey, to support group members from Sisters’ Network and The Rose, and breast cancer survivors who were patients at Kelsey Seybold Clinic. In addition, we advertised the study through M.D. Anderson publications. After baseline assessment, participants were assigned to study arms using a form of adaptive randomization called minimization, which is similar to stratification in that participants’ characteristics are used to assign them to the treatment conditions [43]. In minimization, before a participant is assigned to a treatment group, the numbers of participants in each treatment group with similar covariate characteristics are totaled. Totals are based on the marginal sums of the covariates, so that each covariate is considered separately. The treatment assignment for a participant is then determined according to which treatment group would provide the best overall balance with respect to those covariates. Covariates used in the randomization of participants to our study conditions were baseline physical functioning and vitality (from the self-report Medical outcomes study short form-36 [SF-36] questionnaire), motivational readiness for physical activity, body mass index (BMI), disease stage at diagnosis, time since diagnosis, age, race, and whether the participant had received chemotherapy.

2.2.2. Intervention

The lifestyle physical activity intervention was originally developed for healthy individuals in Project Active at the Cooper Institute [26,27], modified for use with prostate cancer patients [44], and further modified for use with breast cancer survivors for this pilot test. Participants in the lifestyle program attended 90-min group meetings each week for 16 weeks, and every other week for 8 weeks (21 sessions total). Behavior change methods were based on the transtheoretical model [45–49], which emphasizes that individuals adopt behavior change in stages (precontemplation, contemplation, preparation, adoption, and maintenance) and that different types of intervention methods are effective at different stages. Participants were taught to assess their motivational readiness for physical activity, which they did every 4–5 weeks, and they received booklets about increasing physical activity matched to their stage of readiness. The intervention sessions emphasized information and skills such as benefits of physical activity, making small changes, overcoming barriers, goal-setting, rewarding yourself, and self-monitoring. Several methods of self-monitoring were used, including recording minutes of activity and recording steps using a pedometer. Information and skills were sequenced so that cognitive methods (e.g., recognizing benefits of physical activity) were presented in the earlier sessions, and behavioral methods (e.g., monitoring steps, rewarding yourself) were presented in later sessions.

Group sizes ranged from 7 to 15 participants. Group meetings were held at a local church or at the Kelsey-Seybold clinic. The first 50 min of each session were spent teaching cognitive behavioral skills related to exercise and providing brief opportunities (2–10 min) to practice moderately intensive activity such as walking. After a 10-min break, the group reconvened for a presentation or guided discussion on a breast cancer-related topic; written informational materials relevant to the topic of discussion were provided. The written materials dealt with topics relevant to breast cancer survivorship but did not address physical activity. During the 6-month intervention period the standard care participants received two mailings of the same written material, but did not meet as a group.

2.3. Measures

Baseline and 6-month assessments included self-report questionnaires concerning quality of life and motivational readiness, five physical performance tests, a 7-day physical activity recall interview, and lymphedema assessment. Staff conducting the assessments were blind to the participants’ study condition.

2.3.1. Physical performance

Physical performance tests developed by Simmonds [50] were conducted at baseline and 6 months. Participants completed a 6-min endurance walk test (walking as far as comfortably possible in 6 min); a 50-foot walk test (walking 50 feet as fast as comfortably possible); a timed sit-to-stand test (standing and sitting twice as fast as comfortable — after
a few minutes’ rest, the test is repeated and the average score recorded; a timed reach-up test (standing and reaching up with both hands as far as possible and returning hands to side — three repetitions are done at the maximum distance reached and the time recorded); and a forward-reach test (with heels on the floor, reaching forward as far as possible — distance is recorded at the farthest point before the participant loses her balance).

2.3.2. Quality of life (QOL)

Participants completed the SF-36 [51,52], a 36-item self-report measure of health-related quality of life based on eight health concepts: physical function, social function, pain, mental health, energy and fatigue, general health perceptions, role limitations caused by physical problems, and role limitations caused by emotional problems [53]. Internal consistency reliability for the eight scales is high, ranging from 0.78 to 0.93.

2.3.3. Physical activity

The 7-day physical activity recall questionnaire (7-DPARQ) is an interviewer-administered measure assessing physical activity during the past week. Information on the amount of time spent sleeping, and in moderate, hard, and very hard activities is gathered in the interview. The 7-DPARQ has established validity and reliability [54,55]. As another measure of physical activity, motivational readiness was measured by defining moderate lifestyle physical activity of 30 min a day or more on most days of the week, and asking the participant to respond if she was active according to that definition. She could respond (1) yes, for more than 6 months (maintenance stage); (2) yes, for less than 6 months (adoption stage); (3) no, but I intend to in the next 30 days (preparation stage); (4) no, but I intend to in the next 6 months (contemplation stage); or (5) no, and I do not intend to in the next 6 months (precontemplation). A similar question was used by Marcus et al. [46] to assess motivational readiness for exercise.

2.3.4. Body composition and lymphedema

Body mass index (BMI) was calculated from height and weight measurements. Height, weight, and hip and waist circumference were measured without shoes, with the participant wearing a light gown. Hip and waist circumference were measured as the participant stood with feet together, hands at sides, and abdomen relaxed. Waist circumference was measured at the narrowest part of the torso, at the end of a normal expiration, without compressing the skin. Hip circumference was measured similarly at the point of greatest extension of the buttocks. Lymphedema was assessed by a physical therapist who measured arm girth circumferentially at predetermined bilateral points. Jobst measuring tapes were used to take circumferential measurements every inch and a half, starting at the elbow and moving toward the shoulder and toward the wrist.

2.3.5. Patient satisfaction

A brief questionnaire measuring patient satisfaction was administered to participants in the lifestyle program during the last session of the program. This questionnaire was based on one used in our previous trial of the Active for Life program in prostate cancer patients [56].

2.4. Analysis

Between-group differences in physical performance, quality of life, physical activity, and body composition were tested in a 2 (study condition) by 2 (cohort) analysis of variance; the analysis controlled for baseline values of the outcomes tested, age, time since diagnosis, BMI, education, baseline motivational readiness, baseline self-reported physical functioning, and whether the participant had received chemotherapy. All participants who were randomized were included in the analysis, regardless of their attendance at the intervention sessions. Data for participants who did not complete the 6-month assessment were imputed based on regression models predicting outcomes in the remaining sample, using covariates and design variables.

3. Results

3.1. Recruitment

The combined recruitment efforts (M.D. Anderson, Kelsey-Seybold, support groups, and advertising) yielded 364 breast cancer survivors to be contacted for telephone screening. Fig. 1 provides the information on the outcomes of the screening process. Participants were recruited and randomized in two cohorts; when approximately 45 interested and eligible women were identified, they were contacted to schedule baseline assessments and then allocated to study condition. In total, 74 women completed baseline assessments; 14 were excluded after baseline (13 were too active to benefit from participation in the study, and one would be out of the country for most of the next 6 months). The remaining 60 survivors were allocated to the study conditions — 35 to the lifestyle program and 25 to standard care. More women were assigned to the lifestyle program to ensure that we would have an adequate number of women (at least seven) in each intervention group, and also to maximize the amount of process data we would obtain about the conduct of the lifestyle physical activity intervention. In the lifestyle program condition, retention at 6 months was 80%; four participants withdrew before the intervention began (primarily because of schedule conflicts with meeting times), and three more withdrew during the intervention. Retention in standard care was 92% at 6 months; one participant withdrew immediately after randomization because she had wanted to be in the lifestyle program, and another participant died before the 6-month assessment.
3.2. Characteristics of sample

Baseline clinical, demographic, and outcome variables for the two study conditions are provided in Table 1. The sample was diverse with regard to ethnicity and disease stage. The participants in the two conditions did not differ significantly on any of the variables measured at baseline.

3.3. Process data

Of the 35 women who were randomized to the Lifestyle program, four dropped out before starting the program and an additional three participants dropped out during the intervention; these three participants attended 2, 4, and 5 sessions each. Among those who started the intervention, the mean number of sessions attended was 14.6 out of 21 (standard deviation = 5.1), with a range of 2–21 sessions. At the end of the lifestyle program, participants completed a program evaluation. Results indicated they were satisfied with the program format; ratings (from 1 to 5) indicated the content was more than expected (mean = 4.6) and the number of sessions and session length were considered “just right” (means = 3.3 and 3.0, respectively). Ratings were positive with regards to feelings towards group members.

Fig. 1. Patient recruitment, screening, allocation to study condition, and retention by study condition.
(mean = 3.9, with five indicating “as close as I feel towards my family”). Ratings also indicated high levels of comfort in talking openly in the group (mean = 4.1) and an increased willingness to discuss breast cancer with others (mean = 4.3). Participants reported they would definitely recommend the program to other breast cancer survivors (mean = 5.0). They also reported the program increased their activity (mean = 4.6) and their physical (mean = 4.4) and emotional (4.0) well-being.

### 3.4. Physical performance

At the follow-up assessment, the lifestyle group performed significantly better than standard care in the 6 minutes walk test (\(p = 0.005\)), walking 97 feet farther in 6 minutes than standard care participants (Table 2). There were no other significant differences between the two groups in the physical performance tests at the 6-month assessment.

#### 3.5. Quality of life

The lifestyle program group reported better quality of life in several areas at the 6-month assessment (Table 3). Lifestyle participants had significantly higher scores (indicating better QOL) on scales measuring general health (\(p = 0.006\)) and bodily pain (\(p = 0.020\)). Differences in role
limitations due to physical problems and physical functioning ($p = 0.056$ and 0.101, respectively) showed a trend toward significant differences. No significant differences between conditions were seen in scores of mental health, vitality, social functioning, and role limitations as a result of emotional problems.

3.6. Physical activity

At the 6-month assessment the lifestyle participants reported greater motivational readiness for physical activity than did standard care participants (Table 4; $p = 0.024$). The average stage of motivational readiness at baseline for participants in both study conditions was between preparation and action; at the 6-month assessment the lifestyle intervention participants' stage of readiness was between action and maintenance, while that of the standard care participants did not change. There were no significant differences between the study conditions in the number of minutes spent in moderate or more intense physical activity and the number of days on which they did ≥30 min of such activity.

3.7. Body composition and lymphedema

There were no significant differences between the two study conditions at the 6-month assessment in BMI, hip circumference, or waist circumference. However, there was a significant intervention condition x cohort interaction in BMI ($p = 0.048$); in cohort 1 the BMI was lower in the lifestyle intervention than standard care, while in cohort 2 they were nearly identical.

To assess whether the intervention increased the risk of lymphedema, the number of increases in arm circumference greater than 2 cm was calculated for each participant. The study conditions demonstrated no significant differences in

<table>
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<tr>
<th>Physical Activity Variable</th>
<th>Group</th>
<th>Adjusted Mean</th>
<th>Standard Error</th>
<th>$F$</th>
<th>$p$</th>
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<td>Stage of change$^b$</td>
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<td>0.2</td>
<td>5.4</td>
<td>0.024</td>
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<tr>
<td></td>
<td>Standard care</td>
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<td>Minutes of moderate or more intense activity</td>
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<td>43</td>
<td>0.1</td>
<td>0.733</td>
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<tr>
<td></td>
<td>Standard care</td>
<td>404</td>
<td>53</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Days with ≥30 min of moderate or more intense activity</td>
<td>Lifestyle care</td>
<td>4.0 cm</td>
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<tr>
<td></td>
<td>Standard care</td>
<td>4.2 cm</td>
<td>0.4</td>
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</tr>
</tbody>
</table>

$^a$ Adjusted for baseline value, age, education, time since diagnosis, received chemotherapy, body mass index (BMI), baseline physical functioning, and baseline stage of change.


4. Discussion and conclusion

4.1. Discussion

The randomized pilot study demonstrated that the lifestyle physical activity intervention produced improvements in some performance measures of physical functioning and physical aspects of quality of life, above and beyond those of a standard care comparison group. The lifestyle intervention condition participants also reported greater motivational readiness for physical activity than the standard care group; however, the reports of activity in the past 7 days do not reflect these differences.

We assessed the effect of the lifestyle intervention on participants' physical performance of tasks reflecting several dimensions of physical functioning. The intervention group performed better than the control condition on the 6-minute walk, indicating improvements in endurance. Tasks that were more reflective of strength (50-foot walk, sit-to-stand test), flexibility (repeated reach-up), and balance (forward-reach) showed no statistically significant changes. This was not surprising, given that the main emphasis of the lifestyle intervention was to increase walking activities. Participants were taught multiple ways to incorporate activity in their daily life, but most involved walking or other cardiovascular activity. As one way of monitoring activity, participants received pedometers and recorded their number of steps; other options for monitoring activity were provided, but most participants chose to use the pedometer. Flexibility and resistance exercises were taught, but the amount of time spent on them was brief. Most exercise interventions programs for cancer patients and survivors have emphasized cardiovascular activity [10–11,17,57,58], either walking or using a cycle ergometer, and the fitness outcomes have been related to cardiovascular fitness. A notable exception is a study by Segal et al. [9] of a strength-training intervention for androgen-ablated prostate cancer patients, which successfully increased participants' strength and decreased their fatigue.

With regard to quality of life improvements, only dimensions related to physical well-being were affected by the intervention (physical functioning, role limitations due to physical problems, and bodily pain), in contrast to other studies of exercise intervention in which improvements in emotional well-being were found as well [10,12,16,22]. However, the evidence of improved emotional well-being by exercise intervention is not consistent for cancer patients and survivors. One of the larger randomized trials [11] found that exercise had no effect on emotional well-being, and many of the studies found effects on some emotion/mood-related variables but not
others [10,16]. Furthermore, in a mediational analysis, Courneya et al. [10] found that the differences in self-esteem and happiness (the two emotional variables significantly influenced by their exercise intervention) were not mediated by changes in fitness, indicating that either other facets of exercise (e.g., distraction from negative mood) were responsible for the changes, or that certain aspects of the intervention (e.g., attention from intervention staff) affected emotional well-being. The diversity of exercise interventions for cancer patients and survivors may account for the lack of consistency in findings of emotional benefits.

One unexpected finding was that the intervention was related to improvements in motivational readiness, but not physical activity as reported in the past 7 days. Both study conditions reported increases in physical activity on the 7-day recall interviews. According to exploratory paired t-tests to test within-group differences, the lifestyle intervention group increased the number of days on which they did moderate or more intense activity (from 3 to 4, \( p = 0.016 \)), but their increase in total minutes of activity, from 345 to 432, was not statistically significant (\( p = 0.13 \)). The standard care group increased number of days (from 3 to 4.3, \( p = 0.024 \)) and total minutes of activity (from 248 to 430, \( p = 0.003 \)). One explanation for this result may be that assessing physical performance and physical activity was as effective as a 6-month intervention in increasing physical activity. However, this seems unlikely given the difficulty most sedentary people experience in adopting and sustaining a physically active lifestyle. An alternative explanation is also possible. About 2 weeks before the 6-month assessment of our second cohort of participants, research results presented at the American Association of Cancer Research (AACR) meeting showing that breast cancer survivors who exercised were less likely to die of breast cancer [58] received widespread media attention. This information may have caused women in standard care to start exercising, whereas it would have had less effect on the women in the intervention group who had already increased their activity levels. Several findings support this explanation. First, the lifestyle group reported greater motivational readiness than the standard care group, indicating that the intervention participants had been active longer and more regularly than those in standard care. Second, standard care participants in the second cohort, whose behavior could have been affected by the news coverage of the 2004 AACR results, had a larger increase in activity (248 min) than standard care participants in the first cohort (62 min) whose assessments preceded the news coverage. Finally, the standard care participants showed no physical performance improvement, which indicated that although they may have increased activity, the change was not sustained long enough to produce changes in endurance.

There is no indication that lifestyle physical activity poses a risk of increasing lymphedema or other adverse outcomes in breast cancer survivors. The intervention group did not show a significantly larger number of increases in arm circumference (more than 2 cm) than the standard care condition. In this pilot trial, one participant died, and one experienced a recurrence of cancer; both were in standard care. These events could not be attributed to the lifestyle intervention.

### 4.2. Conclusion

The lifestyle physical activity intervention showed promise in its ability to improve endurance and physical aspects of quality of life and to induce changes in physical activity. Although the pilot test involved a small sample and thus had limited power for detecting differences between groups, the results provided a preliminary indication that the lifestyle program may be efficacious and should be rigorously tested in a larger randomized controlled trial. Comparison of the lifestyle physical activity program to a structured approach also should be tested with the goal of examining quality of life outcomes and long-term physical activity adherence.

### 4.3. Practice implications

The results of this study indicate further research of the lifestyle approach is warranted. If this approach to increasing physical activity is shown to be effective in a larger trial, it represents a highly feasible intervention that can be delivered to cancer survivors by health care institutions or community organizations without dedicated exercise facilities and equipment. While our study was limited to breast cancer survivors, lifestyle physical activity interventions may also be beneficial for survivors of other types of cancer, or for individuals with other chronic diseases and conditions who might benefit from a more physically active lifestyle.

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### References


