Feasibility of Institutional Registry-Based Recruitment for Enrolling Newly Diagnosed Breast Cancer Patients in an Exercise Trial

Lisa A. Cadmus Bertram, Gina Chung, Herbert Yu, Peter Salovey, and Melinda Irwin

Background: The purpose of this study was to determine the feasibility of using a tumor registry to recruit newly diagnosed survivors into a randomized controlled exercise trial and to discuss issues related to this recruitment strategy. Methods: A tumor registry-based rapid ascertainment system was used to recruit breast cancer survivors into a 6-month home-based, telephone-administered intervention of moderate-to-vigorous intensity exercise or a usual care group. Results: 468 newly diagnosed cases were identified. Of these, 50 women (15.4% of those for which screening calls were made) were enrolled in the study. Women were randomized, on average, 11 weeks after diagnosis (SD = 4.8). Sixty-four percent were randomized before beginning treatment or within the first week of treatment. Time required to obtain physician consent was the primary determinant of diagnosis-to-randomization latency. Enrolled women were more likely than nonenrolled women to be non-Hispanic White and to have a college degree (P < .05). Conclusion: Tumor registries present a feasible means of recruiting breast cancer survivors before or early in adjuvant treatment. The success of recruiting survivors promptly after diagnosis is largely dependent on ability to rapidly obtain physician consent. Specific effort is needed to counteract self-selection effects that may lead to under-representation of minorities.

Keywords: physical activity, randomized controlled trials

The National Cancer Institute defines a cancer survivor as any person who has been diagnosed with cancer, regardless of time since diagnosis. Due to the combined influences of increased incidence and improved survival, there are an estimated 2.4 million breast cancer survivors in the US, comprising the largest group of female cancer survivors. Many experience unpleasant side effects of treatment such as weight gain, decreased cardiovascular function, and reduced quality of life. Exercise offers substantial benefits to the long-term well-being of breast cancer survivors, including improvements in physical functioning, reduced treatment-related fatigue, prevention of weight gain, and improved quality of life. Exercise has been also shown to reduce the risk of breast cancer incidence and mortality. In one observational study, 84% of survivors of breast, prostate, lung, and colorectal cancer indicated that they would prefer or might prefer to receive exercise counseling during their cancer experience, indicating that structured intervention is an attractive option for many recently diagnosed survivors.

A number of pilot studies and randomized controlled trials have tested the feasibility of exercise during breast cancer treatment and its effects on various outcomes, including treatment-related symptoms (eg, fatigue, nausea), physical and emotional functioning, and quality of life. These studies generally show that exercise during treatment is safe, feasible and may be associated with reductions in fatigue and improvement on other patient-reported outcomes. There is also a growing interest in examining the effect of exercise during treatment on biological outcomes such as biomarkers for breast cancer recurrence.

Proper examination of these aims requires larger, well-controlled randomized trials, which present a number of logistical challenges, including the efficient recruitment of survivors soon after diagnosis. Unlike trials conducted among posttreatment survivors, studies aiming to examine recently diagnosed survivors must reach potential participants within days or weeks of diagnosis. While a handful of papers have reported on the recruitment of breast cancer survivors for exercise trials or trials of exercise plus diet, none have...
focused specifically on recruiting breast cancer survivors before the initiation of treatment. Furthermore, as the majority of these trials have used convenience samples, only a few papers have addressed the pragmatics of the use of tumor registries, which may be a useful tool for recruitment soon after diagnosis.

This paper therefore provides detailed information regarding registry-based recruitment and intervention design and from a recently completed trial, the Increasing or Maintaining Physical Activity during Cancer Treatment (IMPACT) Study. The aim of this paper is to determine the feasibility of recruiting 50 recently diagnosed breast cancer survivors into a home-based exercise trial before or at the beginning of adjuvant treatment (chemotherapy and/or radiation therapy) and to address pragmatic issues specific to the recruitment of participants soon after a breast cancer diagnosis. Secondary aims of the trial were to examine the effect of the intervention on total body fat, fasting insulin, insulin-like growth factors (IGFs), and quality of life; the results of these analyses will be published separately.

**Methods**

All study procedures, including written informed consent, were reviewed and approved by the Yale University School of Medicine Human Investigation Committee.

**Participants**

Participants were 50 women aged 35 to 75 who had been recently diagnosed with Stage 0-IIIA breast cancer and who had completed ≤ 2 cycles of chemotherapy or ≤ 2 weeks of radiation. Women were excluded if they were current smokers, were not physically able to perform regularly moderate-to-vigorous intensity exercise, or if their physician declined to provide consent for their participation. The primary aim was to either increase or maintain prediagnosis physical activity levels; therefore both physically active and inactive women were eligible to join the study. There was not a specific criterion for geographic proximity, although women were deemed ineligible if they failed to agree to travel to the study site for baseline and follow-up visits. Most participants lived within 30 minutes of the study site; the most distant participant lived 80 minutes away.

**Recruitment**

From July 2004 to March 2006, study staff used the Yale-New Haven Tumor Registry to obtain the names of Connecticut women diagnosed with incident breast cancer (~1 to 4 weeks postdiagnosis) by any Yale-affiliated physician. Initiated in 1926, it is the oldest tumor registry in the country and participants in Connecticut’s state Surveillance, Epidemiology, and End Results (SEER) registry. The Yale-New Haven registry contains information for all patients who are diagnosed, treated, or seen by a physician in consult, at either Yale-New Haven Hospital or the Yale Cancer Center.

Batches of reports were received from registry staff every 1 to 2 weeks. In 2004, 2850 Connecticut women were diagnosed with breast cancer; in 2005, 2720 were diagnosed. Of these, several hundred were diagnosed by Yale-affiliated physicians, providing a large pool of potential participants. A core group of surgeons and oncologists were responsible for the vast majority of breast patients and we were able to speak with most of these physicians about the study before initiating recruitment to help ensure cooperation in providing prompt consent.

Within 48 hours of receiving each batch of registry reports, staff contacted each patient’s physician by fax to request permission to contact her. Physicians were asked to provide or deny consent to contact the patient as well as consent for the patient to participate in the exercise program. If a new registry report was received listing physician who had outstanding requests, a fax was sent requesting consent for the new patient(s) as well as for any patients for which we had not yet received a response. Follow-up faxes were sent as necessary if the physician did not reply within 5 days.

Within 48 hours of receiving physician consent to contact and for exercise participation, each woman was mailed a recruitment packet containing an invitation letter, a study brochure, and postcard that could be used to (a) express interest in the study, (b) decline participation in the study but express interest in future studies, or (c) decline participation and request not to be contacted for any study. After mailing each packet, staff allowed a 1-week period to pass before attempting to contact the individual. If the individual declined participation via postcard, no further attempt at contact was attempted. Otherwise, staff telephoned each potential participant to invite her to complete a screening questionnaire and, if the participant was eligible and interested, schedule a baseline visit. Completion of brief demographic questionnaire was requested of those who were not interested or who were immediately recognized as ineligible. Up to 10 calls were made per potential participant, with voicemail messages used only if the first several calls failed to reach the individual. For those who could not be contacted, only that information provided by the tumor registry (age and ethnicity) was recorded.

In addition to women contacted through the tumor registry, 5 women contacted us after hearing about the study verbally through their physicians or had seen a media placement during which the Principal Investigator discussed her research. They were then screened using the same procedure as those recruited via the registry.

**Baseline Visit**

At the baseline visit, interviewer-administered questionnaires were used to collect demographics, medical history, readiness to adopt exercise, and current and prior
physical activity (see Measures). A clinic visit was then scheduled for the following week and the participant was given a pedometer, 7-day physical activity and pedometer logs, and psychosocial questionnaires (see Measures) to complete at home.

Clinic Visit

Physical measurements (height, weight, waist and hip circumferences, blood pressure, resting heart rate (HR), and a whole-body DEXA scan to assess percent body fat) were collected at the General Clinical Research Center at Yale New-Haven Hospital. Staff also reviewed the questionnaires and activity logs for missing data or unclear responses.

Randomization

A computer program was used to assign each participant with equal probability to either the home-based exercise group or the usual care group. Allocation codes were provided by the principal investigator, who was not involved in recruitment or enrollment.

Follow-up Data Collection

The same data that were collected at the baseline visit were collected in a similar manner at 6 months postrandomization.

Exercise Intervention

The intervention was developed using the theory of planned behavior27 and the transtheoretical model,28 and was designed to promote exercise self-efficacy and to help participants recognize the benefits of and overcome common barriers to exercise. Stage of readiness to adopt physical activity and beliefs, attitudes, norms, and intentions about activity (see Measures) were assessed at baseline; these scores were used to adapt the telephone counseling to the needs of each participant.

At an initial in-person exercise meeting, a staff member outlined the program goals and instructed the participant how to use the HR monitor. Each participant received the book Active Living Every Day: 20 Weeks to Lifelong Vitality,29 designed to aid in the adoption and maintenance of a physically active lifestyle. Participants also received worksheets, informational handouts, exercise logs, and pedometer logs. The worksheets followed the topics outlined in the book, such as overcoming barriers and enlisting social support. Information sheets adapted from the Physical Activity for Total Health Study30 covered topics such as stretching, choosing footwear for exercise, and a list of local parks and fitness areas.

The goal was 30 minutes of moderate-to-vigorous physical activity, 5 days/week, at 60 to 80% of maximal HR reserve, in accordance with the American College of Sports Medicine’s (ACSM) physical activity recommendation for adults.31 While the ACSM guideline is aimed at healthy populations, it is not contraindicated for individuals undergoing breast cancer treatment, and we found it to be a suitable benchmark for testing the feasibility of regular exercise in our sample. The program consisted primarily of walking, an activity preferred by most women and breast cancer survivors,32 however participants could meet the exercise goal through any form of sustained aerobic activity. Following each session, participants recorded the type, duration, and perceived intensity of exercise and average HR in physical activity logs and rated nausea and fatigue on 10-point Likert scales. Logs were returned to study staff via mail every 4 weeks.

Each participant was taught exercise techniques and principles during weekly phone-based meetings with 1 of 2 exercise counselors. Both counselors were trained to administer the calls in the same manner. During each call, lasting ~20 minutes, the staff member and participant discussed physical activity performed in the previous week. If the goal was not met, specific barriers and possible strategies for overcoming these were discussed. Intervention group participants also received quarterly newsletters.

Usual Care Group

Women in the usual care group were instructed to continue with their usual activities and were sent quarterly newsletters throughout the study. They received all exercise materials after their 6-month assessment.

Measures

Physical Activity. Physical activity was assessed at baseline and 6 months using an interview-administered Physical Activity Questionnaire (PAQ), a 7-day physical activity log, and a 7-day pedometer log as described below. Adherence was assessed with 7-day physical activity logs (each week) and 7-day pedometer logs (every fourth week).

The PAQ30 is a validated questionnaire used to assess recreational/fitness activity during the past 6 months. For each activity reported, participants were asked to specify the average frequency (eg, days/week) and duration (min/session) of the activity. Hours/week spent in different intensities (light, moderate, vigorous) of activity were then computed using Ainsworth’s Compendium of Physical Activities.33

The 7-Day Physical Activity Log (PAL)30 is a validated log that assesses the type and duration of recreational/fitness activity over a 7-day period. All participants completed the log at baseline and at 6 months. Exercisers also completed the logs during each week of the intervention, including the mean HR from each session. Hours/week spent in moderate-to-vigorous intensity recreational/fitness activity were determined using Ainsworth’s Compendium of Physical Activities.33
The 7-Day Pedometer Log\textsuperscript{32} provides a comprehensive indicator of activity performed each day and was completed both before randomization and at the 6-month follow-up visit. Participants were given a digital pedometer and taught how to use it to measure their daily steps. Intervention group participants also completed the pedometer log during weeks 4, 8, 12, 16, 20, and 24 of the intervention.

**Readiness to Adopt Physical Activity.** Stage of readiness to perform physical activity was assessed using a 4-item questionnaire developed by Marcus et al.\textsuperscript{34} This measure is based on the transtheoretical model\textsuperscript{28} and use the standard physical activity recommendation to classify participants into 1 of 5 stages: precontemplation (not exercising; no intend to adopt exercise), contemplation (not exercising, intent to adopt exercise), preparation (exercising <150 min/week), action (exercising ≥150 min/week for <6 months), and maintenance (exercising ≥150 min/week for ≥6 months).

**Demographics & Medical History.** Demographics, relevant medical history, health habits, and comorbidities were collected at the baseline visit. Information regarding diagnosis and treatment was provided by participants and confirmed by their physicians.

**Anthropometrics & Body Composition.** Height and weight were measured at baseline and 6 months. Participants were weighed on a digital scale in light clothing, without shoes; Height without shoes was measured using a stadiometer. Circumference measurements were taken at the waist, umbilicus, and hips. Total body fat was measured using dual energy x-ray absorptiometry (DEXA) scans, completed at baseline and 6 months. DEXA is the gold standard for the assessment of body fat.\textsuperscript{35}

**Participant Satisfaction.** Women completed a participant satisfaction questionnaire designed by Courneya and colleagues\textsuperscript{36} at 6-month follow-up.

**Statistical Analyses.** Univariate analyses, chi-square tests, and $t$ tests are used to report recruitment results. Analyses were conducted using SAS 9.1.

**Results**

The recruitment process is shown in Figure 1. We were able to obtain prompt approval from the registry, as we were already collaborating with them on a similar study of exercise for posttreatment survivors. A total of 468 pathology reports were received from the tumor registry. Of these, physician consent was obtained for 413; the primary reasons for nonconsent were response directly indicating the patient should not be contacted (n = 23) and failure of physician to respond (n = 9). Overall physician response latencies ranged from 0 to 396 days (mean = 30, SD = 41).

In addition to names received from the registry, 5 women contacted staff after hearing about the study through a physician, friend, or the media. Physician consent was then requested. These women were demographically similar to those recruited via the registry.

Recruitment packets were mailed to 405 women between July 2004 and April 2006. (In 8 of the 413 cases for which physician consent was given, the physician had appended the permission form with a note containing information sufficient to determine that the woman would be ineligible for the study. For example, the physician stated that the patient does not speak English, that patient has a severe mental illness, etc. Recruitment packets were therefore not mailed to those 8 women). Thirty-seven women opted out via postcard. Staff phoned the remaining 368 women; 49 could not be reached. The vast majority, however, were easily contacted using the telephone information listed on the tumor registry reports, with staff placing a mean of 1.5 (SD = 1.4) calls per potential participant to either complete the screening questionnaire or obtain refusal/ineligibility information. Reaching each potential participant took anywhere from 1 to 9 calls, with fewer than 2 phone calls on average.

One hundred twenty-five women were ineligible. The most frequent reasons were completion of >2 cycles chemotherapy or >2 weeks of radiation (n = 56) and age >75 years (n = 23). (Although we requested registry reports for only those women 75 or under, early in the study we erroneously received some registry reports for women >75 and some packets were mailed before our knowledge of the error. In a small number of additional cases, a woman was listed was 75 years of age at diagnosis and a registry report was therefore sent, but by the time we contacted and spoke with her, she was 76 and therefore no longer eligible to enroll.) Other ineligibility criteria included physical disability, language barriers, mental illness, history of cancer, cancer recurrence, and smoking.

One hundred forty-nine women declined participation. Staff probed those who gave vague refusals (eg, “I’m just not interested”); 82 declined to further elaborate. Common reasons for nonparticipation were time and scheduling issues (n = 22) and feelings of being emotionally overwhelmed by the diagnosis and consequent medical appointments (n = 21). Other refusal categories included unwillingness to exercise, be randomly assigned to a study group, travel to the study site, or undergo tests.

In total, of the 373 women for whom screening calls were attempted, we were unable to contact 49 women, 141 refused participation, and 125 were ineligible. Baseline visits were completed for the remaining 58 women. Of these, 50 attended the clinic visit and completed all baseline measures. Twenty-five were assigned to the exercise group and 25 to usual care. The final sample represented 15.4% of those women for whom screening calls were made. Follow-up began in August 2004 and was completed in November 2006.
Latency From Diagnosis to Randomization

Participants were randomized, on average, 11.0 (SD = 4.8) weeks after diagnosis. Registry reports were received, in general, within 2 weeks of diagnosis (range: 1 to 4 weeks). The original aim of the study was to recruit women before initiation of chemotherapy or radiation; however it was soon apparent that due to the time lags in the registry and in the physician consent process, we would not be able to meet our monthly recruitment targets. We therefore modified the criterion to allow women to enroll if they were very early in treatment (<2 cycles chemotherapy or <2 weeks radiation). One group of 4 surgeons chose to provide automatic consent for our study staff to contact any of their patients, allowing us to recruit very quickly. (If the woman was interested and eligible, we then obtained physician approval to perform physical activity.) Ten of the 69 potential participants associated with this surgical group joined the study; they were randomized on average just 8.6 (SD = 3.9) weeks after diagnosis, 3 weeks faster than participants recruited using individual consent to contact (mean = 11.6, SD = 4.9).

Selection Issues

When possible, basic demographic data were obtained for the 423 women who were ineligible or who refused participation. Compared with the 365 ineligibles/refusers for whom both age and ethnicity data were available,
enrolled participants were slightly younger (54.2 ± 9.6 vs. 58.6 ± 12.4 years; P < .05) and more likely to be non-Hispanic White (94% vs. 82%; P < .05). It should be noted that 23 of the 365 ineligibles/refusers were over 75 years of age and therefore unable to enroll; however the age difference remains significant when these cases are removed from the analysis.) Seventy percent had a college education compared with 50% of refusers (P < .05); however this is very difficult to interpret because education data were unavailable for 61% of ineligibles/refusers. The high proportion of missing data for education is due to the fact that it is not included on registry reports, therefore we were not able to obtain it for any woman who could not be reached or who declined to complete the brief refuser questionnaire (by contrast, age is always included on registry reports, and race/ethnicity is often included, hence the lower rate of missing data for those variables).

Sample Characteristics
Participants were middle-aged, primarily non-Hispanic white, and well-educated (see Table 1). The majority (68%) of participants were randomized within 12 weeks of initial diagnosis (see Table 2). Most had early stage cancer and 73% underwent lumpectomy rather than mastectomy. At the time of randomization, 36% had already begun their second cycle of chemotherapy or second week of radiation. Twenty-six percent planned to have radiation only, 26% planned to have chemotherapy only, and 40% planned to have both radiation and chemotherapy. Fifty-four percent planned to take hormonal therapy.

The sample included a wide range of body mass index (BMI), but the majority of participants were overweight (32%) or obese (28%). The mean BMI was 27.6 (SD = 5.3). Whole-body DEXA scans indicated a higher level of adiposity than would be suggested by BMI. Mean % body fat in the total sample was 37.3 (SD = 5.9), but even the 20 women with BMIs in the “healthy” range (18.5 to 24.9) had, on average, 32.3% body fat (SD = 3.9). Mean waist circumference was 85.7 cm (SD = 12.3), with 38% of participants having a waist > 88.9 cm (35 inches). Mean hip circumference was 117.0 cm (SD = 114).

Exercise level varied widely at baseline. Mean minutes/week of moderate-vigorous sports/recreational activity recorded on the 7-day log was 117 (SD = 114), with 29 participants (58%) performing ≥ 60 min/week of moderate-to-vigorous activity. Of these, 16 (32% of total sample) were performing at least 150 min/week. Thirty percent recorded no recreational physical activity. Participants walked an average of 5470 (SD = 2,786) steps/day, with only 6% meeting the “active lifestyle” goal of 10,000 or more steps/day.

Discussion
The IMPACT Study is among the few trials to report on the use a tumor registry-based rapid ascertainment system to recruit women immediately after a diagnosis of breast cancer. Our recruitment rate of 15.4% is comparable to convenience-based exercise trials.\textsuperscript{15,21} We were able to obtain registry reports promptly after diagnosis and to reach potential participants easily, with fewer than 2 phone calls on average. While recruitment using tumor registries is often more expensive than convenience-based sampling and does not necessarily result in a true “population-based” sample, our study demonstrates that the tumor registries can be a feasible avenue for recruitment for breast cancer patients within 3 months of diagnosis for exercise research, and may be a good strategy in environments where relying on direct patient referrals by oncologists and surgeons is not realistic. Furthermore, when physician referral is not a preferred option, allowing investigators to identify and contact patients very soon after diagnosis, tumor registries may allow for faster accrual than convenience methods. There is some evidence that registry-based and convenience samples may differ with regard to important characteristics such as age, tumor stage, and baseline quality of life;\textsuperscript{25} however we were not able to examine this question due to the very small number of self-referred women included in the IMPACT Study.

The pragmatics and results of registry-based recruitment will necessarily vary based on the parameters and policies of the registry used. This research used the field arm of the Connecticut Tumor Registry and we were only able to obtain information on women for whom a Yale-affiliated physician was listed on the pathology report, therefore we were not able to learn about all of the incident diagnoses in our geographic area. The registry we used featured a Rapid Ascertainment System, through which we were able to receive information regarding new diagnoses with a very short (approximately 2 week) latency. Tumor registries vary widely with regard to cost, availability of data, latency from diagnosis to data release, and other factors. Therefore the pragmatics of registry-based recruitment will necessarily differ among states and institutions.

Even using this rapid case-identification system, many women could not be enrolled before treatment. Fifty-six (13.6%) of the 413 potential participants for whom we had physician consent were ineligible because they had completed > 2 cycles of chemotherapy or 2 weeks of radiation. This occurred in part due to the time delay associated with obtaining individual written physician consent to contact each potential participant. While physicians were generally cooperative, there was considerable variability in the speed of their response to our requests. Reducing this time would greatly improve the feasibility of recruiting women before initiation of treatment. As an example, those recruited through the group of surgeons that provided blanket consent for us to contact their patients were enrolled very quickly. When possible, contacting registry patients directly, then obtaining physician consent for each woman to participate, appears to be an effective way to reduce staff burden and streamline the enrollment process.\textsuperscript{38}

In addition to delays in physician response, another major barrier to recruitment was lack of interest on the part of potential participants. The most frequently
Table 1 Baseline Characteristics of Randomized Participants in the Increasing or Maintaining Physical Activity During Cancer Treatment Study (N = 50)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Exercise arm (n = 25) Mean ± SD or %</th>
<th>Control arm (n = 25) Mean ± SD or %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>54.5 (± 8.2)</td>
<td>54.0 (± 10.9)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-Hispanic White</td>
<td>92%</td>
<td>92.0%</td>
</tr>
<tr>
<td>African-American</td>
<td>4.0%</td>
<td>0%</td>
</tr>
<tr>
<td>Other</td>
<td>4.0%</td>
<td>8.0%</td>
</tr>
<tr>
<td>Education (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High school graduate</td>
<td>16.0%</td>
<td>12.0%</td>
</tr>
<tr>
<td>Some school after H.S.</td>
<td>16.0%</td>
<td>16.0%</td>
</tr>
<tr>
<td>College graduate +</td>
<td>68.0%</td>
<td>72.0%</td>
</tr>
<tr>
<td>Time since diagnosis (weeks)</td>
<td>11.1 (± 4.5)</td>
<td>11.0 (± 5.2)</td>
</tr>
<tr>
<td>Disease stage (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In Situ</td>
<td>8.0%</td>
<td>4.0%</td>
</tr>
<tr>
<td>Stage I</td>
<td>48.0%</td>
<td>36.0%</td>
</tr>
<tr>
<td>Stage II</td>
<td>20.0%</td>
<td>32.0%</td>
</tr>
<tr>
<td>Stage IIIA</td>
<td>4.0%</td>
<td>8.0%</td>
</tr>
<tr>
<td>Unknown</td>
<td>20.0%</td>
<td>20.0%</td>
</tr>
<tr>
<td>Type of surgery (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lumpectomy/partial mastectomy</td>
<td>84.0%</td>
<td>64.0%</td>
</tr>
<tr>
<td>Simple mastectomy</td>
<td>0%</td>
<td>24.0%</td>
</tr>
<tr>
<td>Double simple mastectomy</td>
<td>4.0%</td>
<td>0%</td>
</tr>
<tr>
<td>Had not yet had surgery at baseline</td>
<td>12.0%</td>
<td>12.0%</td>
</tr>
<tr>
<td>Treatment plans (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>0%</td>
<td>8.0%</td>
</tr>
<tr>
<td>Radiation only</td>
<td>24.0%</td>
<td>28.0%</td>
</tr>
<tr>
<td>Chemotherapy only</td>
<td>24.0%</td>
<td>28.0%</td>
</tr>
<tr>
<td>Radiation and chemotherapy</td>
<td>48.0%</td>
<td>32.0%</td>
</tr>
<tr>
<td>Don’t know</td>
<td>4.0%</td>
<td>4.0%</td>
</tr>
<tr>
<td>Postmenopausal</td>
<td>64%</td>
<td>56%</td>
</tr>
<tr>
<td>Hormone therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>24.0%</td>
<td>12.0%</td>
</tr>
<tr>
<td>Yes</td>
<td>52.0%</td>
<td>56.0%</td>
</tr>
<tr>
<td>Unknown</td>
<td>24.0%</td>
<td>32.0%</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>75.6 (± 17.0)</td>
<td>84.3 (± 10.5)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>27.8 (± 5.3)</td>
<td>27.4 (± 5.4)</td>
</tr>
<tr>
<td>Waist circumference (cm)</td>
<td>87.1 (±13.9)</td>
<td>84.3 (± 10.5)</td>
</tr>
<tr>
<td>Hip circumference (cm)</td>
<td>106.8 (±9.7)</td>
<td>109.3 (± 11.4)</td>
</tr>
<tr>
<td>% total body fat (DEXA&lt;sup&gt;a&lt;/sup&gt;)</td>
<td>36.7 (± 5.9)</td>
<td>38.0 (± 6.1)</td>
</tr>
<tr>
<td>Daily activity log (min/wk sports/rec PA)</td>
<td>111.0 (± 104.2)</td>
<td>84.2 (± 88.6)</td>
</tr>
<tr>
<td>Pedometer steps/day</td>
<td>5637 (± 3,051)</td>
<td>5437 (± 2,392)</td>
</tr>
<tr>
<td>Stage of readiness to exercise&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contemplation/preparation</td>
<td>60.0%</td>
<td>68.0%</td>
</tr>
<tr>
<td>Action/maintenance</td>
<td>40.0%</td>
<td>32.0%</td>
</tr>
</tbody>
</table>

<sup>a</sup> Dual-energy X-ray absorptiometry.

<sup>b</sup> To perform 30 minutes of sports/rec exercise 5+ days/week (or a total of at least 150 min/wk).

*Note.* None of the comparisons between these baseline characteristics of intervention and control participants were statistically significant ($P < .05$).
The increasing interest in biomarker collection and assessment in exercise trials complicates the recruitment process, as additional eligibility criteria are usually required to ensure interpretability of biomarker data. It is important to note that, although the IMPACT Study excluded smokers, we did not exclude premenopausal women (who comprised 50% of our total sample). Future exercise trials aiming to enroll only newly-diagnosed, postmenopausal survivors may wish to employ extra strategies to boost recruitment, particularly if sedentary lifestyle is also an eligibility criterion. In these cases, resource-intensive strategies may be warranted, such as conducting baseline visits at the participant’s home or offering appealing attention control groups.

Consistent with similar trials, our sample was highly educated, relatively affluent, and the majority of participants were non-Hispanic white. Unlike previous studies, however, our recruitment approach allowed quantification of self-selection, revealing that non-Whites and those with a college education were less likely to be randomized. Thus, although tumor registries allow investigators to approach all survivors within a particular institution or catchment area, special attention may still need to be directed toward the recruitment of less-educated or minority women.

In light of evidence that women tend to decrease activity levels after a breast cancer diagnosis,12 the goal of the IMPACT study was to help women to maintain or increase physical activity throughout chemotherapy and/or radiation therapy; therefore both physically active and inactive women were eligible. The baseline physical activity levels of our sample were higher than those reported in a similar trial by Courneya.15 This is likely due to the fact that we assessed physical activity during the past 6 months, so for many women, their baseline physical activity level essentially reflects the prediagnosis lifestyle, not the lifestyle they are likely to lead during cancer treatment.

The 2 primary limitations of this study were (a) the use of a registry linked to a specific institution (Yale University), which captures many but not all of the incident cases in the geographic catchment area and (b) inability to obtain complete demographic information (particularly educational level) for all potential participants who either refused enrollment or were ineligible. Without full information, our comparison of the demographic characteristics of enrolled vs. nonenrolled women is subject to potential bias. The primary strength of this study is that it is the first to provide detailed information about registry-based recruitment for exercise trials among newly diagnosed breast cancer survivors. Other strengths included efficient processing of registry reports (physician consent requests were faxed within 48 of receipt of each registry report) and prompt mailing of recruitment packets (within 48 hours of receipt of physician consent).

While selection bias is a concern, recruiting women into a 6-month, structured, home-based aerobic exercise intervention study is feasible soon after diagnosis of breast cancer. As the number of long-term breast cancer survivors continues to grow, lifestyle and behavioral strategies will become an integral part of promoting health and reducing the risk of recurrence and mortality. More studies are needed to further compare the effectiveness, speed, and economic considerations of various strategies for rapid recruitment after a cancer diagnosis.

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References


