

Running head: OBJECTIVE BEHAVIOR CHANGE DURING CANCER TREATMENT

Title: Changes in objectively measured activity behavior among women undergoing breast cancer treatment: longitudinal cohort study.

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Abstract

Purpose: Activity behaviors of breast cancer survivors (BCS) during treatment are unlikely to be at levels sufficient enough to gain health benefits. Previous activity research among BCS have been mainly post treatment and generally cross-sectional. This study aimed to determine the prevalence and changes in objectively measured moderate-to-vigorous physical activity (MVPA), light (LPA) and sedentary behavior (SED) among BCS undergoing adjuvant/palliative therapy.

Methods: Participants completed baseline surveys and wore accelerometers to measure activity during waking hours during treatment and again 6 months later. Hierarchical Linear Modelling (HLM) was used to determine changes.

Results: 77 BCS participated. 91% provided PA data for ≥ 3 valid days at baseline (T1) and 72% at 6 months (T2); 29% met PA guidelines at T1 and 41% at T2. Daily LPA and SED did not change from T1 to T2 (133 vs. 138 minutes; 595 vs 597 minutes). Controlling for BMI at the intercept, HLM revealed MVPA significantly increased from T1 to T2 (+5.62, $p=.015$).

Conclusion: An increase in objectively measured total daily MVPA over six months was found; at which time, fewer BCS were currently receiving chemo- or radiotherapy and may theoretically be feeling better. However, fewer T2 measures may bias and artificially inflate the results.

Though total MVPA minutes increased at T2, less than half were meeting guidelines and had high amounts of LPA/SED during treatment with insignificant change over time (71% at T1; 59% at T2). Practitioner intervention may help reduce SED while increasing LPA and MVPA behavior among those currently on treatment.

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Keywords: accelerometry, adjuvant or palliative therapy, longitudinal behavior change, observational study.

Introduction

Recent research shows that engaging in physical activity (PA) after a cancer diagnosis can help lower the risk of breast cancer-specific and all-cause mortality.^{1, 2} PA interventions during and after adjuvant/palliative therapy have been shown to be safe and feasible^{1, 3-6} and can result in improvements in body composition, cardiovascular fitness, and chemotherapy completion rates in breast cancer survivors (BCS).^{1, 7} Despite the numerous benefits associated with PA, research suggests that as many as 85% of BCS are not active enough to meet the recommended activity.^{8, 9} Accelerometer studies show that the proportion of waking hours spent in moderate-to-vigorous PA (MVPA) is quite small, with only about 3% of waking hours being allocated to MVPA and spend an average 8 hours per day sedentary.⁸⁻¹¹

The majority of prior research focuses on those who have completed treatments and those without advanced disease. While there may be more barriers to activity during treatment, much less is known about levels of free-living activity among BCS currently on treatment, particularly MVPA.^{1, 12} Studies have shown that engaging in activity while on treatment can help mitigate side-effects and therefore, is recommended by the American Cancer Society.¹³ This study addresses this important research gap with an aim to investigate free-living activity levels in BCS while on treatment.

In addition to a significant proportion of BCS being inactive, recent research in non-diseased populations has directed its attention to sedentary behavior (SED).¹⁴ Studies show that high levels of SED is negatively associated with health-related QoL (HRQoL) outcomes like increased fatigue and lower physical well-being,¹⁰ and clinical risk factors linked to longevity in BCS independent of MVPA levels such as increased waist circumference and BMI.¹¹ Cross-sectional studies suggest that BCS spend approximately 55% to 66% of their day engaging in

sedentary activities,^{8, 10} which suggests that upwards of 600 minutes (i.e., 10 hours) per day is spent engaged in SED. This is comparable to older adult women in the general population assessed by the Canadian Health Measures Survey who also accumulated 600 minutes of SED during their waking hours.¹⁵

Recent research among the general population¹⁶⁻¹⁹ and some chronic disease populations¹⁹⁻²² have also demonstrated the potential of using standing and light intensity PA (LPA) to break up sitting time, rather than structured MVPA, to improve health outcomes.²³ Research also suggests that MVPA and SED should not be examined in isolation, but rather their interplay should be examined. The literature has identified four mutually exclusive categories²⁴⁻²⁷ based on these behaviors (Figure 3) and found that up to 47% were classified as Inactive; a group that has been shown to have the poorest health and QoL measures compared to any other category.²⁴⁻²⁷ We sought to measure LPA and categorize the activity behavior into one of four groups in a group of breast cancer survivors to make an important addition to the literature.

--Figure 1 near here--

To address these gaps in the literature, the current study's first objective was to assess the potential changes over six months in MVPA, LPA, and SED of BCS during adjuvant or palliative therapy. As with previous accelerometer studies, we hypothesized that sedentary time would make up the largest proportion of waking hours with little MVPA or LPA⁸⁻¹¹ performed and that these results would remain stable from baseline to follow-up. The second exploratory objective of this study was to determine the behavioral categories of BCS at baseline and follow-up. We also hypothesized that the majority of BCS would be classified as 'Inactive' at both time-points.²⁴⁻²⁷

Materials and Methods

Study design and participants

A longitudinal study of free-living activity among BCS undergoing adjuvant or palliative treatment was employed. Participants were eligible if they were female patients with breast cancer who met the following criteria: 1) ≥ 18 years of age; 2) able to read and write English; 3) were currently receiving adjuvant or palliative therapy (i.e., chemotherapy, trastuzumab, radiation therapy, or hormone therapy). Exclusion criteria included those with carcinoma in-situ or those who are unable to participate due to significant medical or physical limitations. Participants did not have to be on treatment at the follow up measure after 6 months.

Recruitment

Participants were recruited from the Nova Scotia Cancer Clinic at the Queen Elizabeth II Health Science Centre – Victoria General Site one of two ways. The first way, potentially eligible patients were screened by a member of the oncology care team, and those that indicated an interest in participating were given study information and consented by a RA. Next, the participant was fitted with an accelerometer and GPS unit that was worn for all waking hours of the day for 9 consecutive days. She was asked to record the time she put the devices on and took them off each day (i.e., via a wear time log) and the types of activities she engaged in (i.e., via a physical activity log). Finally, the participant was asked to ensure she completed the PA behavior questionnaire at the beginning of the measurement period (day 1), then the SED questionnaire at the end of the measurement period (day 9). Once completed, an appointment was made to collect the materials either in the clinic or the RA would meet the participant at her home. The second method of recruitment was via posters in the clinic. Here, a potential participant would contact the RA directly and if she was interested, she was asked for permission to contact her oncology

health care team to confirm eligibility. If she remained eligible, she was contacted to obtain consent and provide study package materials.

Approximately 5½ months later, the participant was contacted by phone to collect the 6-month assessment. If she was no longer interested in participating, she was thanked for her time. If she agreed to do the assessment, an appointment was made for the RA to go to her home and fit her with the accelerometer and GPS unit and provide the same logs and questionnaire. An appointment was then made to pick up the devices after the 9-day wear time period. For both assessments, if a device malfunctioned or had inadequate data, the participant was asked to wear the devices for another 9 consecutive days. Finally, for purposes of the current paper, only the accelerometer data was analyzed as the wear-time logs were not consistently completed. This study was approved by the (then) Capital District Health Authority Research Ethics Board.

Measures

Demographic, medical, and behavioral information

Demographic and medical variables were self-report and chart review. Demographic variables included age, marital status, ethnicity, years of education, employment status, income level, and height and weight to calculate body mass index (BMI). Medical variables collected were disease stage, month and year of diagnosis, treatment type, length of treatment, comorbidities, and perceived general health. Health behaviors measured were smoking status, alcohol consumption, and sleep habits.

Physical activity and sedentary behavior

MVPA was measured via the Actigraph GT3X accelerometer which has been shown to be a valid and reliable tool for personal activity measurement.^{28, 29} In brief, the accelerometer is designed to detect vertical accelerations ranging in magnitude from 0.05 to 2.00 g with a

frequency response of 0.25 to 2.50 hertz. These parameters allow for the measurement of normal human motion while rejecting high frequency vibrations from other sources. The accelerometer was placed on the right hip of each patient and held firmly in place via a belt clip to ensure consistent positioning. The accelerometer data was reduced to five-second counts (or epochs) and categorized according to physical activity intensity. Participants were asked to wear the accelerometer for nine consecutive days. If data were present for all nine days, the first and last day were removed. However, if the participant didn't have seven valid days between days two and eight, days one and/or nine were included to obtain as many valid days as possible up to seven. A day was considered valid if wear time was at least 600 minutes.^{10, 26} Using Actilife v6 software, for each valid day, time spent in sedentary, light, moderate and vigorous activity was calculated using the following accepted cut-points³⁰: <100 counts per minute (cpm) for sedentary, 100 - < 2020cpm for light, 2020 - <5999 for MVPA. Time spent in bouts of MVPA lasting 10 minutes or more were also calculated; this measure was used to determine those meeting PA guidelines (i.e., 0 if ≤ 150 minutes per week of MVPA; 1 if ≥ 150 minutes per week of MVPA). Finally, the daily time spent in each intensity of activity (i.e., MVPA, LPA, and SED) was calculated as a percentage. As with previous studies objectively measuring activity in BCS, participants were included in this analyses if they provided at least three valid days of accelerometer data.¹⁰ All measures were divided by the number of valid days to provide a 'per day' outcome.

Statistical Analyses

Analyses were completed using IBM SPSS Statistics 22 (IBM Analytics, Armonk, NY) and HLM7 Student Version (SSI, Inc. Skokie, IL). Descriptive statistics were used to describe the sample and the activity behavior at baseline and 6 months. Skewness was determined and

data were normalized where applicable. To address objective 1 (i.e., to determine potential changes in activity variables), HLM was used. Prior to conducting the main analyses, however, preliminary models were run with each medical and demographic variable to determine its potential relationship with a given activity outcome variable (i.e., to identify potential covariates for the main HLM models). Specifically, a Level-1 model was specified wherein the intercept (e.g., MVPA at baseline) was allowed to vary randomly (i.e., vary across BCS) and the slope for the linear trend was constrained to be fixed (i.e., the same across BCS). At Level-2, each medical and demographic variable was entered separately to predict the intercept and slope. Variables that were significant ($p \leq 0.05$) were then retained as covariates for the main HLM analyses. Once the covariates were identified, the next series of analyses examined the potential changes in each activity variable controlling for the covariates. To address objective 2 (i.e., to determine the proportion of BCS that are in each behavioral category), quartiles were created for the minutes per day of SED. As there are no defined criteria for being low vs. highly sedentary in BCS, we assigned the bottom quartile to be 'low sedentary behavior'.²⁴ Next, using the baseline data, four mutually exclusive groups were determined based on whether participants met MVPA guidelines or not, and whether they had high or low levels of SED.^{24, 26} Finally, we examined the number of BCS who remained in the same category or changed categories at 6 months.

Results

Participants

The detailed flow of participants can be found in Figure 1. There were 114 BCS that either were identified as eligible by the oncology care team ($n=102$) or directly contacted the RA after seeing a recruitment poster in the cancer clinic ($n=12$). Of those deemed eligible and potentially interested in the study ($n=98$), 77 provided informed consent and completed baseline

measures (Table 1). The majority of participants were Caucasian (97%), married (67%), employed full- or part-time (51%), non-smokers (87%), social drinkers (64%), had postsecondary education (51%), and a household income of \geq \$75,000 (51%). Average age and BMI were 57 (\pm 9.4) years and 27.9 (\pm 6.9) kg/m² respectively. Most participants reported stage II disease (44%), currently receiving one or more type of therapy (95%), reported fewer than 2 comorbidities (75%), and a perceived general health of very good or excellent (56%). A small proportion of participants (4%) were receiving palliative treatment at baseline. At the 6-month follow-up, 57 provided completed measures for a 74% retention rate. At T2, 20% of participants were not currently receiving treatment. The reasons given for not completing follow-up measures were ‘no longer interested’ (n=6), ‘health issues’ (n=5), ‘too busy’ (n=2), ‘work conflict’ (n=1), and ‘felt demotivating’ (n=1). We were unable to contact four participants for follow-up and only collected survey data for one participant.

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Physical activity and sedentary behavior

Detailed MVPA, LPA, and SED results can be found in Table 2. At baseline, participants were accumulating a daily average of 40.0, 132.9, and 594.7 minutes per day of MVPA, light, and SED. Total MVPA in bouts was an average 15.5 minutes per day; 29% of the sample were meeting the PA guidelines; approximately 77% of the BCS’ day was spent sedentary.

--Table 2 near here--

Changes in physical activity and sedentary behavior

Unadjusted models showed significant changes in total MVPA minutes (+5.87; p=.012) and MVPA in bouts (+4.87; p=.016). No significant change was found for either light (+4.23;

$p=.241$) or sedentary minutes (-2.82 ; $p=.701$). We found that BMI had a significant influence on the intercept for MVPA with higher BMIs associated with fewer MVPA minutes. No other characteristics were found to be significant; however, BMI was kept in the final models for each activity variable to keep the covariates consistent across models. Final adjusted models found the changes in total MVPA minutes ($+5.62$; $p=.015$) and MVPA in bouts ($+4.72$; $p=.020$) remained significant. The non-significant changes in LPA ($+4.12$; $p=.257$) SED minutes (-2.92 ; $p=.693$) also remained (see Table 3).

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Behavioral categories

To address objective 2, participants were classified into behavioral categories in the following proportions at baseline: 9% Busy Bees; 20% Sedentary Exercisers; 16% Light Movers; and 56% Inactive. At 6-month follow-up, classifications were as follows: 13% Busy Bees; 29% Sedentary Exercisers; 13% Light Movers; and 46% Inactive. Figure 2 shows the change in behavioral categories from baseline to follow-up.

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Discussion

This study was among the first to examine changes in objectively measured SED, LPA, and MVPA in a sample of BCS undergoing active treatment. We found that BCS are spending most of their day (i.e., 77% of their waking time) engaged in sedentary activities with little time spent in LPA (17%) or MVPA (5%). Further, results showed that SED and LPA remained stable over the 6-month period. These findings are consistent with research among BCS post-treatment and studies with other cancer types^{8-10,31} and the general population.^{25,26} Given the emerging

evidence of the health risks associated with high amounts of SED and low levels of LPA,^{8, 19, 23,}
²⁴ future research needs to focus on strategies for reducing the time spent in SED and increasing the time spent in LPA throughout the breast cancer journey. For example, recent studies have highlighted displacing sedentary time with LPA as a way of reducing the risks of SED among other populations such as people with diabetes.^{16-19, 22, 23}

Reducing the amount of time sitting by incorporating more time in LPA was found to be an effective method of managing symptoms in people with type 2 diabetes, as was reported in a recent proof-of-concept study.²² This study compared three activity regimens over three weeks. Results showed similar beneficial effects in both the “Sit Less” and “Exercise” activity regimens compared to the “Sitting” regimen indicating that breaking up sitting time with standing or LPA, such as walking, may be a more appropriate intervention for populations unable to perform activities at a higher intensity.¹⁹⁻²³ It is often easier for chronic disease populations to focus simply on moving more whenever possible rather than trying to get enough MVPA minutes to meet PA guidelines.¹⁹⁻²³ Therefore, this strategy may be applicable to BCS and should be a focus of future research.

In contrast to the results published by Sabiston and colleagues, we found a significant increase in MVPA from baseline to 6 months. They assessed BCS’ post-treatment activity levels every three months for twelve months and found that sedentary activity was high and remained stable over time (ranging from 77.6 to 78.6% over the year).⁹ They also showed MVPA levels significantly decreased over time. The current study contributes additional knowledge about PA among BCS patients by measuring MPVA and SED during treatment. While our average accelerometer wear-time was slightly lower than previous studies,^{8-11, 32} it is unclear whether this difference is significant enough to account for the more active sample. One explanation may be

that Sabiston's sample was post-treatment, whereas ours was during treatment. Near the end of curative intent treatment tends to be when women are starting to feel better and may be moving around more than they were in the previous months while on adjuvant therapy. Further potential explanations are discussed in the limitations section.

When classified into behavioral categories, our results showed most participants were identified as "Inactive" at both time-points. These results supported our hypothesis and are similar to previous studies in non-diseased populations.²⁴⁻²⁷ Research shows an association between those who are more active having a reduced risk of adverse breast cancer outcomes (e.g. recurrence and death);³³ however, there is little research examining the combination of sedentary behavior and MVPA. A recent study by Maddison and colleagues (2016) analyzed data from the National Health and Nutritional Examination Survey (NHANES) in the United States to characterize activity profiles and determine any associated cardiovascular disease (CVD) risk based on similar behavioral categories as we reported.²⁶ They found that when compared to the Busy Bee group, the Inactive group had the highest CVD risk followed by the Light Movers, with no difference between the Sedentary Exercisers. Due to our small sample size, we were under powered to perform association analyses across the four groups. A recent cohort study among breast cancer survivors examined risk of cardiovascular events and also reported that incidence had a graded reduction as exercise levels increased.³⁴ As BCS have a higher risk of subsequent comorbidities, like heart disease,^{35,36} it is important that future research assess health outcomes related to these behavioral categories and the interplay of MVPA and SED.

Despite the novel findings of the study, there are limitations that need to be considered. First, the transparency of the type of study being performed may have resulted in biased sample of more active women. It is a common limitation in behavior change research to have selection

bias with those recruited being more likely to be more active than those that declined participation. Future studies should attempt to recruit the less motivated population. Second, the majority of the sample was white, well-educated, and wealthier. Future research, particularly regarding SED, should aim to recruit a more representative sample. Third, the smaller sample size meant we were underpowered to ascertain which demographic and/or clinical variables were more likely to belong to a particular behavioral grouping and future research needs to address this issue, especially for the various treatment types that may impact activity levels differently. In addition, there may be other unknown comorbidities or occult disease (e.g. recurrence or treatment effects) that may impact activity levels that we are unable to determine. Finally, most participants that dropped out indicated either lack of interest or health concerns as their reasons for doing so. These participants may have been less likely to have improvements in their activity levels leaving us with a more active sample for the follow-up. Future studies should attempt to recruit a larger sample to ensure measures are robust enough to determine meaningful changes. Additionally, efforts to retain participants for follow-up measures are necessary to ensure results are representative.

This is the first longitudinal study to examine objective measures of activity among a sample of BCS undergoing adjuvant or palliative therapy. It adds to the literature of accelerometer studies among cancer survivors that shows high levels of sedentary activity with comparatively low LPA and MVPA. Additionally, this is the first study to classify BCS into behavioral categories, which highlighted the importance of examining both physical activity and sedentary behavior concurrently rather than separately, which is the current norm. Though research has shown behavioral interventions targeting MVPA to be modestly successful,^{1, 12} they do little to address LPA or sedentary behavior. Future research among cancer survivors should

build on results from non-diseased populations that shows interventions that target MVPA, LPA and sedentary behavior are more effective at changing sedentary behavior than MVPA interventions alone.^{20-22, 24-27}

Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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Table legends

Table 1. Baseline demographic, medical, and behavioral characteristics of breast cancer survivors (n=77) in Nova Scotia, Canada.

Table 2. Average activity measures at baseline and 6 month follow up for breast cancer survivors with ≥ 3 valid days of accelerometer data.

Table 3. Results from the hierarchical linear modeling analyses examining change over the 6-month period for the activity variables

Figure legends

Figure 1. Behavioral categories based on whether they are meeting the PA guidelines of 150 minutes per week (High MVPA vs. Low MVPA) and whether they are accumulating high amounts of sedentary minutes (High SED vs. Low SED). ^aCategories are derived from data driven quartiles. Following a conservative approach, Q1 was determined to be the “low amount of sedentary time” group.

Figure 2. Detailed flow of participants through the study.

Figure 3. Average minutes of activity at T1 and T2. 3a indicates the average daily minutes in bouts of MVPA; 3b indicates the average daily total minutes in MVPA; 3c indicates the average daily minutes in SED; 3d indicates the average daily minutes in LPA.

Figure 4. Number of participants in four mutually exclusive categories at baseline and the change at 6 months. 2a indicates the distribution of baseline Busy Bees at follow-up; 2b indicates the distribution of baseline Sedentary Exercisers at follow-up; 2c indicates the distribution of baseline Light Movers at follow-up; 2d indicates the distribution of baseline Inactives at follow-up.

Table 1. Baseline demographic, medical, and behavioural characteristics of breast cancer survivors (n=77) in Nova Scotia, Canada.^a

Demographic/ Behaviour Variables	N (%)
Age [Mean (SD)]	56.8 (9.4)
≤ 59	24 (25%)
60-69	41 (43%)
≥ 70	30 (32%)
Ethnic origin	
White	76 (99%)
Other	1 (1%)
Marital status	
Married/Partner	52 (68%)
Not married	25 (32%)
Education	
Total years of formal schooling	14.9 (2.7)
Family Income	
< 60,000	23 (32%)
≥ 60,000-99,999	25 (36%)
≥ 100,000	23 (32%)
Employment	
Employed	38 (51%)
Not employed	37 (49%)
Smoking status	
Not at all	67 (87%)
Occasionally	2 (3%)
Daily	8 (10%)
Alcohol consumption per week	
None	38 (50%)
1-2 days	23 (30%)
3-4 days	9 (12%)
5 or more days	6 (8%)
Disease Stage	
Stage I	18 (27%)
Stage II	30 (44%)
Stage III	16 (23%)
Stage IV	4 (6%)
Current Treatment^{b,c}	
Chemotherapy	31 (40%)
Radiation therapy	30 (39%)
Hormone therapy	50 (65%)
Number of current treatments at baseline^c	
1	47 (61%)
2	14 (18%)

3	12 (16%)
Time since diagnosis in Months [Mean (SD)]^c	22.5 (36.6)
< 5 years	70 (91%)
≥ 5 years	7 (9%)
Co-morbidity status	
Less than 2 co-morbidities	58 (75%)
2-3 co-morbidities	12 (16%)
≥ 4 co-morbidities	7 (9%)
Body mass index [Mean (SD)]	27.9 (6.9)
Healthy weight	28 (39%)
Overweight	23 (32%)
Obese	21 (29%)

^a Values given are N(%) unless otherwise specified.

^b May have been on more than one treatment, percentages do not add up to 100%

^c Data from chart review

Table 2. Average activity measures at baseline and 6 month follow up for breast cancer survivors with ≥ 3 valid days of accelerometer data.^a

Activity Measure	Baseline (n=70) M (SD)	6 months (n=56) M (SD)
Average daily wear time	767.7 (80.55)	780.1 (78.77)
Average daily MVPA minutes	40.0 (21.86)	45.9 (23.63)
Average daily LPA minutes	132.9 (37.59)	138.1 (37.09)
Average daily Sedentary minutes	594.7 (74.01)	597.3 (65.27)
Percent of day MVPA	5.3%	5.9%
Percent of day LPA	17.2%	17.6%
Percent of day Sedentary	77.3%	76.5%
Average daily MVPA Bout Duration	15.5 (15.45)	20.4 (18.32)
Meeting PA guidelines	29%	41%

Abbreviations: MVPA, moderate-to-vigorous physical activity; LPA, light physical activity; PA, physical activity

^a Values given are mean (standard deviation).

Table 3. Results from the hierarchical linear modeling analyses examining change over the 6-month period for the activity variables.^a

Outcome	Intercept	Slope	p-value
Daily MVPA minutes	39.99	5.62	.015
Daily MVPA in Bouts	15.49	4.72	.020
Daily LPA minutes	132.90	4.12	.257
Daily SED minutes	594.72	-2.92	.693

Abbreviations: MVPA, moderate-to-vigorous physical activity; LPA, light physical activity; SED, sedentary behaviour.

^aAll analyses controlled the intercept for BMI at level-2 based on preliminary covariate analyses

	Low Sedentary ^a (Q1)	High Sedentary ^a (Q2-4)
High MVPA (≥ 150 minutes)	Busy Bee	Sedentary Exerciser
Low MVPA (<150 minutes)	Light Mover	Inactive

Figure 1.

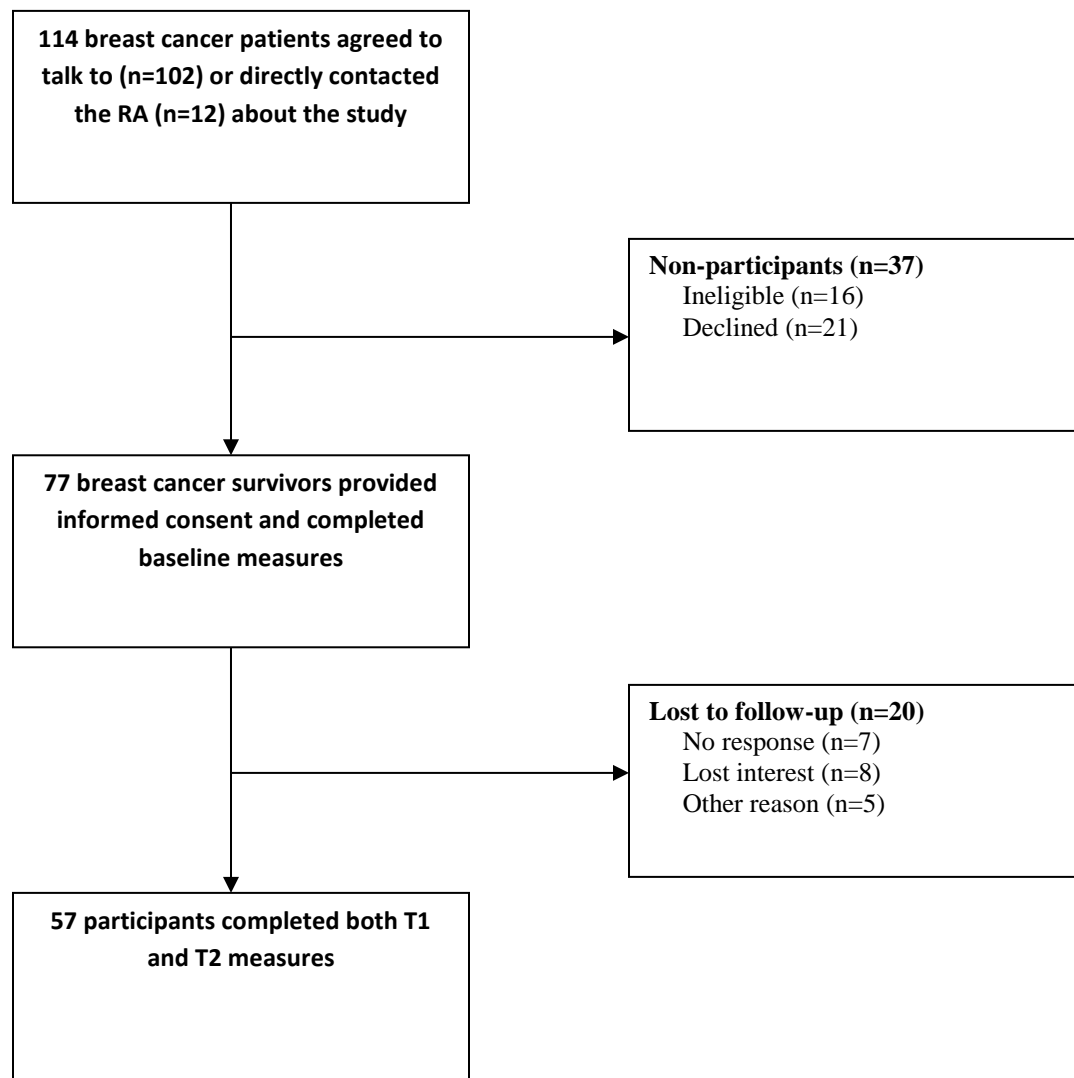


Figure 2.

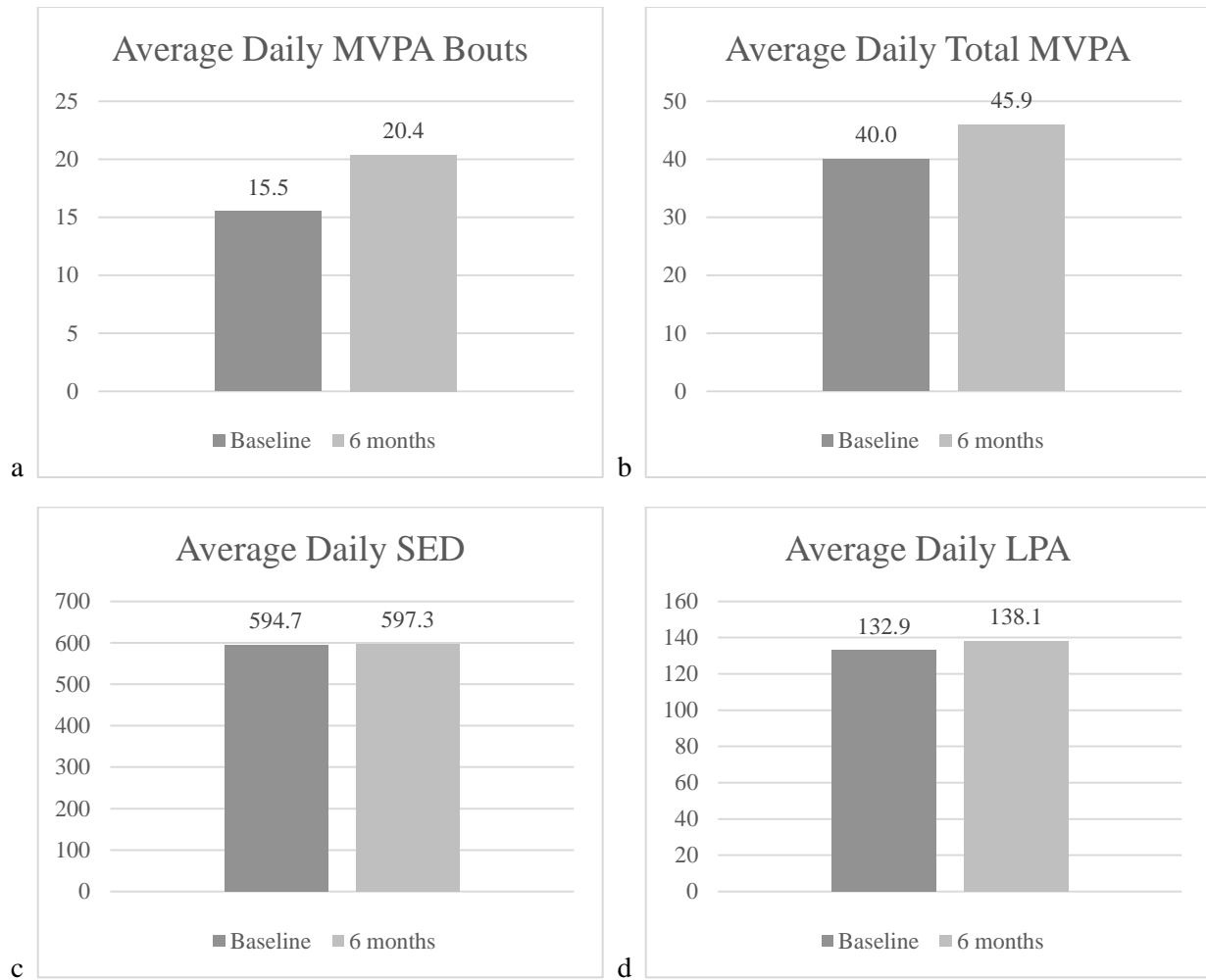


Figure 3.

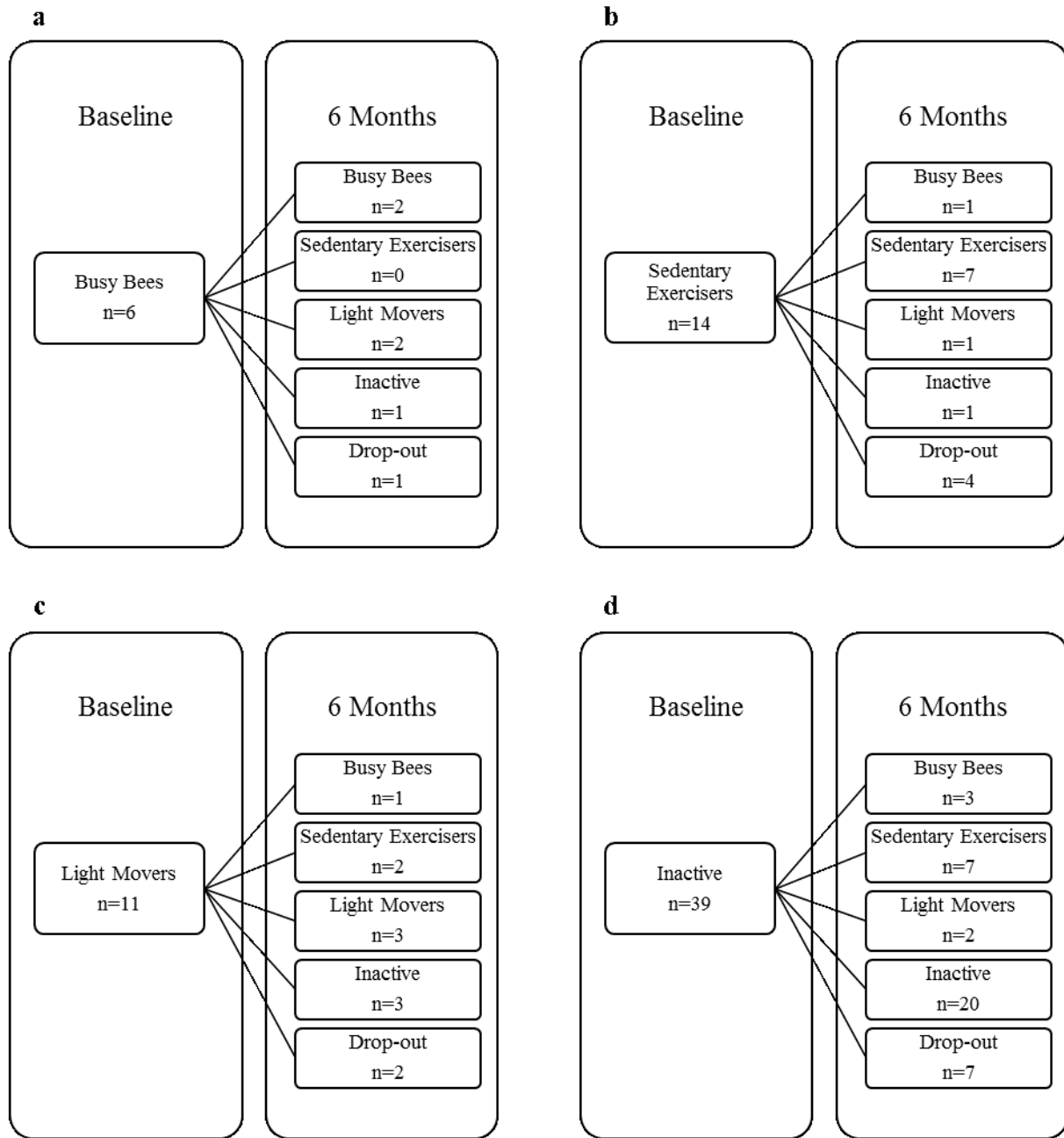


Figure 4.

STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (b) For matched studies, give matching criteria and number of exposed and unexposed
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) If applicable, explain how loss to follow-up was addressed (e) Describe any sensitivity analyses
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyzed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram

Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarize follow-up time (eg, average and total amount)
Outcome data	15*	Report numbers of outcome events or summary measures over time
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	summaries key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalizability	21	Discuss the generalizability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at <http://www.strobe-statement.org>.