



# Feasibility and acceptability of intensive longitudinal data collection of activity and patient-reported outcomes during chemotherapy for breast cancer

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## Abstract

**Purpose** Ecological momentary assessment (EMA) may help us better understand biopsychosocial determinants and outcomes of physical activity during chemotherapy, but may be burdensome for patients. The purpose of this study was to determine the feasibility and acceptability of using EMA to assess activity, symptoms, and motivation among early-stage breast cancer patients undergoing chemotherapy.

**Methods** Women were instructed to wear an accelerometer 24/7 (hip during day and wrist overnight). Text message prompts were sent 4 times/day concerning patient-reported symptoms and motivational factors for 10 consecutive days (3 days pre-, day of, and 6 days post-chemotherapy dose). These measures occurred at the beginning, middle, and end of a full course of chemotherapy. At study conclusion, participants reported on perceived study acceptability, burden, and reactivity.

**Results** Of the 75 women who consented to participate, 63 (84%) completed all 3 assessment time points. Participants responded to 86% of total text prompts and had valid accelerometer data on 82% of study days. Compliance was similar across all time points. The majority (78%) rated their study experience as positive; 100% were confident in their ability to use study technology. Reactivity varied with 27% indicating answering symptom questions did not affect how they felt and 44% and 68% indicated answering questions and wearing the accelerometer, respectively, made them want to increase activity.

**Conclusions** Findings indicate EMA methods are feasible for breast cancer patients undergoing chemotherapy. EMA may help us better understand the biopsychosocial processes underlying breast cancer patients' activity in the context of daily life.

**Keywords** Physical activity · Chemotherapy · Breast cancer · mHealth · Patient-reported outcomes

## Introduction

Approximately 1 in 8 women will be diagnosed with breast cancer during their lifetime; two-thirds of these women will receive chemotherapy [1]. Breast cancer patients undergoing chemotherapy may experience a myriad of negative side effects ranging from acute (e.g., anemia, nausea) to chronic (e.g., depression, fatigue), which may result in compromised quality of life (QOL) [2]. Increased physical activity during chemotherapy has been associated with improved physical functioning and symptom burden (e.g., nausea, pain, constipation, fatigue) [3–5] and may reduce the need for chemotherapy dose adjustments [3] and improve disease-free survival [6] among breast cancer patients. Additionally, higher physical activity during chemotherapy is associated with higher activity post-treatment, which is consistently associated with improved health and disease outcomes [5,

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7, 8]. Despite these benefits, existing data, largely based on infrequently assessed self-report retrospective measures, suggest physical activity declines post-diagnosis and does not return to pre-diagnosis levels, while sedentary behavior remains high [9–12]. However, activity patterns likely fluctuate daily during chemotherapy due to changes in clinical (e.g., time since chemotherapy dose), biopsychosocial (e.g., fatigue, nausea), and motivational (e.g., self-efficacy, goal-setting) factors. Daily activity patterns during chemotherapy may be a proxy of overall health and functioning [13] and an indicator of treatment adherence and short- and long-term disease prognosis [14]. For example, a patient may demonstrate declines in activity prior to hospitalization or a missed chemotherapy dose. However, to our knowledge, no studies have examined objectively measured activity patterns during chemotherapy for breast cancer within the context of potential clinical, biopsychosocial, and behavioral antecedents and outcomes.

Ecological momentary assessment (EMA) methodology may be useful for understanding fluctuations in activity patterns in relation to clinical, biopsychosocial, and behavioral factors during chemotherapy. EMA involves sampling an individual's experiences (i.e., behaviors, cognitions, affect) in real time in one's natural environment [15]. High smartphone ownership rates [16] and increased device capabilities allow for real-time collection of more passive, reliable EMA data in various contexts at greater frequencies than previously possible. Similarly, advancements in wearable activity monitors' usability (e.g., ActiGraph, Fitbit) including increased device comfort, affordability, storage capacity, and battery life [17] allow for the low burden collection of a large volume of objective data [14]. Thus, EMA data collection combined with data from wearable devices may provide a more granular understanding of predictors and outcomes of activity participation in breast cancer patients receiving chemotherapy through repeated sampling of subjects' behaviors and experiences in real time, in participants' natural environments [18] and provide important information for improving interventions and health outcomes in this population.

Research in children, adolescents, healthy adults, older adults, and other clinical populations has demonstrated EMA data collection using smartphones or computers to collect short survey responses combined with accelerometry is feasible, acceptable and valid [19–21]. To our knowledge, no studies have explored the feasibility of collecting these data during chemotherapy in any cancer population. Chemotherapy can cause physical and mental side effects including fatigue, nausea, headaches, depression, and anxiety [2], which may increase the physical and psychological burden of responding to multiple EMA data collection prompts per day during this time. Wearable devices may also be uncomfortable during chemotherapy

treatment due to side effects including dry, sensitive skin, and neuropathy [22, 23]. The purpose of this study was to determine the feasibility and acceptability of EMA data collection via smartphone and accelerometers in breast cancer patients undergoing chemotherapy.

## Methods

### Recruitment

Patients were identified  $\leq 7$  days from their first breast oncology appointment at a large, urban, academic medical center using electronic medical records. Patients were either (a) approached in the clinic post-oncology appointment, (b) referred by their oncologist, or (c) sent an email endorsed by their oncologist (if consented to contact regarding research projects). Inclusion criteria were (a) female  $\geq 18$  years of age; (b) diagnosed with stage I–III breast cancer; (c) scheduled to receive chemotherapy at study site and able to complete first data collection time point prior to/during second chemotherapy cycle; (d) have/had an operable tumor; (e) no history of other primary cancer with the exception of non-melanoma skin cancer; (f) own a smartphone; (g) access to computer with Internet, and (h) able to read and write in English. Participation was not restricted on overweight/obesity status, current activity, or age.

Patients recruited in the clinic were approached by a study team member in an exam room following their oncology consultation and provided with a brief study description. Interested patients were screened to determine eligibility. Patients who were uncertain about participation were given a study pamphlet and completed a contact information form. Patients recruited via email and oncologist referral were emailed a study description and secure link to complete eligibility screening online, if interested. Individuals who were not interested were asked to indicate this in an email response. All recruitment materials, regardless of modality, stated that the study aimed to understand changes in activity patterns in women with breast cancer undergoing chemotherapy and highlighted the low burden of study procedures (i.e., no in-person lab visits and completion of all procedures online or via mail). Because of the time-sensitivity of study recruitment, potential participants were followed up with via phone or email if they did not respond within 24–48 h of initial contact. All eligible and interested individuals completed informed consent. Consented individuals completed a study orientation session in-person or on the phone depending on patient preference and treatment timing and were given (in-person) or mailed (phone) study materials.

### Study design and procedures

This is a prospective, longitudinal, observational study using EMA methodology. Patients were asked to participate in 10 days of data collection at three time points: the beginning [first or second cycle; Time 1 (T1)], middle [Time 2 (T2)], and end [last cycle; Time 3 (T3)] of chemotherapy. The 10-day assessment included 3 days pre-, day of, and the 6 days post-chemotherapy (see Fig. 1). At each time point, participants were emailed an individualized, secure link to an online questionnaire battery and provided with an

assessment packet including the ActiGraph, wear log, ActiGraph and EMA prompt instructions, and a self-addressed stamped envelope. At baseline, assessment packets were given to participants during (in-person) or mailed prior to (phone) orientation. Study orientation consisted of instructions on study procedures and EMA prompting system set-up (see Fig. 2). Assessment packets were mailed at all subsequent time points. Participants were instructed to go about their usual activities and begin wearing the ActiGraph 24 h/day for ten consecutive days beginning 3 days prior to their chemotherapy dose. Following completion, they

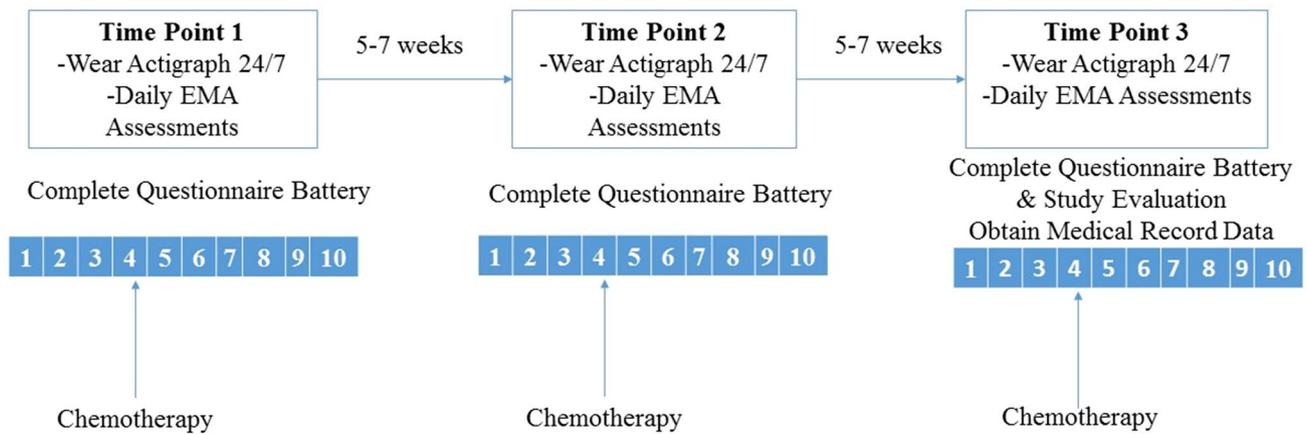


Fig. 1 Study design

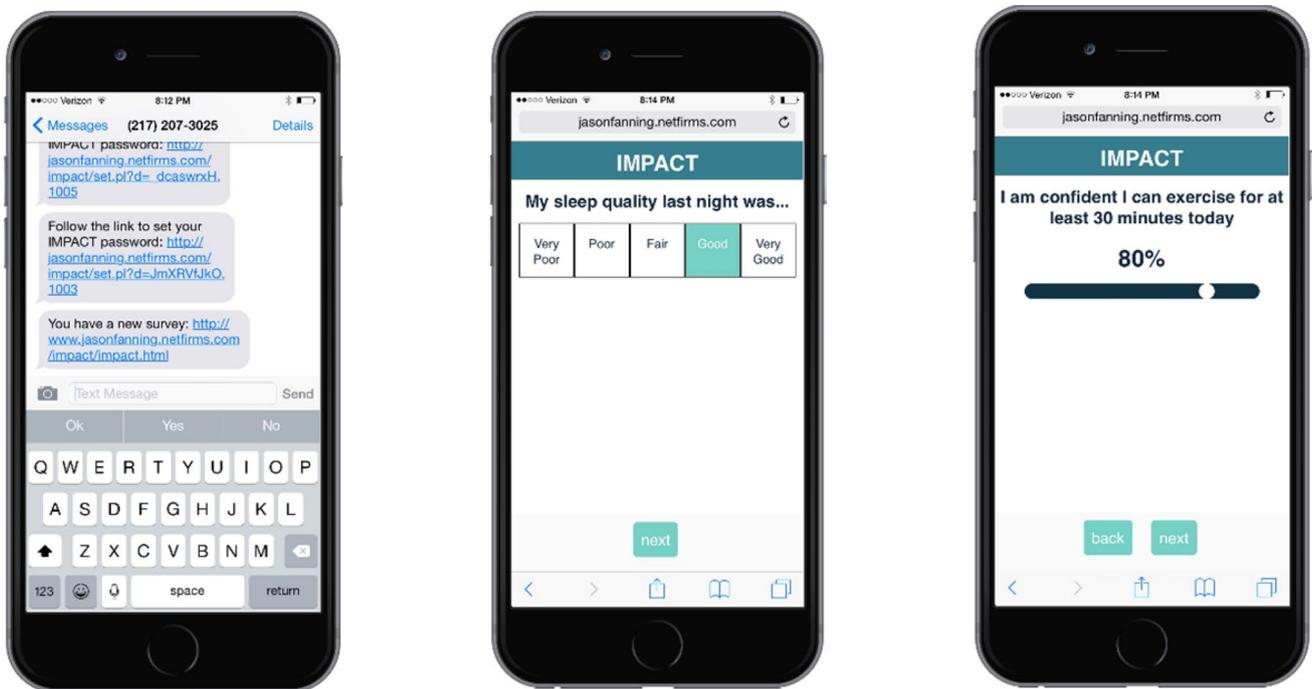


Fig. 2 EMA prompting system

were instructed to mail the ActiGraph back to the study team in the provided envelope. The same procedures were repeated during the middle and last cycle of chemotherapy. The study team worked with the patient and oncologist to ensure assessment timing accuracy.

To enhance compliance with study procedures, participants were sent an email reminder the day before each data collection period started and were sent a “check-in” email on day 5 to ensure they were not having difficulties with study procedures. Additionally, if no EMA prompts received a response on a given day, participants were emailed and called to ensure they were well and understood study procedures. Participants were paid \$100 at each time point regardless of compliance. All procedures were approved by the Institutional Review Board.

## Measures

### Demographics and disease characteristics

Patients self-reported age, race, ethnicity, income, education, employment status, marital status, height and body weight to calculate body mass index (BMI), number of comorbidities, and health status. BMI and age were confirmed via medical records. Data on disease stage and each chemotherapy dose date were extracted from participants’ electronic medical records. Participants also completed a modified version of the Godin Leisure Time Exercise Questionnaire [24] to report typical times per week and minutes per session of mild, moderate, and vigorous physical activity prior to cancer diagnosis. Times per week and minute per session of moderate and vigorous activity were multiplied and added to obtain total minutes of moderate to vigorous physical activity prior to diagnosis.

### Recruitment and retention

Study accrual (number enrolled/number eligible individuals contacted) and retention (number withdrew/number enrolled) rates were determined at data collection completion.

### EMA prompts

Table 1 details measures used and schedule. Participants were sent 4 text message prompts per day during each data collection period with a link to complete patient-reported outcomes assessments with between 7 and 13 items depending on prompt number. Prompt 1 was sent at a random time < 2 h from the participant’s reported wake time. Prompts 2 and 3 were sent at random times  $\geq 2$  h from the previous prompt. Prompt 4 was sent < 2 h from the participant’s reported bedtime and  $\geq 2$  h since the prior prompt.

Prompts were open for 60 min with text message reminders every 15 min (3 total) if no response was received. Symptom burden (affect, depression, anxiety, fatigue, pain, physical and cognitive function) was assessed at all 4 prompts using single items from the Patient-Reported Outcomes Measurement Information System (PROMIS) modified to assess symptoms at the present moment [25]. Patients reported sleep quality on the first prompt responded to each day using a single item from PROMIS modified for previous night’s sleep [26]. Motivational factors for increasing physical activity and reducing sedentary behavior were measured using items modified for the current (Prompt 1) and next day (Prompt 4) including self-efficacy [27], physical and psychological outcome expectations [24], and exercise goal-setting [28]. Finally, at Prompt 4, participants indicated whether they had engaged in any exercise that day. If yes, they self-reported minutes of strenuous, moderate, and mild activity using the Godin Leisure Time Exercise Questionnaire modified for current day activity [29].

### Accelerometer

Participants were instructed to wear the ActiGraph accelerometer, (model wGT3X-BT, ActiGraph Corporation, Pensacola, FL), a valid and reliable objective activity measure [21, 30], 24/7 during each 10-day data collection period. This model of the ActiGraph accelerometer has dimensions of 4.6 cm  $\times$  3.3 cm  $\times$  1.5 cm and weighs 19 g. For comparison, the dimensions of the Fitbit Flex, which was on the market at the time study procedures were complete, are 1.5 cm  $\times$  1.0 cm and the Fitbit Flex weighs 11.3 g, and can be worn attached like a watch on the wrist. Participants were instructed to wear the ActiGraph on a belt around the waist on their non-dominant hip during waking hours, and on a wristband on their non-dominant wrist during sleeping hours. Participants were sent email reminders for when they should start and stop wearing the ActiGraph at each data collection period. Additionally, participants were instructed to record times the monitor was switched from hip to wrist and any non-wear time on the provided wear log. Activity data were collected in 1-min intervals (epochs). ActiLife version 6.13.3 was used to derive wear time. Non-wear time was defined as intervals of at least 90 consecutive minutes of zero counts, with allowance for  $\leq 2$  min of observations < 100 counts/min within the non-wear interval [31]. A valid day of accelerometer wear was defined as  $\geq 10$  h of wear time during waking hours [31, 32].

### Acceptability

Following T3 data collection, participants completed a study evaluation rating their perceptions of (a) satisfaction with study participation and procedures, (b) answering EMA

**Table 1** EMA prompt items and schedule

| Construct                 | Item/response options  | Prompt number asked |   |   |   |
|---------------------------|--|---------------------|---|---|---|
|                           |  | 1                   | 2 | 3 | 4 |
| Behavior                  |  |                     |   |   |   |
| Sleep [26]                | <b>Q:</b> My sleep quality last night was...<br><b>R:</b> 5 point Likert scale from 1 (very poor) to 5 (very good)   | ✓                   |   |   |   |
| Physical activity [29]    | <b>Q:</b> Did you exercise today?<br><b>R:</b> If YES, then:<br><b>Q:</b> For how long in minutes did you the following kinds of exercise today?<br>a) STRENUOUS EXERCISE (HEART BEATS RAPIDLY) (i.e., running, jogging, basketball, cross country skiing, judo, roller skating, vigorous swimming, vigorous long distance bicycling)<br>b) MODERATE EXERCISE (NOT EXHAUSTING) (i.e., fast walking, baseball, tennis, easy bicycling, volleyball, badminton, alpine skiing, easy swimming, popular and folk dancing)<br>c) MILD EXERCISE (MINIMAL EFFORT) (i.e., yoga, archery, fishing from river bank, bowling, horseshoes, golf, snow-mobiling, easy walking) |                     |   |   | ✓ |
| Motivational factors      |  |                     |   |   |   |
| Self-efficacy [27]        | <b>Q:</b> I am confident I can exercise for at least 30 min today.<br><b>R:</b> 0% to 100% with 10 point increments  | ✓                   |   |   |   |
|                           | <b>Q:</b> I am confident I can exercise for at least 30 min tomorrow.<br><b>R:</b> 0% to 100% with 10 point increments   |                     |   |   | ✓ |
|                           | <b>Q:</b> I am confident I can replace at least 60 min of sitting and/or lying down with standing or light intensity activities today (i.e., household chores, light walking, etc.).<br><b>R:</b> 0% to 100% with 10 point increments  | ✓                   |   |   |   |
|                           | <b>Q:</b> I am confident I can replace at least 60 min of sitting and/or lying down with standing or light intensity activities <b>tomorrow</b> (i.e., household chores, light walking, etc.).<br><b>R:</b> 0% to 100% with 10 point increments  |                     |   |   | ✓ |
| Outcome expectations [24] | <b>Q:</b> Exercise will improve my overall body functioning today.<br><b>R:</b> 5 point Likert scale from 1 (strongly disagree) to 5 (strongly agree)  | ✓                   |   |   |   |
|                           | <b>Q:</b> Exercise will improve my overall body functioning <b>tomorrow</b> .<br><b>R:</b> 5 point Likert scale from 1 (strongly disagree) to 5 (strongly agree)   |                     |   |   | ✓ |
|                           | <b>Q:</b> Exercise will improve my psychological state today.<br><b>R:</b> 5 point Likert scale from 1(strongly disagree) to 5 (strongly agree)  | ✓                   |   |   |   |
|                           | <b>Q:</b> Exercise will improve my psychological state <b>tomorrow</b> .<br><b>R:</b> 5 point Likert scale from 1(strongly disagree) to 5 (strongly agree)   |                     |   |   | ✓ |
| Goal-setting [39]         | <b>Q:</b> I have plans to engage in some form of exercise for at least 30 min today.<br><b>R: I have already exercised today (check if yes) and</b> 5 point Likert scale from 1 (strongly disagree) to 5 (strongly agree)  | ✓                   |   |   |   |
|                           | <b>Q:</b> I have plans to engage in some form of exercise for at least 30 min <b>tomorrow</b> .<br><b>R:</b> 5 point Likert scale from 1 (strongly disagree) to 5 (strongly agree)   |                     |   |   | ✓ |
| Symptoms                  |  |                     |   |   |   |
| Mood [26]                 | <b>Q:</b> My worries overwhelm me right now.<br><b>R:</b> 5 point Likert scale from 1 (strongly disagree) to 5 (strongly agree)  | ✓                   | ✓ | ✓ | ✓ |
|                           | <b>Q:</b> How would you rate your depression right now?<br><b>R:</b> 5 point Likert scale from 1 (none) to 5 (very severe)   | ✓                   | ✓ | ✓ | ✓ |
| Fatigue [26, 40]          | <b>Q:</b> How would you rate your fatigue right now?<br><b>R:</b> 5 point Likert scale from 1 (none) to 5 (very severe)  | ✓                   | ✓ | ✓ | ✓ |
| Physical function [26]    | <b>Q:</b> To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries or moving a chair right now?<br><b>R:</b> 5 point Likert scale from 1 (completely) to 5 (not at all)   | ✓                   | ✓ | ✓ | ✓ |
|                           | <b>Q:</b> Are you physically able to go for a walk for at least 15 min right now?<br><b>R:</b> 5 point Likert scale from 1 (without any difficulty) to 5 (unable to do)  | ✓                   | ✓ | ✓ | ✓ |
| Pain [26]                 | <b>Q:</b> What is your level of pain right now?<br><b>R:</b> 0 (no pain) to 10 (worst imaginable pain)   | ✓                   | ✓ | ✓ | ✓ |
| Cognitive function [26]   | <b>Q:</b> My mind is as sharp as usual right now.<br><b>R:</b> 5 point Likert scale from 1 (not at all) to 5 (very much)   | ✓                   | ✓ | ✓ | ✓ |

Q= Question asked; R= Response options

prompts, (c) wearing the accelerometer, and (d) reactivity (i.e., acting or feeling a specific way in response to study procedures). See Table 2 for full list of questions asked and response choices.

## Data analyses

Descriptive statistics including means and standard deviations (continuous variables) and frequencies (categorical variables) were calculated for demographic and disease characteristics, accrual and retention, and EMA prompt and accelerometer compliance and acceptability. We also estimated multi-level logistic regression models to examine EMA non-response (answered vs. unanswered) and daily accelerometer data validity (valid vs. not valid) with time-invariant: a) demographic factors [age (continuous); education ( $\geq$  college degree vs.  $<$  college degree); household income ( $\geq$  \$100,000 vs.  $<$  \$100,000); race (White vs. non-White); weight status ( $< 25$  kg/m<sup>2</sup> vs.  $\geq 25$  kg/m<sup>2</sup>)] and b) disease characteristics [disease stage (stage I/II vs. stage III); type of chemotherapy (neoadjuvant vs. adjuvant)] and time-varying temporal processes including (a) day of week (weekend vs. weekday); (b) prompt timing (morning vs. afternoon/evening); (c) time point (T1 vs. T2 vs. T3); and (d) chemotherapy treatment status (pre-treatment vs. day off/post-treatment). Analyses were conducted in SAS version 9.4 (Cary, NC) [33].

## Results

### Participants

Participant flow through the study is detailed in Fig. 3. In total, we approached 318 patients. Of these, 218 (68.5%) were not screened for the following reasons: not interested prior to screening ( $n=82$ ), not receiving chemotherapy ( $n=64$ ), not receiving treatment at study site ( $n=38$ ), and no response to screening attempts ( $n=33$ ). A total of 104 patients completed screening; 75 of these (72.1%) consented. Reasons for screening failure included not enough time before chemotherapy dose to enroll ( $n=10$ ); did not own smartphone ( $n=5$ ); unable to read and write English ( $n=3$ ); diagnosed with Stage IV disease ( $n=3$ ); no computer access ( $n=2$ ); and history of other primary cancer ( $n=1$ ). Of the 75 patients who consented, 67 participated in at least one data collection time point, and 63 (84%) completed all 3; 8 participants withdrew prior to baseline data collection completion because they felt study procedures were too burdensome and 5 were lost to follow-up ( $n=1$  discontinued chemotherapy prior to T2,  $n=2$  discontinued chemotherapy prior to T3,  $n=1$  had health complication at T3). A total of 41 of the 63

(65.1%) participants who completed T3 EMA data collection completed the post-study evaluation.

Data on demographic and disease characteristics for all patients who completed at least one time point of data collection ( $n=67$ ,  $M_{age}=48.5$ ,  $SD=10.3$ ) are presented in Table 3. The majority of participants were White (76.6%), non-Hispanic/Latina (87.1%), and highly educated (78.1%  $\geq$  college degree). Most (80%) had stage I/II disease and were undergoing adjuvant chemotherapy (65.7%). About one-third (35.8%) of participants began study participation during cycle 1 and 64.2% began participation during cycle 2. Participants retained in the study did not differ from those who withdrew on age, race, education, BMI, number of comorbidities, or health status.

### Acceptability

Study evaluation results are detailed in Table 2. Participants who completed the study evaluation ( $n=41$ ) did not differ by age, race, education, or BMI from those who did not ( $n=22$ ). They reported significantly ( $p=0.04$ ), although not clinically meaningful, more comorbidities ( $M=1.3 \pm 1.6$ ) than non-completers ( $M=0.5 \pm 0.9$ ). The majority (78%) of participants rated their overall study experience as positive/very positive. All participants (100%) felt contact level with study staff was adequate and rated the study staff responsiveness as good/very good. Most participants (73.2%) indicated they felt 10 days was appropriate for each data collection period. Almost all participants (97.6%) rated the study technology as easy/very easy to use. All participants (100%) were confident/somewhat confident in their ability to use the study technology.

### EMA prompts

Most participants thought 4 EMA prompts per day (75.6%) and three text message reminders (90.2%) were appropriate. The majority of participants (82.9%) indicated answering prompts interfered with their daily routine a little or not at all. Approximately two-thirds of participants (68.3%) indicated answering questions about their activity levels made them want to increase their activity. In contrast, 73.2% indicated questions about symptoms did not influence how they felt.

### Accelerometer

The majority of participants (92.7%) thought the ActiGraph was easy/very easy to use; 100% were somewhat/extremely confident in their ability to use it. Most participants (85.4%) indicated wearing the ActiGraph interfered with their daily routine a little or not at all. The majority also rated wearing the ActiGraph monitor on their hip (97.6%) and wrist

**Table 2** Study evaluation ratings of acceptability ( $n=41$ )

| Question  | Rating frequency $n$ (%) |
|---|--------------------------|
| Overall study acceptability   |                          |
| Overall experience as a participant (very negative to very positive)              |                          |
| Positive/very positive  | 32 (78.0)                |
| Neutral   | 9 (22.0)                 |
| Level of contact with study staff (not enough, adequate, too much)                |                          |
| Adequate  | 41 (100.0)               |
| Staff responsiveness (very poor to very good)                                     |                          |
| Very good/good  | 41 (100.0)               |
| Confidence in ability to use study technology (not at all to extremely)           |                          |
| Extremely/somewhat confident  | 41 (100.0)               |
| EMA prompt acceptability  |                          |
| Ease of using EMA prompts (very hard to very easy)                                |                          |
| Easy/very easy  | 40 (97.6)                |
| Neutral   | 1 (2.4)                  |
| Number of daily EMA prompts (way too few to way too many)                         |                          |
| Too many/way too many   | 9 (22.0)                 |
| Neutral   | 31 (75.6)                |
| Too few/way too few   | 1 (2.4)                  |
| Number of reminders to answer EMA prompts (way too few to way too many)           |                          |
| Too many/way too many   | 3 (7.3)                  |
| Neutral   | 37 (90.2)                |
| Too few/way too few   | 1 (2.4)                  |
| Extent that EMA prompts interfered with daily routine (not at all to very much)   |                          |
| Not at all/a little bit   | 34 (82.9)                |
| Somewhat  | 6 (14.6)                 |
| Quite A bit/very much   | 1 (2.4)                  |
| Accelerometer acceptability   |                          |
| Confidence using the accelerometer (not at all to extremely)                      |                          |
| Extremely/somewhat confident  | 41 (100.0)               |
| Ease of using the activity monitor (very difficult to very easy)                  |                          |
| Very easy/easy  | 38 (92.7)                |
| Neutral   | 3 (7.3)                  |
| Interference of the monitor with daily routine (not at all to very much)          |                          |
| Not at all/a little bit   | 35 (85.4)                |
| Somewhat  | 4 (9.8)                  |
| Quite a bit/very much   | 2 (4.8)                  |
| Comfort level of wearing the accelerometer on the hip (not at all to extremely)   |                          |
| Extremely/mostly comfortable  | 34 (82.9)                |
| Somewhat comfortable  | 6 (14.6)                 |
| Not very/not at all comfortable   | 1 (2.4)                  |
| Comfort level of wearing the accelerometer on the wrist (not at all to extremely) |                          |
| Extremely/mostly comfortable  | 22 (53.7)                |
| Somewhat comfortable  | 11 (26.8)                |
| Not very/not at all comfortable   | 8 (19.5)                 |
| Number of days asked to wear the activity monitor (way too few to way too many)   |                          |
| Way too many/too many   | 11 (26.8)                |
| Neutral   | 30 (73.2)                |
| Size of the monitor (too big/good size/too small)                                 |                          |

**Table 2** (continued)

| Question   | Rating frequency <i>n</i> (%) |
|--|-------------------------------|
| Good size  | 29 (70.7)                     |
| Too big  | 12 (29.3)                     |
| Would you wear the ActiGraph again as part of another study (yes/maybe/no)   |                               |
| Yes  | 27 (65.9)                     |
| Maybe  | 14 (34.1)                     |
| What location would you prefer to wear the monitor in a future study?  |                               |
| Waist = day/wrist = night  | 17 (41.5)                     |
| Wrist 24/7   | 17 (41.5)                     |
| No preference  | 7 (17.1)                      |
| Preference for wearing a commercially available monitor (i.e., Fitbit) or the ActiGraph (commercial monitor, ActiGraph, no preference) |                               |
| Commercial monitor   | 28 (68.3)                     |
| No preference  | 12 (29.3)                     |
| ActiGraph  | 1 (2.4)                       |
| Reactivity   |                               |
| Questions about symptoms made me (feel better/did not influence/feel worse)  |                               |
| Did not influence how I felt   | 30 (73.2)                     |
| Feel better  | 8 (19.5)                      |
| Feel worse   | 3 (7.3)                       |
| Questions about physical activity motivation made me want to (decrease/stay same, increase) physical activity                          |                               |
| Increase physical activity   | 28 (68.3)                     |
| Do the same amount of physical activity as usual   | 13 (31.7)                     |
| Wearing the accelerometer monitor made me want to (decrease/stay same, increase) physical activity                                     |                               |
| Increase physical activity   | 18 (43.9)                     |
| Do the same amount of physical activity as usual   | 23 (56.1)                     |

All ranges in parentheses represent range for 5 point Likert scale unless otherwise indicated

(80.5%) as somewhat/extremely comfortable. Most participants (68.3%) reported they would wear the accelerometer again; 26.8% stated they would maybe wear it again. The majority of participants (68.3%) indicated that they would prefer to wear a commercially available activity monitor rather than the ActiGraph.

### Factors influencing compliance with study procedures

Data on factors associated with response to EMA prompts and valid accelerometer data are displayed in Table 4. We also present descriptives by each factor examined in this table.

#### EMA prompts

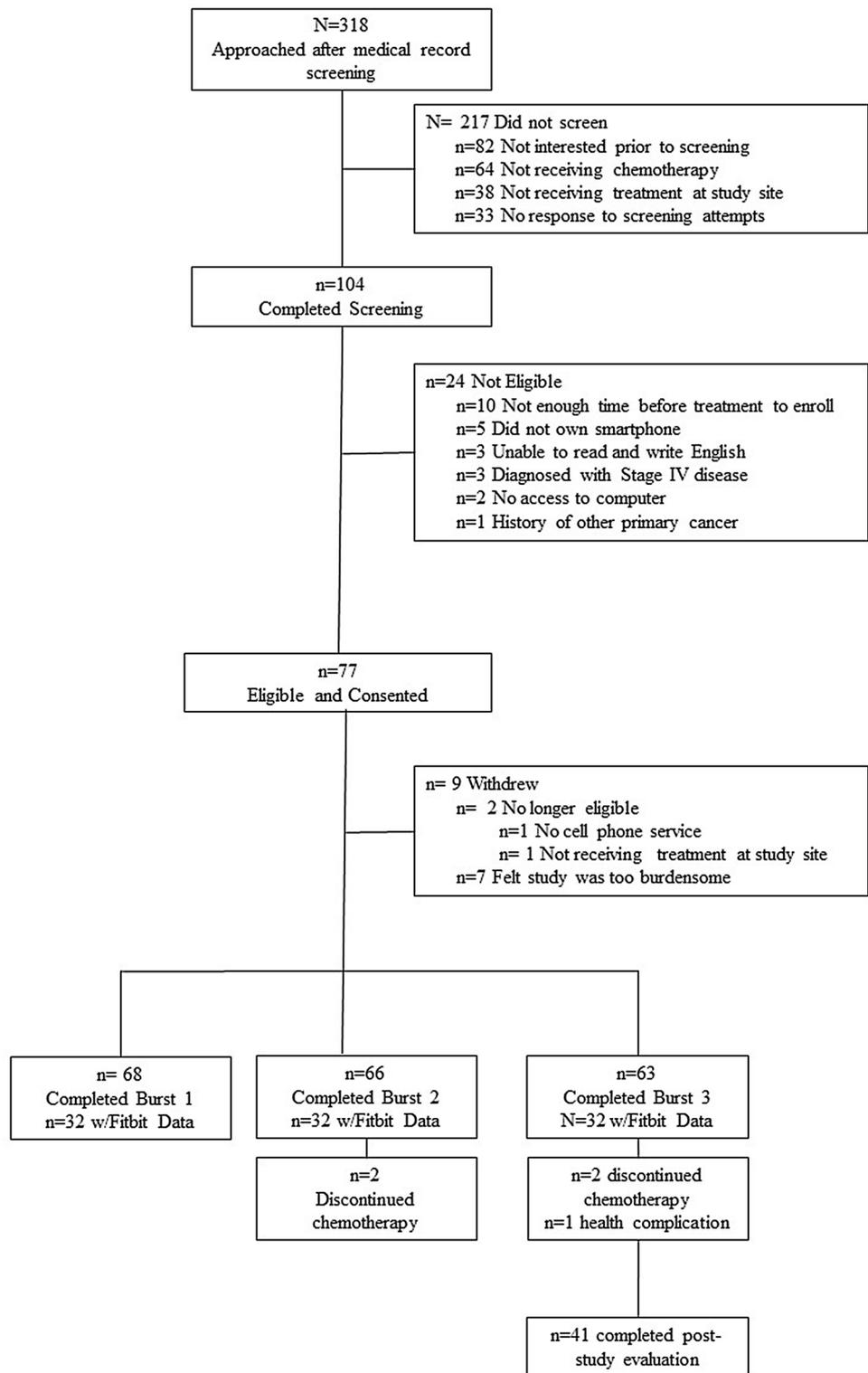
Of the 1160 programmed EMA prompts, 976 (86%) received a response. Of those that did not receive a response, 6.7% were related to an issue with the technology used to generate the prompts and 3.0% were due to a staff or communication

issues (i.e., scheduled prompts to start on the wrong day or appointment changes). Overall, participants responded to an average of 94.5 of 120 prompts (78.7%) and it took 1.6 (0.94) EMA prompts to receive a response with an average response time of 13.8 (SD = 4.6) minutes. Significant predictors of valid EMA prompt data included time point and treatment status. Compared to T1, participants had a 21% lower odds (OR = 0.79; 95% CI (0.67, 0.93);  $p < 0.01$ ) at T3. Pre-chemotherapy dose response rates were 82.6% (SD = 37.9), and day of/post-treatment response rates were 86.9% (SD = 33.7). Participants were 30% less likely [OR = 0.70; 95% CI (0.61, 0.80);  $p = 0.01$ ] to respond to a prompt on a pre-treatment day as a day of/post-treatment day.

#### Accelerometer

Overall, participants had valid accelerometer data on 82.3% of study days. On average, they wore the monitor 24.5 (SD = 4.8) of 30 study days and 8.2 of 10 days at each time point. Significant predictors of valid ActiGraph days included time point and day of the week. Days during T2

**Fig. 3** Participant flow through the study



and T3 were less likely to be considered valid than days during T1 [OR = 0.63; 95% CI (0.53, 0.74);  $p < 0.01$  and OR = 0.39; 95% CI (0.33, 0.46);  $p < 0.01$ , respectively]. Weekend days were less like to have a valid ActiGraph

day compared to week days [OR = 0.48; 95% CI (0.40, 0.58);  $p < 0.01$ ].

**Table 3** Sample demographic and disease characteristics ( $n=67$ )

| Factor                         | Proportion $n$ (%) |
|--------------------------------|--------------------|
| Days in the study mean [range] | (90.6) [10–144]    |
| Age mean [range]               | 48.6 [31–71]       |
| BMI mean [range]               | 27.6 [17.9–52.5]   |
| Race                           |                    |
| White                          | 51 (76.6)          |
| African American               | 8 (10.9)           |
| Asian/Pacific Islander         | 4 (6.3)            |
| Other                          | 4 (6.3)            |
| Ethnicity                      |                    |
| Hispanic or Latino             | 9 (12.9)           |
| Education                      |                    |
| At least college degree        | 52 (78.1)          |
| Less than college degree       | 15 (21.9)          |
| Employment status              |                    |
| Working at least part-time     | 45 (67.2)          |
| Full time homemaker            | 5 (7.5)            |
| Retired, not working           | 4 (6.0)            |
| Unemployed                     | 1 (1.5)            |
| Other                          | 9 (13.4)           |
| Unanswered                     | 3 (4.5)            |
| Annual household income        |                    |
| > \$100,000                    | 31 (46.3)          |
| < \$100,000                    | 21 (31.5)          |
| Prefer not to answer           | 12 (17.9)          |
| Unanswered                     | 3 (4.5)            |
| Marital status                 |                    |
| Married/partnered              | 45 (67.2)          |
| Single                         | 11 (16.4)          |
| Divorced/separated             | 5 (7.5)            |
| Widowed                        | 3 (4.5)            |
| Unanswered                     | 3 (4.5)            |
| Chronic disease diagnosis      |                    |
| Asthma                         | 10 (16.9)          |
| Depression                     | 9 (15.3)           |
| Arthritis                      | 8 (13.6)           |
| Obesity                        | 7 (12.1)           |
| Upper gastrointestinal disease | 5 (8.5)            |
| Osteoporosis                   | 4 (6.8)            |
| Anxiety or panic disorders     | 4 (6.8)            |
| Visual impairment              | 4 (6.8)            |
| Diabetes                       | 3 (5.1)            |
| Degenerative disc disease      | 3 (5.1)            |
| Hearing impairment             | 2 (3.4)            |
| COPD                           | 1 (1.7)            |
| Congestive heart failure       | 1 (1.7)            |
| Experienced menopause          | 18 (30.5)          |
| Overall health                 |                    |
| Excellent/very good            | 35 (52.2)          |
| Good                           | 25 (37.3)          |
| Fair/poor                      | 5 (7.5)            |

**Table 3** (continued)

| Factor                                  | Proportion $n$ (%) |
|---|--------------------|
| Unanswered                              | 2 (3.0)            |
| Meeting MVPA recommendations pre-cancer | 28 (44.4)          |
| Disease stage                           |                    |
| Stage I                                 | 17 (26.2)          |
| Stage II                                | 35 (53.8)          |
| Stage III                               | 13 (20.0)          |
| Chemotherapy type                       |                    |
| Neoadjuvant                             | 23 (34.3)          |
| Adjuvant                                | 44 (65.7)          |
| Treatment cycle number at baseline      |                    |
| Cycle 1                                 | 24 (35.8)          |
| Cycle 2                                 | 43 (64.2)          |

## Discussion

High levels of physical inactivity and sedentary behavior during chemotherapy for breast cancer can negatively impact health and disease outcomes (e.g., high fatigue levels, poor cardiovascular health, poor physical health) [34, 35]. Intensive smartphone-facilitated EMA data collection, paired with wearable device data, may be useful for understanding changes in activity patterns in relation to clinical, biopsychosocial, and behavioral factors during chemotherapy for breast cancer. Although prior studies report EMA data collection methods to be feasible in older adults and other clinical populations [17, 18, 20], breast cancer patients receiving chemotherapy may have unique barriers to this methodology, including discomfort and increased burden due to side effects and treatment demands [2]. Accrual rates into the present study were modest and 10% of participants withdrew due to burden during baseline data collection. However, retention (84%) and compliance (82–86%) and acceptability rates were high. Thus, study findings suggest that enrolling patients into EMA studies during chemotherapy may be challenging, but that data collection methods are feasible and acceptable.

Our study's high compliance rates are comparable to other studies using similar EMA prompt [17, 18, 20] and accelerometer [19–21] methods, suggesting these methods are feasible for cancer patients undergoing chemotherapy. In addition, similar to study findings in other populations [19–21], no demographic factors were related to EMA prompt response or accelerometer wear in the present study. However, participants were more likely to answer EMA prompts on post-chemotherapy dose days and at baseline and were more likely to have valid accelerometer data at baseline and on weekdays. This could be due to higher motivation at baseline when the study was novel or desensitization to study methods as time in the study increased.

**Table 4** Multi-level model results examining potential correlates of compliance to EMA prompts and accelerometer wear

| Correlate   | Complete EMA prompt (yes/no) |                           |                  | Valid ActiGraph day (yes/no) |                           |                  |
|---|------------------------------|---------------------------|------------------|------------------------------|---------------------------|------------------|
|   | Overall <i>M</i> % (SD)      | Completed OR (95% CI)     | <i>p</i> value   | <i>M</i> % (SD)              | Valid day OR (95% CI)     | <i>p</i> value   |
| Age   | NA                           | 1.01; (0.98, 1.03)        | 0.54             |                              | 1.01 (0.97, 1.04)         | 0.71             |
| Education   |                              |                           |                  |                              |                           |                  |
| ≥ College degree  | 86.3 (34.0)                  | 1.03; (0.58, 1.84)        | 0.92             | 83.8 (36.8)                  | 1.29 (0.56, 2.95)         | 0.54             |
| < College degree  | 83.3 (36.7)                  |                           |                  | 75.6 (43.0)                  |                           |                  |
| Income  |                              |                           |                  |                              |                           |                  |
| ≥ \$100,000   | 86.7 (34.0)                  | 0.95; (0.54, 1.66)        | 0.86             | 83.3 (37.3)                  | 1.38; (0.63, 3.03)        | 0.42             |
| < \$100,000   | 84.0 (36.8)                  |                           |                  | 80.0 (40.0)                  |                           |                  |
| Race  |                              |                           |                  |                              |                           |                  |
| White   | 86.5 (34.2)                  | 1.44; (0.83, 2.50)        | 0.19             | 82.0 (38.6)                  | 0.99; (0.24, 2.22)        | 0.98             |
| Non-white   | 82.7 (37.8)                  |                           |                  | 82.7 (37.8)                  |                           |                  |
| Weight status   |                              |                           |                  |                              |                           |                  |
| BMI < 25  | 86.5 (34.1)                  | 1.22 (0.70, 1.81)         | 0.64             | 86.9 (33.7)                  | 1.75 (0.94, 3.26)         | 0.08             |
| BMI ≥ 25  | 84.9 (35.8)                  |                           |                  | 79.3 (40.5)                  |                           |                  |
| Disease stage   |                              |                           |                  |                              |                           |                  |
| Stage I and II  | 85.5 (35.2)                  | 0.82; (0.45, 1.48)        | 0.51             | 82.1 (38.4)                  | 0.75; (0.33, 1.72)        | 0.50             |
| Stage III   | 86.1 (34.6)                  |                           |                  | <b>81.8 (38.6)</b>           |                           |                  |
| Treatment type  |                              |                           |                  |                              |                           |                  |
| Neoadjuvant   | 84.1 (36.6)                  | 0.85; (0.52, 1.38)        | 0.52             | 82.0 (38.4)                  | 1.05; (0.53, 2.06)        | 0.88             |
| Adjuvant  | 86.3 (34.3)                  |                           |                  | 82.7 (37.8)                  |                           |                  |
| Weekend   |                              |                           |                  |                              |                           |                  |
| Weekend   | 85.0 (35.7)                  | 0.91;(0.77, 1.06)         | 0.24             | <b>86.5 (34.2)</b>           | <b>0.48; (0.40, 0.58)</b> | <b>&lt; 0.01</b> |
| Week day  | 87.0 (33.6)                  |                           |                  | <b>92.3 (26.6)</b>           |                           |                  |
| EMA prompt timing (1.2 vs. 3.4)                         |                              |                           |                  |                              |                           |                  |
| Prompt 1  | 83.1 (37.5)                  | 1.07; (0.94, 1.22)        | 0.33             | NA                           | NA                        | NA               |
| Prompt 2  | 87.1 (33.5)                  |                           |                  |                              |                           |                  |
| Prompt 3  | 86.5 (34.2)                  |                           |                  |                              |                           |                  |
| Prompt 4  | 85.7 (35.0)                  |                           |                  |                              |                           |                  |
| Study time point  |                              |                           |                  |                              |                           |                  |
| Time Point 1  | <b>86.4 (34.4)</b>           | <b>Ref</b>                |                  | <b>86.6 (34.1)</b>           | <b>ref</b>                |                  |
| Time Point 2  | 85.7 (35.0)                  | 0.94; (0.79, 1.10)        | 0.42             | <b>82.5 (37.8)</b>           | <b>0.63; (0.53, 0.74)</b> | <b>&lt; 0.01</b> |
| Time Point 3  | <b>84.7 (36.0)</b>           | <b>0.79; (0.67, 0.93)</b> | <b>&lt; 0.01</b> | <b>76.5 (42.4)</b>           | <b>0.39 (0.33, 0.46)</b>  | <b>&lt; 0.01</b> |
| Pre-chemotherapy dose vs. day of/post-chemotherapy dose |                              |                           |                  |                              |                           |                  |
| Pre-dose  | <b>82.6 (37.9)</b>           | <b>0.70; (0.61, 0.80)</b> | <b>0.01</b>      | 80.8 (39.4)                  | 0.87; (0.76, 1.00);       | 0.05             |
| Day of/post-dose  | <b>86.9 (33.7)</b>           |                           |                  | 82.5 (38.0)                  |                           |                  |

Values in bold indicate statistical significance

Participants may be more likely to answer EMA prompts post-chemotherapy when symptoms are more salient and have more valid accelerometer days on weekdays because their schedule is more routine than on weekends. Participants were not incentivized based on compliance (i.e., per prompt or valid accelerometer day) in the present study. Future studies should examine whether such an incentive structure would enhance compliance and ensure more complete data for analysis.

The high acceptability ratings of overall study methodology, EMA prompts, and accelerometer wear are encouraging and consistent with previous studies using similar

methodology [18, 20]. These data indicate that despite the potential burden of data collection methods on participants, most individuals were confident in their abilities to use study technology and did not feel overly burdened by study procedures. Future studies should examine similar methods in other cancer patient and survivor populations along the cancer continuum including those undergoing treatment (e.g., radiation, immunotherapy) or recovering from surgery. Lastly, these methods should be tested with different protocol iterations (e.g., varied number of measurement time points, study days, or daily EMA prompts) to confirm feasibility and acceptability and determine whether an optimal

study length or data collection intensity exists for obtaining valuable intensive longitudinal data, limiting participant burden, retaining feasibility and acceptability, and preventing desensitization to study methods [19, 20].

With regard to reactivity, few participants indicated responding to EMA prompts about symptoms influenced how they felt or that wearing the accelerometer made them want to increase activity. However, about two-thirds of participants reported answering EMA prompts about activity made them want to increase activity. Most studies examining reactivity in relation to symptom burden have demonstrated answering EMA prompts does not influence symptom ratings [15, 20, 36]. In contrast, prior research has reported conflicting findings regarding whether answering EMA prompts influences activity with some finding answering these prompts results in less accelerometer activity and more sedentary behavior after the prompt [19, 37] and others finding no difference [38]. Because we asked participants to recall activity only at Prompt 4, we anticipate reactivity was limited. However, we were unable to directly assess reactivity in this study because we could not separate potential reactivity from naturally occurring changes symptoms and activity in response to chemotherapy. Future studies should explore methods for disentangling these effects.

This study is not without limitations. The sample size was relatively small, although appropriately powered for within-persons analyses. Participants were recruited from an academic medical setting and may value research more than the typical patient, which could contribute to the low withdrawal and high compliance rates. In addition, we did not have specific protocols for wearing the monitor on the wrist for women with lymphedema which could impact acceptability ratings of the ActiGraph. Lastly, this study did not include women with metastatic (stage IV) breast cancer. Women with stage IV disease may have additional and/or different symptoms and treatment side effects with potential to influence their experiences with activity monitors and EMA data collection that may not have been represented by the sample within this study. Thus, findings might not be generalizable to all women undergoing chemotherapy for breast cancer. Future research should test similar study designs in community hospitals or non-academic oncology clinics including a larger sample size to capture a more diverse sample. Additionally, only 61% of participants completed the voluntary post-study evaluation, and may represent more highly motivated and engaged participants which could bias our acceptability findings. Lastly, misclassification of non-wear time using the ActiGraph is possible during extremely long periods of sedentary behavior, which may be more common in this population due to chemotherapy side effects. Although we used less conservative wear time algorithms to account for this, future studies should consider using devices with wear sensors capabilities or accessories to more accurately

distinguish between sedentary behavior and non-wear time and/or devices with built-in inclinometers to determine body position.

Despite potential limitations, this is the first study to use accelerometry and EMA prompts via smartphone during chemotherapy for breast cancer patients with objectively measured compliance. Additionally, no study visits were required to participate, participants used their own smartphone devices, and our sample represents a range of demographic and disease characteristics which enhances the generalizability of our findings. Future research should explore EMA methodology feasibility and acceptability in individuals diagnosed with other cancer types and undergoing additional cancer treatments (i.e., radiation, hormone therapy) across longer time periods from diagnosis to extended survivorship. Future studies should consider the feasibility and acceptability of integrating additional passive sensor data (e.g., GPS, heart rate) to expand our understanding of the determinants and outcomes of activity pattern changes during chemotherapy. Finally, as wearable technology becomes more ubiquitous, using commercially available devices to monitor activity or integrating both activity monitoring and EMA prompting into one device (e.g., smartwatch) may increase data collection volume by encompassing longer periods of time (i.e., entire duration of chemotherapy), compliance, and acceptability compared to our multiple discreet time point design. Understanding the trade-offs between being able to collect more data and burden on participants will be important in identifying optimal methods for capturing meaningful intensive longitudinal data in cancer populations. Although the shape and size of the ActiGraph are comparable to those of many commercially available monitors, commercially available activity monitors may be more attractive to participants because of their ability to provide feedback on activity levels during wear time, and because of the aesthetic form of commercial devices purposefully designed for consumer wear. These features may influence patient preference and, potentially, increase acceptability of wearing an activity monitor during a study.

The high retention, compliance, and acceptability rates observed in the present study indicate EMA data collection utilizing smartphones and accelerometers is feasible and acceptable for breast cancer patients undergoing chemotherapy, especially once baseline data collection is completed. However, many patients expressed concern over committing to a study prior to starting chemotherapy because they were unsure of severity of treatment side effects. Even though we did allow for some flexibility (i.e., able to enroll after one cycle of chemotherapy), this uncertainty is reflected in the lower recruitment rate and significant drop out rate at study start, indicating it is important to fully educate participants about the research value and potential burden. Overall, EMA methodology may be an acceptable tool to help increase the

understanding of antecedents and outcomes of activity pattern changes in cancer patients undergoing treatment to build more effective interventions and improve health and disease outcomes and QOL in this population.

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## Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest.

**Ethical approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of and approved by the Northwestern University IRB (STU00201472) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This article does not contain any studies with animals performed by any of the authors.

**Informed consent** Informed consent was obtained from all individual participants included in the study.

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