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Clinical Trial Results

Physical Activity Intervention in Patients with Metastatic Breast Cancer During Active Treatment: Quality of Life and Function

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Abstract

Background: In this study, we explore recruitment, retention, and potential quality of life (QoL) and function benefits from a self-directed, home-based walking intervention in women during active treatment for metastatic breast cancer (MBC).

Methods: In this single-arm pilot study, women with stage IV BC wore an activity tracker (FitbitTM) to measure steps per week throughout the intervention study. Participants were asked to walk 150 min per week at a comfortable and safe pace. Patient-reported outcome measures (PRO) were collected at baseline and follow-up.

Results: Target recruitment of 60 patients was achieved. In 52 patients who completed all baseline measures, mean age was 55 (SD 11.1), 23% were pre-menopausal, and 19% non-White. Forty patients (77%) were retained at 3 months and 29 (56%) at 6 months. Baseline walking was the strongest predictor of retention at 3 months ($P = .02$). For 24 patients (46%) with analyzable Fitbit data at 3 months, mean steps/week rose from 19,175 to 31,306. Higher number of steps correlated with larger improvements FACT-G General well-being (FACT-G, rho = 0.55, $P = .01$), FACT-G Physical well-being (rho = 0.48, $P = .03$), and PROMIS Mental Health (rho = 0.55, $P = .01$).

Conclusion: Recruitment into a walking intervention is feasible (a priory target of $N = 60$) in women during treatment for MBC, but retention at 3 months follow-up fell short (77% versus a priori 80%), yet there were potential benefits in general and physical well-being and mental health.

ClinicalTrials.gov Identifier: NCT02682836.

Key words: breast cancer; quality of life.

Lessons Learned

- Recruitment and retention into a self-directed, home-based walking program in feasible in women during treatment for metastatic breast cancer (MBC).
- Achievement and maintenance of daily walking goals were difficult for most participants, but positive benefits were seen in patient-reported outcomes for general, physical and mental well-being.
- Encouragement of moderate walking exercise during active treatment for MBC is warranted on a case-by-case basis.

Discussion

This study investigated the feasibility of recruitment and retention and preliminary evidence of impact on quality of life and function of a home-based "walking" intervention in women with metastatic breast cancer who were about to start a new line of treatment.

Recruitment was challenging, taking 3.5 years to consent 60 patients, our a priori target. Fifty-two patients completed all baseline requirements, and 40 patients were retained at 3-month follow-up ($N = 40/52$, 77% of the a priori goal of 80%).

Participants were asked to walk an average of 150 min per week and to wear a Fitbit during their waking hours. Twenty-four participants had usable Fitbit data at 3 months follow-up–steps uploaded into our Excel database during routine treatment visits (Fig. 1).

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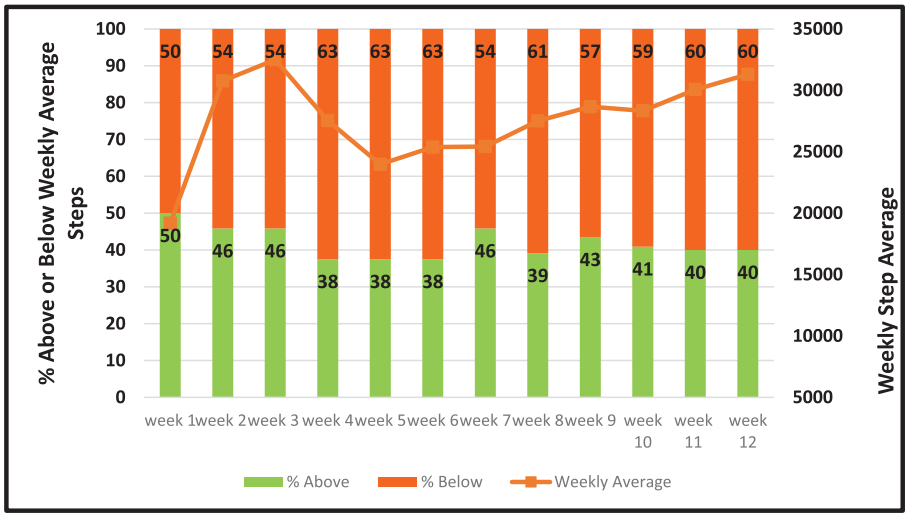

Figure 1. Activity tracker steps/week.

The a priori walking goal of 150 min/week (about 44,000 steps/week) was not achieved by most participants, although many showed considerable success during the first 3 weeks by increasing their steps from baseline and then again from week 6 onward, with sizeable proportions (38%-50%) averaging above the mean number of steps/week for the group as a whole.

At 3 months follow-up, self-reported PA minutes/week increased (P = .04) and anxiety was reduced (P = .02). Among participants with analyzable Fitbit data, higher self-reported physical activity (P = .009) and higher PROMIS Physical Function (P = .04) at baseline were associated greater steps/week during the first 12 weeks of the intervention. Greater number of Fitbit steps was associated with improved overall well-being (FACT-G, P = .01), physical well-being (P = .03), and mental health (P = .01).

A limitation of our study was the use of a snap-on rather than wristband Fitbit, and the need to upload tracker data during infusion visits rather than remotely, which greatly reduced the sample of participants with usable tracker data. Our study was conducted at a single institution but with characteristics common to most university-based referral centers. Our sample included a mix of patients receiving different treatments—biological treatment such as CDK4/6 inhibitors or chemotherapy—where the type and incidence of side effects can vary greatly. During the recruitment interview, all patients reported low levels of activity, but in response to a questionnaire item 11/49 (22%) reported more than 150 min per week prior to the intervention study. A final limitation is the single-arm, non-randomized study design, which does not allow for comparison between intervention and control. A future study that is randomized and controlled would enable a deeper investigation of causality.

Nevertheless, a strength of our study is that it provides information that could be used to improve future exercise intervention studies in women with MBC. Our intervention was minimalist (it did not entail supervision, special equipment or facilities), but it does depend on the participant's self-motivation. Our study adds to the evidence that moderate, self-directed walking can improve overall well-being and specifically physical well-being and mental health in some patients with metastatic breast cancer.

Author disclosures and references available online.

Trial Information	
Disease	Breast cancer in women
Stage of disease/treatment	Stage 4
Prior therapy	Up to 3 lines of systemic therapy for metastatic disease.
Type of study	Interventional single arm feasibility study.
Primary endpoint	Estimate the proportion of patients whose fatigue is eased or managed (no more than a 3-point increase in PROMIS Fatigue scores) during the first 3 months after starting a new treatment regimen.
Secondary endpoints	–Measure feasibility of the physical activity intervention study by reporting the proportion of study participants who report walking, on average, 150 min a week between baseline, 3 months, and 6 months. –Evaluate changes in the following scales from baseline to 3 months: PROMIS Fatigue, PROMIS Global, PROMIS Depression, PROMIS Anxiety, PROMIS Sleep Quality, PROMIS Pain Interference, PROMIS Physical Function, FACT-General, FACIT Fatigue, Perceived Self-Efficacy for Fatigue Self-Management (PSEFSM), and Outcome Expectations from Exercise (OEE). –Assess walking intervention satisfaction at 3 months.
Investigator's analysis	Active and should be pursued further.

Patient Characteristics	
Number of patients, male	0
Number of patients, female	52
Stage	4
Age: median (range)	55 (34-71) years
Number of prior systemic therapies: mean (range)	2 (1-3)
Performance status: ECOG	0: 28 (54%) 1: 20 (39%) 2: 2 (4%) 3: 0 (0%) 4: 0 (0%)

Primary Assessment Method

Study Participants

This single-arm feasibility study was limited to women aged 21 or older who were scheduled to start a new line of treatment for MBC. Treatment was selected based on a shared decision-making discussion between the treating oncologist and the patient; there was no random or other assignments of treatment. Eligible patients could have had no more than three prior chemotherapy regimens. Treating oncologists were asked to provide approval for the patient to engage in moderate physical activity, and patients provided written informed consent. The accrual period was Nov 2015-May 2019. The study was approved by the UNC Lineberger Comprehensive Cancer Center Protocol Review Committee (PRC) and UNC Institutional Review Board (IRB) and registered in clinicaltrial.gov (NCT02682836).

The Intervention

We used a tested, scalable intervention previously shown effective in clinical practice.[1] Participants received a Fitbit ZipTM (Fitbit Inc., San Francisco CA) that they were asked to wear during their waking hours. This Fitbit was a clip-on, not a wrist band. A Fitbit account (www.fitbit.com) was set up at study enrollment, and Fitbit data was up-loaded directly into the research database during regularly scheduled BC treatments at the NC Cancer Hospital. The Study Coordinator provided exercise encouragement and answered questions during those infusion visits; otherwise, there was no other interaction with study participants. Participants also received a 1-page "Walking during Chemotherapy" motivational flyer, a copy of the Walk with Ease workbook[2] with tips for starting and sustaining self-directed walking. And, the were asked to maintain a daily walking diary for the purpose of self-monitoring and self-motivation.

Consented patients were asked to walk safely and comfortably at a pace that was sustainable throughout their treatment, with a goal of averaging 150 min per week.[3,4] The Study Coordinator provided exercise encouragement and answered questions during those visits. In our previous research in patients with early BC, we have estimated that walking 150 min per week at a moderate pace would be about 44,000 steps per week.[1]

Measures

Feasibility

Basic feasibility was (1) recruitment/consenting of 60 patients and 3-month retention rate of 80%.

Walking Activity

Fitbit steps were uploaded into an Excel database and summed each week. Self-reported physical activity data were collected at baseline and at 3 and 6 months by asking: (1) How much time do you usually spend per day when you go for a walk in or around your neighborhood or elsewhere? (2) How many times per week do you engage in vigorous physical activity?

Patient-reported Outcome Measures

At baseline, 3 and 6 months, participants completed questionnaires pertaining to their function and quality of

life: Functional Assessment of Cancer Therapy-Breast (FACT-B Version 4),[5] Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F Version 4),[6] and PROMIS (Patient-Reported Outcomes Measurement Information System)[7,8] measures—Global Health, Fatigue, Depression, Anxiety, Sleep Quality, Pain Interference, and Physical Function. Participants also completed questionnaires pertaining to their Outcome Expectations from Exercise (OEE)[9] and Perceived Self-Efficacy for Fatigue Self-Management (PSEFSM).[10]

Medical Chart Review

Electronic medical records (EMR) of study participants were reviewed throughout treatment for evidence of adverse events, including hospitalizations and dose delays, dose reductions, and treatment discontinuations. EMR data pertaining to age, race, BC diagnosis and treatment, height, weight, and Body Mass Index (BMI) were also extracted.

Statistical Methods

Patient characteristics were summarized using descriptive statistics, including frequencies and percentages for categorical variables and means and ranges for continuous variables. Associations between baseline patient characteristics and (i) retention at 3 months and (ii) patients with analyzable Fitbit data at 3 months follow-up were calculated using Fisher's exact tests for categorical measures and Wilcoxon rank sum tests for continuous measures. Wilcoxon signed-rank tests were used to evaluate the change from baseline to 3 months of function and quality of life measures. Univariate associations between patients' median number of steps per week over the first 12 weeks and (i) baseline patient characteristics and (ii) the change in function and quality of life measures from baseline to 3 months were calculated using Spearman correlations for continuous measures and Wilcoxon rank sum tests for two-level categorical variables or Kruskal–Wallis tests for categorical measures with more than two levels.

Results

Study Participants

Participants at Baseline

Of 60 patients who consented to participate in the study (our target), 52 (87% of 60) completed baseline questionnaires, 40 (77% of 52) completed the 3-month follow-up (below pour feasibility target of 80%), and 29 (73% of 40) completed the 6-month follow-up (Fig. 2). Deaths or worsening ECOG/disease progression accounted for 38% of overall attrition (32 of 60, 53%), withdrawal for no reason 22%, and other reasons that included moving out of the UNC system, not completing questionnaires, canceling all future appointments, and otherwise lost to follow-up (40.6%).

Mean age was 55 (range 34-77), 23% were premenopausal at study enrollment, 17% Black, and mean BMI was 29 (SD 6.2, range 15-46). Fifty-six percent were ECOG 0, 40% were ECOG 1, and 4% ECOG 2. An average number of years since MBC diagnosis was 1 year (SD 1.9). Mean number of metastatic sites was 2.0 (range 1-4), including bone (65%), lung (46%), liver (33%), brain (21%), soft tissue (14%), or other (12%). Forty-six percent were starting their first line of treatment at study enrollment, 22% second line, 15% third line, and 15% fourth line. Fifty-eight percent were scheduled to receive chemotherapy (plus/minus biologic agent) and 42% endocrine combined with biological (ie, CDK 4/6 inhibitors) treatment. Attrition at 3-month follow-up. Twelve of the 52 patients (23%) did not complete study measures at 3 months. Neither of the 2 patients who were ECOG 2 at baseline was retained, and HER2 negative patients dropped out at higher rates than HER2 positive (33% vs. 9%, $P = .05$). Patients who were retained at 3 months self-reported greater minutes of walking at baseline (mean 124 min/week vs. 31 min/week, $P = .02$) and higher mental health (mean 50.2 vs. 45.6, $P = .06$).

Adverse Events During Study Enrollment

During active treatment, participants had 1 (12%) or 2 (8%) hospitalizations, 15% had 1 (11%) or 2 (4%) dose reductions, 37% had 1 (31%) or 2 (6%) dose delays, and 8% had early treatment discontinuation.

Fitbit Steps

Twenty-four study participants (46%) had analyzable Fitbit data (data uploaded into our research computer at their last infusion) at 3 months follow-up. Efforts to up-load Fitbit steps during routine treatment visits were often frustrated by the patient not having the Fitbit with her during the visit or finding that she had lost or damaged the Fitbit. A few patient characteristics showed borderline association with Fitbit use (Table 1). Fifty-two percent of White participants used the Fitbit during study, compared to only 20% of Blacks/Unknown race participants ($P = .08$). Patients who used the Fitbits reported higher self-efficacy for fatigue management (7.96 vs. 6.79, $P = .06$) and better physical function (48.5 vs. 44.2, $P = .07$) at baseline compared to those who did not use the Fitbit. Fig. 1 illustrates the average number of Fitbit steps per week, rising during the first 3 weeks (peaking at 32 500 steps), declining in weeks 4 and 5 (declining to 23 978 steps), and then rising again through week 12 (peak 31 306 steps). Fig. 1 also shows the proportion of participants averaging above (in orange) or below (in grey) the weekly Fitbit steps during the first 12 weeks of the intervention period.

Correlations with Median Fitbit Steps/Week

Table 2 presents Spearman correlations of median Fitbit steps/week ($N = 24$ participants with usable Fitbit data) with changes in measures of function and quality of life at 3 months. Higher number of Fitbit steps during treatment were correlated with larger improvements in FACT-G Total (rho = 0.54, $P = .01$), FACT-G Physical (rho = 0.48, $P = .03$), and PROMIS Mental Health (rho = 0.55, $P = .01$) (Fig. 3).

Measures of Function and Quality of Life at 3 Months

Limited to baseline participants retained at 3 months follow-up ($N = 40$), Table 3 presents changes in patient-reported measures of function and quality of life at 3 months. Self-reported physical activity minutes/week increased from 124.2 (SD 134.7) to 170.9 (SD 140.7) minutes ($P = .04$). Anxiety levels decreased from 52.2 (SD 9.2) to 48.5 (SD 8.6) ($P = .02$).

Assessment, Analysis, and Discussion

Completion	Study completed
Investigator's assessment	Active and should be pursued further

This study investigated the feasibility or recruitment and retention and impact on quality of life and function of a home-based "walking" intervention in women with metastatic breast cancer who were about to start a new line of treatment. Recruitment was challenging, taking 3.5 years to consent 60 patients. It is a limitation of our study that we did not record the number of potentially eligible patients whose participation in our study was not endorsed by their treating oncologist or the number of patients who declined to participate. Deaths or worsening ECOG/disease progression accounted for 37.5% of overall attrition; however, two-thirds of the attrition was due to participant withdrawal for various reasons including moving out of the UNC system, not completing questionnaires, canceling all future appointments, and being lost to follow-up. These findings illustrate the challenges of enrolling and retaining women with MBC in an exercise intervention, even a very moderate and self-directed program. Our transparency in numbers and reasons can provide guidance for future studies aiming to enroll women undergoing active treatment for Stage IV BC. In a previous study that reported adherence and compliance to an unsupervised walking program[1] in a small cohort of women with MBC (n = 8), only 2 women adhered to the self-directed walking program and none achieved the desired volume of walking. That study also included supervised resistance training, which might have been tiring to the patients.

For our intervention, participants were asked to walk an average of 150 min per week and to wear a Fitbit during their waking hours. Only 24 participants had usable Fitbit data at 3 months follow-up—evidence of steps uploaded into our Excel database during routine treatment visits. It is the most serious limitation of our study that patients were unwilling or unable to attach the tracker at any time during the day. This finding motivated our research team to utilize wristband devices in all of our activity tracker studies going forward.

We had previously estimated that 150 min a week was the equivalent of about 44 000 steps/week at a moderate walking pace[2]. This average was not achieved by our MBC participants, although many did show considerable success during the first 3 weeks in increasing their steps and then again from week 6 onward, with sizeable proportions (38%-50%) averaging above the mean number of steps/week for the group as a whole. Ligibel and colleagues have investigated physical activity, weight, and outcomes in patients receiving chemotherapy for MBC (n = 766) and reported that 47.6% engaged in less than 3 metabolic equivalents of task (MET) hours of PA per week (<1 h of moderate PA). They also reported that in participants who completed more than 9 MET hours per week of PA relative to those who completed 0-9 MET hours per week of PA, there was a marginally significant increase in Progression Free Survival (HR = 0.83, 95% CI, 0.79-1.02; P = .08) and overall survival (HR = 0.81, 95% CI, 0.65-1.02; P = .07).[11]

At 3 months follow-up (N = 40), self-reported PA minutes/week increased (P = .04) and anxiety was reduced (P = .02). No other patient-reported outcomes measures changed significantly. In a prospective study of women undergoing treatment for MBC (N = 62), higher anxiety levels were correlated with a lower level of QoL.[12]

Looking only at participants with analyzable Fitbit data (N = 24), higher self-reported physical activity (P = .009) and higher PROMIS Physical Function (P = .04) at baseline were associated with greater steps/week during the first 12 weeks of the intervention. And, greater number of Fitbit steps were associated with improved overall well-being (FACT-G, P = .01), physical well-being (P = .03), and mental health (P = .01). This is the most encouraging evidence that moderate self-directed walking during active treatment can benefit women with metastatic breast cancer.

Our study has additional limitations, beyond the ones already noted above. Our final sample was small, but our single-arm design was intended primarily to explore feasibility. Our study was conducted at a single institution but with characteristics common to most university-based referral centers. Our sample included a mix of patients receiving different treatments—biological treatment such as CDK4/6 inhibitors or chemotherapy—where the type and incidence of side effects can vary greatly. A high proportion of our participants received chemotherapy and the retention of these women at 3 months did not differ significantly from the non-chemotherapy group (P = 1.00).

A strength of our study is that it provides information that could be used to improve future exercise intervention studies in women with MBC. We demonstrated the feasibility of recruitment and retention, but also the need for careful documentation of reasons for attrition over time. The pre-approval of treating oncologists is crucial in this patient population but should be tracked because it may reveal reasons for disapproval that are not uniform among clinicians and is worth further exploration. Our intervention was minimalist (it does not entail supervision, special equipment, or facilities), but it does depend on the participant's self-motivation. Switching to a wrist-band tracker and greater attention to educating participants on how to monitor their steps on their smart phone or computer may enhance self-motivation. Our study provides further evidence that moderate, self-directed walking can improve overall well-being and specifically physical well-being and mental health in some patients with metastatic breast cancer.

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Conflict of Interest

The authors indicated no financial relationships.

Data Availability

The data underlying this article will be shared on reasonable request to the corresponding author.

References

1. Nyrop KA, Deal AM, Choi SK, et al. Measuring and understanding adherence in a home-based exercise intervention during chemotherapy for early breast cancer. *Breast Cancer Res Treat*. 2018;168(1):43-55. https://doi.org/10.1007/s10549-017-4565-1.
2. Arthritis Foundation. Walk with Ease: Your Guide to Walking for Better Health, Improved Fitness and Less Pain (Third Edition). *Arthritis Foundation* 2010.
3. Rock CL, Doyle C, Demark-Wahnefried W, et al. Nutrition and physical activity guidelines for cancer survivors. *CA Cancer J Clin*. 2012;62(4):243-274. https://doi.org/10.3322/caac.21142.
4. Doyle C, Kushi LH, Byers T, Courneya KS, et al. Nutrition and physical activity during and after cancer treatment: an American Cancer Society guide for informed choices. *Cancer J Clin*. 2006;56:323-353.
5. Brady MJ, Cella DF, Mo F. Bonomi AE, Tulsky DS, al. e. Reliability and validity of the Functional Assessment of Cancer Therapy-Breast (FACT-B) quality of life instrument. *J Clin Oncol*. 1997;15(3):974-986. https://doi.org/10.1200/JCO.1997.15.3.974
6. Webster K, Cella D, Yost K. The Functional Assessment of Chronic Illness Therapy (FACIT) measurement system: properties, applications, and interpretation. *Health Quality Life Outcomes*. 2003;1(1):79. https://doi.org/10.1186/1477-7525-1-79.
7. Cella D, Riley W, Stone A, et al; PROMIS Cooperative Group. The Patient-Reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005–2008. *J Clin Epidemiol*. 2010;63(11):1179-1194. https://doi.org/10.1016/j.jclinepi.2010.04.011.
8. Reeve BB, Burke LB, Chiang YP, et al. Enhancing measurement in health outcomes research supported by Agencies within the US Department of Health and Human Services. *Quality Life Res*. 2007;16(Suppl 1):175-186. https://doi.org/10.1007/s11136-007-9190-8.
9. Resnick B, Zimmerman S, Orwig D, Furstenberg AL, Magaziner J. Model testing for reliability and validity of the outcome expectations for exercise scale. *NursRes*. 2001;50(5):293-299.
10. Hoffman AJ, Von Eye A, Gift AG, et al. The development and testing of an instrument for perceived self-efficacy for fatigue self-management. *Cancer Nurs*. 2011;34(3):167-175. https://doi.org/10.1097/NCC.0b013e31820f4ed1.
11. Ligibel JA, Huebner L, Rugo HS, et al. Physical activity, weight, and outcomes in patients receiving chemotherapy for metastatic breast cancer (C40502/Alliance). *JNCI Cancer Spectr*. 2021;5(3):pkab025. https://doi.org/10.1093/jncics/pkab025.
12. Dragomir BI, Fodoreanu L. Correlations between state anxiety and quality of life in metastatic breast cancer patients. *Rev Med Chir Soc Med Nat Iasi*. 2013;117(3):610-615.

Figures and Tables

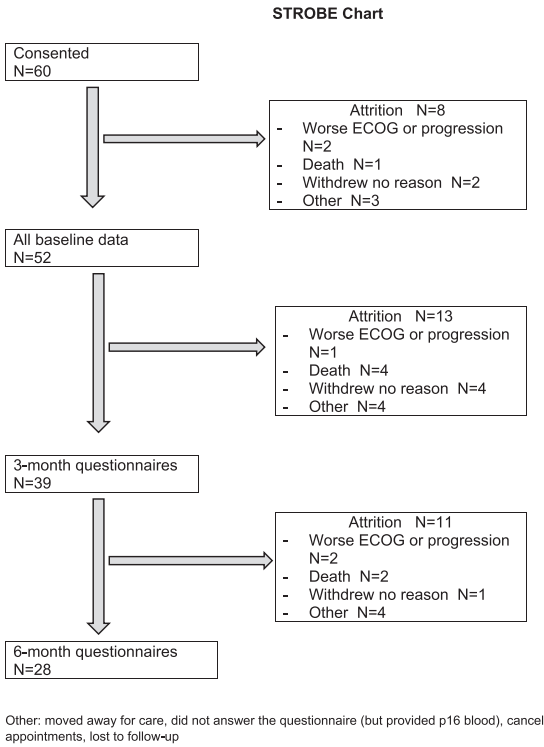

Figure 2. STROBE chart.

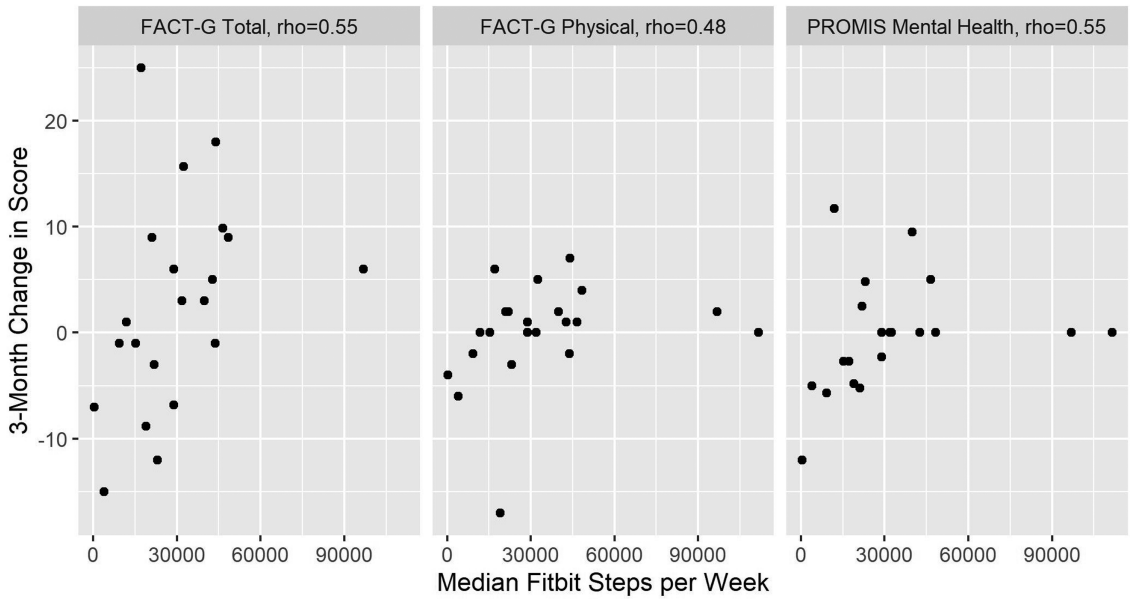

Figure 3. Correlations between median steps and score changes.

Table 1. Participants characteristics at baseline (*N* = 52), retained at 3-months follow-up (*N* = 40), and having usable Fitbit data (*N* = 24).

Variable	Recruited *N* = 52	Retained at 3 months *N* =40	*P* value*	Fitbit cohort *N* = 24	*P* value**
Age at enrollment in the study, years	55 (SD 11.1) Range 34-77	55.2 (SD 11.1) Range 34-77	.897	57.2 (SD 10.6) Range 35-77	.43
Menopausal status					
Pre-menopausal	12 (23%)	9 (23%)	1.00	3 (12%)	.11
Post-menopausal	40 (77%)	31 (77%)		21 (88%)	
Race					
Not white	11 (21%)	9 (23%)	1.00	2 (8%)	.05
White	41 (79%)	31 (77%)		22 (92%)	
BMI—at enrollment in the study	29 (SD 6.5) Range 18-50	28.1 (SD 6.1) Range 15-46	.42	27.1 (5.4) Range 15-36	.19
ECOG—at enrollment in the study					
0	28 (56%)	21 (55%)	.05	14 (61%)	.56
1	20 (40%)	17 (45%)		9 (39%)	
2	2 (4%)	0 (0%)		0 (0%)	
Breast cancer history					
Hormone receptor					
Negative	12 (38%)	9 (36%)	1.00	5 (38%)	1.00
Positive	20 (62%)	16 (64%)		8 (72%)	
HER2					
Negative	30 (58%)	20 (50%)	.05	11 (46%)	.16
Positive	22 (42%)	20 (50%)		13 (54%)	
Triple negative					
No	43 (83%)	35 (88%)	.19	20 (83%)	1.00
Yes	9 (17%)	5 (12%)		4 (17%)	
Breast cancer treatment during study enrollment					
Line of treatment) at enrollment					
1	21 (46%)	16 (44%)	.42	9 (43%)	.89
2	10 (22%)	8 (22%)		6 (29%)	
3	7 (15%)	7 (19%)		3 (14%)	
4	7 (15%)	4 (11%)		3 (14%)	

Table 1. Continued

Variable	Recruited *N* = 52	Retained at 3 months *N* =40	*P* value*	Fitbit cohort *N* = 24	*P* value**
missing	1 (2%)	1 (3%)		0 (0%)	
Chemotherapy plus/minus biologic agent					
No	21 (42%)	16 (41%)	1.00	9 (39%)	.78
Yes	29 (58%)	23 (69%)		14 (61%)	
Endocrine treatment plus biologic agent					
No	32 (65%)	25 (66%)	1.00	13 (59%)	.55
Yes	17 (35%)	13 (34%)		9 (31%)	
Biologic agent					
No	18 (37%)	14 (37%)	1.00	8 (36%)	1.00
Yes	31 (63%)	24 (63%)		14 (64%)	
Years since metastatic breast cancer diagnosis	1 (SD 1.9) Range 0-8	1.0 (SD 1.7) Range 0-8	.93	0.96 (SD 1.6) Range 0-6	1.00
Site of metastasis (check all that apply)					
Bone—yes	34 (65%)	25 (69%)	.51	15 (63%)	.77
Brain—yes	11 (21%)	9 (25%)	1.00	3 (13%)	.19
Lung—yes	24 (46%)	20 (56%)	.35	11 (46%)	1.00
Liver—yes	17 (33%)	14 (39%)	.73	9 (38%)	.56
Soft tissue—yes	7 (14%)	6 (17%)	1.00	3 (13%)	1.00
Other—yes	6 (12%)	5 (14%)	1.00	4 (17%)	.40
Number of metastases sites	2.0 (SD.84) Range 1-4	2.1 (SD 0.9) Range 1-4	.21	2.0 (SD 0.9) Range 1-3	1.00
Baseline self-reported physical activity (minutes/week)	103.4 (SD 125.4)	124.2 (SD 134.7)	.02	131.8 (SD 154.9)	.36
OEE/outcome expectations from exercise (higher score = greater self-efficacy) (range 1-5)	1.9 (SD 0.7)	1.9 (SD 0.6)	.69	1.9 (SD 0.7)	.87
PSEFSM/perceived self-efficacy for fatigue self-management (higher score = greater self-efficacy) (range 1-10)	7.4 (SD 2.2)	7.3 (SD 2.3)	.84	8.0 (SD 2.0)	.06
FACT-General (higher score = greater well-being)					
Total score (range 0-108)	82.1 (SD 16.2)	82.2 (SD 16.3)	.83	82.7 (SD 17.2)	.69
Physical well-being (range 0-28)	21.0 (SD 5.5)	21.1 (SD 5.5)	.87	21.3 (SD 5.7)	.68
Social/family well-being (range 0-28)	23.8 (SD 4.6)	23.9 (SD 4.7)	.96	24.8 (SD 5.0)	.24
Emotional well-being (range 0-24)	18.2 (SD 4.2)	17.9 (SD 4.3)	.31	17.5 (SD 4.5)	.33
Functional well-being (range 0-28)	18.9 (SD 5.7)	19.2 (SD 5.6)	.53	19.5 (SD 5.5)	.48
FACIT-Fatigue (reverse scored so that higher scores = less fatigue) (range 0-52)	35.8 (SD 11.8)	35.7 (SD 12.1)	1.0	37.0 (SD 12.4)	.42
PROMIS Global Health (higher score = xxx)	42.9 (SD 10.7)	43.8 (SD 10.9)	.15	44.3 (SD 10.4)	.45
PROMIS mental health (higher score = worse mental health)	49.2 (SD 7.2)	50.2 (SD 6.9)	.06	50.5 (SD 7.0)	.21
PROMIS fatigue (higher scores = more fatigue)	53.8 (SD 9.1)	53.5 (SD 9.2)	.62	53.0 (SD 9.5)	.35
PROMIS anxiety (higher scores = greater anxiety)	51.9 (SD 9.2)	52.2 (SD 8.9)	.67	52.9 (SD 9.3)	.77
PROMIS depression (higher scores = greater depression)	48.1 (SD 8.9)	48.3 (SD 8.6)	.64	47.7 (SD 8.9)	.81
PROMIS sleep quality (higher scores = lower sleep quality)	52.5 (SD 8.5)	52.2 (SD 8.2)	.60	53.2 (SD 7.2)	.93
PROMIS pain interference (higher score = greater pain interference)	51.8 (SD 9.2)	50.8 (SD 9.3)	.12	50.3 (SD 8.8)	.19
PROMIS physical function (higher score = higher function)	46.2 (SD 7.9)	46.3 (SD 8.5)	.89	48.5 (SD 8.6)	.07

*Comparison between study participants who were retained at 3 months and those who were not retained.
**From the baseline cohort, comparison between study participants who had usable Fitbit data and those who did not

Table 2. Median activity tracker steps/week and correlations with (1) PRO scores at baseline* and (2) change in PRO scores from baseline to 3 months*, limited to participants with Fitbit data (*N* = 24)

Variable	Rho – PRO value at baseline*	*P* value	Rho – change in PRO at 3 months**	*P* value
Age at enrollment in the study	–0.187	.38	–	–
Race			–	–
Not white (*N* = 2)	24 187	.80		
White (*N* = 22)	22 451			
Body mass index (BMI)–Mean SD –at enrollment in the study	0.02	.93	–	–
ECOG (Eastern Cooperative Oncology Group)			–	–
0 (fully ambulatory) (*N* = 14)	40 098	.17		
1 (ambulatory/light work) (*N* = 9)	23 456			
Breast cancer treatment				
Line of treatment (any) at enrollment in the study			–	–
1 (*N* = 9)	34 105	.27		
2 (*N* = 6)	44 865			
3 (*N* = 3)	27 048			
4 (*N* = 3)	15 826			
Chemotherapy plus/minus biologic agent			–	–
No (*N* = 9)	31 710	.73		
Yes (*N* = 14)	34 254			
Endocrine treatment plus/minus biologic agent			–	–
No (*N* = 13)	37 840	.60		
Yes (*N* = 9)	24 965			
Years since metastatic breast cancer diagnosis	–0.08	.73	–	–
Baseline self-reported physical activity (minutes/week)	0.53	.009	--	–
OEE/outcome expectations from exercise (higher score = greater self-efficacy)	–0.33	.14	--	–
PSEFSM/perceived self-efficacy for fatigue self-management (higher score = greater self-efficacy)	0.16	.43	--	–
FACT-general (higher score = greater well-being)				
Total score	0.05	.81	0.54	.01
Physical well-being	0.08	.70	0.48	.03
Social/family well-being	0.11	.59	–0.05	.80
Emotional well-being	–0.14	.50	0.32	.16
Functional well-being	0.06	.78	0.34	.13
FACIT-fatigue (reverse scored so that higher scores = less fatigue) (range 0-52)	0.07	.73	0.39	.07
PROMIS global health (higher score = better health)	0.13	.57	0.26	.32
PROMIS mental health (higher score = worse mental health)	–0.13	.57	0.55	.01
PROMIS fatigue (higher scores = more fatigue)	–0.25	.24	–0.19	.39
PROMIS depression (higher scores = worse depression)	0.08	.70	–0.31	.16
PROMIS anxiety (higher scores = worse anxiety)	––0.10	.63	–0.39	.10
PROMIS sleep quality (higher scores = worse sleep quality)	0.02	.90	–0.29	.19
PROMIS pain interference (higher score = greater pain interference)	–0.06	.78	–0.33	.14
PROMIS physical function (higher score = higher function)	0.43	.04	0.29	.19

*Correlation of median activity tracker steps/week during first 3 months with baseline Patient Reported Outcome (PRO) scores.
**Correlation of median activity tracker steps/week during first 3 months with change in PRO scores from baseline to 3 months.

Table 3. Change in patient-reported outcome measures among participants retained at 3 months ($N = 40$).

Measures	Baseline	Three months	*P* value
Baseline self-reported physical activity (minutes/week)	124.2 (SD 134.7)	170.9 (140.7)	.04
OEE/outcome expectations from exercise (higher score = greater self-efficacy)	1.9 (0.6)	1.8 (0.7)	.28
(range 1-5)			
PSEFSM/perceived self-efficacy for fatigue self-management	7.3 (2.3)	7.2 (2.3)	.97
(higher score = greater self-efficacy) (range 1-10)			
FACT-general (higher score = greater well-being)			
Total score (range 0-108)	82.2 (16.3)	83.9 (17.7)	.25
Subscales			
Physical well-being (range 0-28)	21.1 (5.5)	21.5 (6.0)	.36
Social/family well-being (range 0-28)	23.9 (4.7)	23.5 (5.1)	.54
Emotional well-being (range 0-24)	17.9 (4.3)	18.8 (4.6)	.12
Functional well-being (range 0-28)	19.2 (5.6)	20.1 (5.6)	.11
FACIT-fatigue (reverse scored so that higher scores = less fatigue) (range 0-52)	35.7 (12.1)	37.0 (10.8)	.31
PROMIS global health (higher score = better health) (range 16.2-67.7)	43.9 (10.9)	45.6 (11.2)	.49
PROMIS mental health (higher score = worse mental health) (range 21.2-67.6)	50.2 (SD 6.9)	50.6 (SD 6.7)	.78
PROMIS fatigue (higher scores = more fatigue) (range 29.4-83.2)	53.5 (9.2)	53.7 (10.0)	.63
PROMIS depression (higher scores = greater depression) (range 37.1-81.1)	48.3 (8.6)	46.4 (8.6)	.09
PROMIS anxiety (higher scores = greater anxiety) (range 36.3-82.7)	52.2 (8.8)	48.5 (8.6)	.02
PROMIS sleep quality (higher scores = lower sleep quality) (range 28.9-76.5)	52.5 (8.2)	51.4 (7.8)	.18
PROMIS pain interference (higher score = greater pain interference) (range 41.0-78.3)	50.8 (9.4)	50.2 (8.0)	.60
PROMIS physical function (higher score = higher function) (range 14.1-61.7)	46.3 (8.6)	46.0 (8.3)	.97

Abbreviations: FACT, Functional Assessment of Cancer Therapy; FACIT, Functional Assessment of Chronic Illness Therapy; PROMIS, Patient Reported Outcomes Measurement Information System.