Randomized Trial of a Fitbit-Based Physical Activity Intervention for Women

Lisa A. Cadmus-Bertram, PhD, Bess H. Marcus, PhD, Ruth E. Patterson, PhD, Barbara A. Parker, MD, Brittany L. Morey, MPH

Introduction: Direct-to-consumer *m*Health devices are a potential asset to behavioral research but rarely tested as intervention tools. This trial examined the accelerometer-based Fitbit tracker and website as a low-touch physical activity intervention. The purpose of this study is to evaluate, within an RCT, the feasibility and preliminary efficacy of integrating the Fitbit tracker and website into a physical activity intervention for postmenopausal women.

Methods: Fifty-one inactive, postmenopausal women with BMI $\geq$25.0 were randomized to a 16-week web-based self-monitoring intervention (n=25) or comparison group (n=26). The Web-Based Tracking Group received a Fitbit, instructional session, and follow-up call at 4 weeks. The comparison group received a standard pedometer. All were asked to perform 150 minutes/week of moderate to vigorous physical activity (MVPA). Physical activity outcomes were measured by the ActiGraph GT3X+ accelerometer.

Results: Data were collected and analyzed in 2013–2014. Participants were aged 60 (SD=7) years with BMI of 29.2 (3.5) kg/m^2. Relative to baseline, the Web-Based Tracking Group increased MVPA by 62 (108) minutes/week ($p<0.01$); 10-minute MVPA bouts by 38 (83) minutes/week (p=0.008); and steps by 789 (1,979) (p=0.01), compared to non-significant increases in the Pedometer Group (between-group p=0.11, 0.28, and 0.30, respectively). The Web-Based Tracking Group wore the tracker on 95% of intervention days; 96% reported liking the website and 100% liked the tracker.

Conclusions: The Fitbit was well accepted in this sample of women and associated with increased physical activity at 16 weeks. Leveraging direct-to-consumer *m*Health technologies aligned with behavior change theories can strengthen physical activity interventions.
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Introduction

Given the established relationship between inactivity and chronic disease, physical activity (PA) promotion is a priority for postmenopausal women.[1–4] Accelerometer-based tracking devices and apps are of interest for use in scalable PA interventions because they can encourage the use of theory-driven self-regulation skills known to be associated with behavior change success.[5,6] One example is the Fitbit tracker, which collects activity data, uploads it to the web, and produces simple graphs and charts. Published studies examining the Fitbit as an intervention tool are currently limited to two single-arm studies[7,8] and one randomized trial.[9] The aims of this trial are to examine (1) the acceptability of the Fitbit among postmenopausal, overweight/obese women; and (2) the effect of a Fitbit-based intervention on PA (Figure 1).

From the Department of Kinesiology (Cadmus-Bertram), University of Wisconsin–Madison, Madison, Wisconsin; and the Department of Family Medicine and Public Health (Marcus, Patterson), Department of Medicine (Patterson, Parker), and Moores Cancer Center (Morey), University of California, San Diego, San Diego, California

Address correspondence to: Lisa A. Cadmus-Bertram, PhD, University of Wisconsin–Madison, 2000 Observatory Drive, Madison WI 53706. E-mail: cadmusbertra@wisc.edu.

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Methods

Participants

Participants were 51 overweight, postmenopausal women performing <60 minutes/week of moderate to vigorous physical activity (MVPA)[10] (to ensure they were well below the recommended 150 minutes/week[11]) who were regular Internet users, owned a computer/tablet, and could exercise safely.[12]

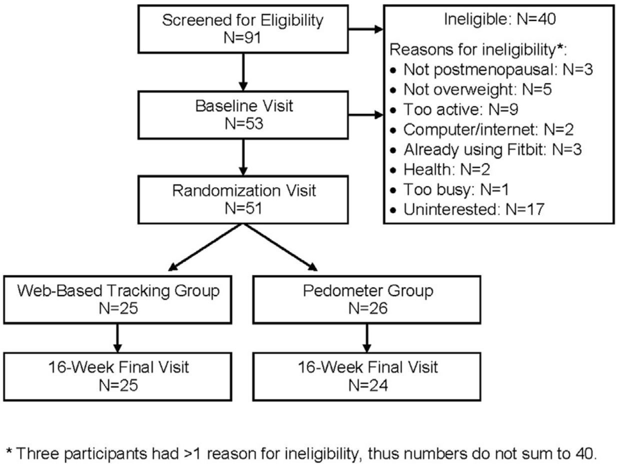

Figure 1. CONSORT Diagram.

Study Visits

Participants attended three visits at the University of California, San Diego (UCSD). Procedures were approved by the UCSD Human Research Protections Program. At the initial visit, informed written consent was obtained and the participant received baseline assessments. At the second visit, a web app assigned participants with equal probability (blocked on age and BMI) to the Web-Based Tracking Group or Pedometer Group. The participant was then oriented to her group. Participants returned for a Final Visit at 16 weeks and received $20 for study completion.

Measures

The ActiGraph GT3X+ (ActiGraph, Pensacola, FL) was worn on the hip for 7 days at baseline and 16 weeks. Standard thresholds were used to aggregate data into sedentary, light, moderate, and vigorous activity.[13] Height and weight were measured using standard procedures.

The Baseline Questionnaire included demographics and technology use (www.pewinternet.org). The Final Questionnaire evaluated the assigned study arm. For participants in the Web-Based Tracking Group, this included frequency of Fitbit wear, use of the website, perceived helpfulness of specific features, and perceived benefits/barriers.

Intervention Groups

This study compared (1) a low-touch, Fitbit-based PA intervention focused on self-monitoring/self-regulation skills[5,6] (Web-Based Tracking Group) and (2) provision of a basic step-counting pedometer (Pedometer Group). Both were asked to perform 150 minutes/week of MVPA and walk 10,000 steps/day.

Participants in the web-based tracking group received a Fitbit One, an accelerometer-based device that clips to the waistband or bra, or is placed in a pocket. Summary data are shown on the tracker's display and PA intensities and temporal patterns are available on the website. Prior to randomization, the study coordinator initialized a tracker for each participant (in case she was randomized to the Fitbit group) and modified the online "dashboard" to display only PA data. At the Randomization Visit, the study coordinator demonstrated how to download/install the software and use the website. This training was reinforced with a study-specific handbook. The intervention was based on the Coventry, Aberdeen, and London—Refined (CALO-RE) framework, which identifies self-monitoring, combined with other self-regulatory skills (e.g., goal setting, frequent behavioral feedback), as the most important theory-driven component of successful behavior change.[5,6] Individualized goals were set for the first 4 weeks of the study (using data observed on the baseline ActiGraph) and the participant committed to a specific plan to achieve these. A follow-up call at 4 weeks was used to evaluate progress and refine goals.

Pedometer group participants received a basic pedometer and printed materials with tips for increasing steps. They also completed a brief goal-setting process, based on steps observed on the ActiGraph.

Data Management and Statistical Analysis

Data were collected/managed in 2013–2014[14] and analyzed in 2014 using SAS, version 9.4, according to the intent-to-treat principle. Baseline characteristics were compared using chi-square and *t*-tests. ActiGraph data were adjusted for number of valid days (95% had 7 valid days, 5% had 5–6). PA changes from baseline to Week 16 were assessed using repeated-measures ANCOVA, adjusted for age and ActiGraph daily wear time to address potential residual confounding. Missing data (n=2 from the Pedometer Group) were imputed by carrying forward baseline values.

Results

Participants (N=51) were aged 60.0 (SD=7.1) years with a BMI of 29.2 (3.5) and groups were comparable on key characteristics (Table 1). At baseline, women were performing 33 (56) minutes/week of MVPA in bouts ≥10 minutes in length (as specified by the PA guidelines[15]) and accumulating 5,866 (2,195) steps/day.

Relative to baseline, the Web-Based Tracking Group increased MVPA in bouts by 38 (83) minutes/week ($p<0.01$); increased total MVPA by 62 (108) minutes/week (p=0.008); and increased steps/day by 789 (1,979) (p=0.01) (Table 2). The Pedometer Group experienced non-significant increases in PA. No adverse events occurred.

Ninety-six percent of participants reported wearing the tracker ≥4 days/week. Wear time was corroborated by Fitbit data, which showed the median days of any wear (≥2,000 steps accrued) was 106 of 112 prescribed days. Eighty-eight percent used the website, with 52% logging in 2–3 days/week. Participants were most engaged with the device itself (72% viewing tracker data ≥1 time/day), using a passive approach to the website (viewing feedback but not changing goals or manually logging behaviors).

Barriers were low: 80% had no computer issues, 80% reported no technical difficulty with the tracker, and 84%

Table 1. Baseline Characteristics of Study Participants

	Web-based tracking group (*n*=25)	Pedometer group (*n*=26)	*p*-value for difference
Age, M (SD)	58.6 (6.5)	61.3 (7.5)	0.17
Weight, kg, M (SD)	82.4 (14.7)	79.3 (12.2)	0.42
BMI, M (SD)	29.2 (3.8)	29.1 (3.2)	0.94
Non-Hispanic white, *n* (%)	23 (92)	23 (88)	0.61
College degree or higher, *n* (%)	14 (56)	18 (69)	0.33
Moderate to vigorous physical activity[a]			
Performed in Freedson bouts, minutes/week, M (SD)	24 (39)	42 (68)	0.26
Meeting physical activity guidelines, %	0	8	0.15
Total moderate to vigorous activity, minutes/week, M (SD)	172 (83)	176 (117)	0.89
Steps[a]			
Average steps per day, M (SD)	5,906 (1,964)	5,823 (2,431)	0.90
% walking ≥10,000 steps/day, %	4	8	0.99
Technology use, %			
Daily Internet user	84	88	0.64
Comfortable using computers and the Internet[b]			0.99
Neutral	4	0	
Somewhat comfortable	12	15	
Very comfortable	84	85	
Enjoys using computers and the Internet[c]			0.38
Neutral	17	4	
Somewhat enjoy	21	23	
Very much enjoy	62	73	
Type of primary computer			0.38
Desktop	32	50	
Laptop	64	42	
Tablet	4	8	
Operating system of primary computer			0.99
Windows	64	65	
Mac	36	31	
Other (e.g., Linux)	0	4	

[a]As measured by ActiGraph GT3X+ accelerometer.
[b]Women who responded "very uncomfortable" or "somewhat uncomfortable" were ineligible for this study.
[c]Women who responded "very much do not enjoy" or "somewhat do not enjoy" were ineligible for this study.

had no issues with a lost/broken tracker. Ninety-six percent of women liked the Fitbit website, and 100% liked the tracker. Seventy-six percent said that they would recommend the Fitbit to a friend. When asked about future preferences, 56% of participants preferred a clip-on tracker, 20% preferred a wrist-worn tracker, and 24% had no preference. Ninety-six percent rated the Fitbit as "somewhat or very" helpful for increasing PA, compared to only 32% of the Pedometer Group who found the basic pedometer "somewhat or very" helpful.

Table 2. Baseline to 16-Week Changes in Objectively Measured Physical Activity and Body Weight

	Web-based tracking group (n=25)				Pedometer group (n=26)				Between-group	Effect size
	Baseline	16 weeks	Change	p-value	Baseline	16 weeks	Change	p-value	p-value	(Cohen's d)
Minutes/week of physical activity										
Moderate to vigorous intensity (total)	172 (83)	234 (119)	62 (108)	0.008	176 (117)	189 (99)	13 (98)	0.51	0.11	0.48
Moderate to vigorous intensity (in bouts)	24 (39)	62 (82)	38 (83)	0.01	42 (68)	57 (69)	16 (76)	0.26	0.28	0.28
Light intensity	1,276 (311)	1,262 (320)	−14 (204)	0.49	1284 (383)	1,252 (317)	−33 (225)	0.82	0.54	0.09
Average steps per day	5,906 (1,968)	6,695 (2,708)	789 (1,979)	0.01	5,827 (2,431)	6,188 (2,423)	362 (1,605)	0.17	0.30	0.24
Body weight (kg)	82.4 (14.7)	82.2 (16.0)	−0.3 (2.4)	0.49	79.3 (12.2)	79.2 (13.2)	0.01 (2.3)	0.98	0.61	0.06

Discussion

In this study, a Fitbit-based intervention was associated with increased PA, with no change observed in the Pedometer Group. Although between-group tests did not reach significance, this may be due to sample size. The increase of 62 minutes/week of MVPA observed in the Fitbit arm is substantial, particularly if maintained over time. This maintenance would likely require progressive goal increases established via periodic contact with investigators via web or telephone. This study's findings differ from those of Thompson et al.,[9] who found that a Fitbit with feedback did not increase PA among older adults. This may be partly because of the approximately 20-year difference in participant age.

Barriers to Fitbit use were low and technical issues were resolved quickly. Participants adhered well to wearing and viewing feedback on the tracker. Participant feedback indicated that women liked the website but either found the tracker sufficient for their needs or were otherwise unmotivated to explore the website beyond its basic functions; several mentioned the desire for additional hands-on training. Such training may help increase effect size by enhancing participants' engagement with the website.

Strengths of this study include the use of the ActiGraph, detailed participant feedback, and use of Fitbit data to corroborate adherence. Limitations include a small sample, short duration, and lack of generalizability. Further research is needed to better understand the potential of direct-to-consumer devices for PA promotion, particularly over the long term.

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