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Journal

Pediatric Nephrology, 39(8)

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Publication Date

2024-08-01

DOI

10.1007/s00467-024-06340-6

Peer reviewed

HHS Public Access

Author manuscript

Pediatr Nephrol. Author manuscript; available in PMC 2024 December 12.

Published in final edited form as:

Pediatr Nephrol. 2024 August ; 39(8): 2467–2474. doi:10.1007/s00467-024-06340-6.

Use of activity trackers to improve blood pressure in young people at risk for cardiovascular disease: a pilot randomized controlled trial

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Abstract

Background—Promoting physical activity among young individuals with cardiovascular disease (CVD) risk factors such as hypertension, diabetes, or chronic kidney disease can lower systolic blood pressure (BP). We sought to determine whether a 6-month intervention using a physical activity tracker was feasible and effective, compared with usual care.

Methods—Participants were recruited at a single academic medical center. Those aged 8–30 years were randomized in a 2:1 ratio to either the intervention (use of a Fitbit physical activity tracker coupled with feedback regarding the participant's step count) or usual care. The primary feasibility outcomes were screening-to-enrollment ratio and 6-month retention rates; the primary clinical outcome was a change in systolic BP from 0–6 months.

Results—Sixty-three participants were enrolled (57% male; mean age: 18 ± 4 years). The screening-to-enrollment ratio was 1.8:1. Six-month retention was 62% in the intervention group and 86% in the control group ($p = 0.08$). Mean change in systolic BP in the intervention group was not significantly different from the control group at 6 months (− 2.3 mmHg; 95% CI − 6.5, 1.8 vs. 3.0 mmHg; 95% CI − 2.5, 8.4, respectively, $p = 0.12$).

Conclusions—Among children and young adults at elevated CVD risk, the use of a physical activity tracker coupled with tailored feedback regarding their step count progress was feasible but

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Author contribution EK conceived and developed the study intervention and design and contributed to all manuscript drafts, EK and DS executed all recruitment and study procedures, CM provided initial statistical input and throughout the study execution and analysis, FL conducted the initial statistical analysis with regard to clinical outcomes, and AB performed the feasibility and statistical analysis and wrote the first draft of the manuscript. All authors provided a critical review of the final draft and approved its submission.

Competing interests AB, DS, CM, and FL: nothing to disclose. EK: support from Natera and CareDX in the form of grants; American Journal of Kidney Diseases Associate Editor; American Kidney Fund Health Equity Coalition.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00467-024-06340-6.

Ethical approval The University of California, San Francisco Institutional Review Board approved this pilot trial and it was registered at ClinicalTrials.gov (identifier: NCT03325426).

not sustained over time. Physical activity tracker use did not have a statistically significant effect on BP after 6 months. Augmented strategies to mitigate risk in young patients at high risk for early-onset CVD should be explored. This trial is registered at ClinicalTrials.gov (NCT03325426).

Keywords

Hypertension; Physical activity; Pedometer; Adolescent; Young adult

Background

The popularity of wearable health technology—including devices such as activity trackers, pedometers, and smart devices—has been growing in the USA. Wearable devices provide a potential avenue to increase patient self-monitoring and disease management remotely [1]. Interventions using pedometers or physical activity trackers to increase physical activity as a means of reducing cardiovascular disease (CVD) risk have been moderately successful among adults [2–4]. In a systematic review of healthy children, the use of these devices appears to be associated with short-term increases in daily physical activity [5]. Prior systematic reviews have shown that among adults at elevated CVD risk, activity tracker use led to modest but reproducible reductions in systolic BP by approximately 4 mmHg [3, 6].

Identifying ways to reduce CVD risk is an important issue for population health since the number of children with essential hypertension is increasing [7], and hypertension is associated with cardiovascular events later in life [8]. However, few studies have examined the potential effects of pedometer or physical activity tracker use on cardiovascular risk factors among children and young adults with high CVD risk [9–11]. Of those that have been published, even fewer studies have specifically examined the effect of pedometer- or activity tracker-driven interventions on BP in trials. For example, a 12-week study of 20 overweight or obese adolescents who used activity trackers showed an improvement in systolic BP (by 10 mmHg) in a pre-post observational study design [9]. In contrast, an intervention aimed at increasing physical activity through the use of pedometers in children with chronic kidney disease [12] was not associated with increased daily step count among participants; however, changes in BP were not included as an outcome measure [11]. Thus, although improving BP is particularly important for young people with increased CVD risk, few interventions have explored BP control as an outcome in the younger at-risk population.

Fitbits (wireless activity trackers worn on the wrist that sync with a smartphone) have been previously validated for step count accuracy in children and adults [13, 14], and their use has been shown to be feasible and acceptable among children with chronic health conditions [15]. The objective of this pilot randomized controlled trial was to determine whether the use of activity trackers (Fitbit Flex 2) coupled with study team feedback on daily step count progress was feasible regarding enrollment and retention and effective at lowering systolic BP in children and young adults at elevated cardiovascular risk over a 6-month period.

Methods

Study design

This was a pilot phase 2 randomized trial of the use of physical activity trackers in conjunction with study team feedback on daily step counts over 6 months. Participants were randomized in a 2:1 ratio to intervention versus control (usual care) to generate sufficient feasibility data surrounding the intervention. To incentivize study enrollment, patients randomly assigned to the control group then had the opportunity to cross over—to receive the intervention after a 6-month period of usual care if they were willing to continue in the study. Intervention participants were also offered the opportunity to continue in the study for a total of 12 months if they were willing (see Table 1). Here, we report on 6-month outcomes given that this was the prespecified primary clinical outcome.

Participants

Participants were recruited from a single academic center and screened for eligibility or referred to the study by their nephrologists. Participants were recruited from November 2017 through March 2020 (when recruitment was halted due to research restrictions related to the COVID-19 pandemic and was not resumed thereafter).

Eligible participants were aged 8–30 years and receiving antihypertensive therapy, or had a pre-existing diagnosis of hypertension, or had type 1 or 2 diabetes mellitus, or had non-dialysis-requiring chronic kidney disease (including kidney transplant recipients with functional allografts). Participants were required to have a smartphone to enable syncing of the Fitbit device and to speak English to ensure they could work with the Fitbit app and receive study team feedback (which was in English).

Patients receiving chronic dialysis were excluded to limit the heterogeneity of the study population and the low number of eligible patients at our center. We also excluded patients with uncontrolled hypertension (BP > 180/110 mmHg at the last clinic visit for adults or patients whose providers did not feel were appropriate for participation in the study based on their hypertension control, adherence, or other considerations), those with comorbidities that precluded performance of age-appropriate levels of physical activity (e.g., moderate or severe cerebral palsy), and those already using a physical activity tracker or pedometer. Vulnerable groups including pregnant and imprisoned individuals, and those with cognitive impairment, were also excluded. The University of California, San Francisco Institutional Review Board approved this pilot trial, and the trial was registered at ClinicalTrials.gov (identifier: NCT03325426).

Intervention

Participants randomly assigned to the intervention group received a Fitbit Flex 2 wristband activity tracker at the time of informed consent (and assent when applicable) for use during the study.

Study personnel remotely reviewed participants' step count data weekly. If the mean daily step count was below the recommended age-appropriate reference (10,000 steps/day

for adults and adolescents [16] and 12,000 steps/day in school-age children [17, 18]), participants were provided with ideas on how to increase daily step counts (e.g., parking further from their destination and walking, taking stairs instead of elevator) via secure email or phone call (per the family or patient's preference). For the second 6 months of the intervention, participants in the intervention group were instructed to continue using the Fitbit and to attend quarterly study visits but were not provided with additional study feedback on their achieved step counts.

Participants randomized to the control group received usual care and were then offered the intervention after a 6-month period if they were willing to continue in the study. All participants completed a baseline visit and study assessments quarterly (at the end of 3, 6, 9, and 12 months) to ascertain BP, height, and weight (Table 1).

Outcomes and statistical approach

Baseline characteristics and clinical outcomes were compared by *t*-tests, the Wilcoxon rank-sum tests, or chi-squared tests where appropriate.

Feasibility outcomes

The primary feasibility outcomes were screening-to-enrollment ratio and retention at 6 months in the intervention group. Secondarily, we examined intervention uptake and adherence to the intervention over time (see Supplemental Material for Barriers to Participation Survey).

Clinical outcomes

The primary clinical outcome was a change in mean systolic BP using an intention-to-treat approach over the initial 6 months of the intervention (when the control group was not using the physical activity tracker). Blood pressures were measured using a standardized approach for all participants in accordance with guidelines [19] by trained study personnel. Because the number of participants < 13 years of age was low (and diagnostic thresholds for pediatric hypertension are based on absolute BP after 12 years of age [19]), and because we were interested in the change in systolic BP, absolute systolic BP rather than a BP *z*-score was used as the primary outcome. Data regarding antihypertensive agent use was collected during the study.

Statistical approach

All analyses were conducted using an intention-to-treat approach. Based on power estimates made prior to the start of the trial, a sample size of 75, with an estimated 25% dropout rate, would yield 80% power (alpha = 0.05) to detect a mean 7 mmHg difference between the two arms. We used *t*-tests to compare changes in systolic BP at 6 months by randomized assignment and differences in secondary and exploratory outcomes.

Secondary and exploratory outcomes

A secondary outcome included the change in systolic BP from month 6 to month 12, when all participants were eligible for intervention. An exploratory outcome of interest included a change in weight in kilograms over the first 6 months. In exploratory sensitivity analyses,

we repeated our analysis for the outcome of change in BP, excluding participants < 13 years of age at enrollment. We also explored whether there were differences in the number of new antihypertensive medications required at months 6 and 12 in the subset with such data available.

Results

Demographics and patient characteristics

A total of 63 participants were enrolled in the trial: 42 in the intervention group and 21 in the control group. There were no statistically significant baseline differences between groups (see Table 2). Nearly half of participants self-identified as Hispanic (48%) and more than half were male (57%), with a median age of 18 years. Only 5 participants were younger than 13 years of age. The baseline median daily step count was 8900 steps/day in the intervention group and 7000 steps/day in the control group ($p = 0.76$).

The etiology of increased cardiovascular risk varied among participants. Eighteen out of 42 participants (43%) in the intervention group and 7 out of 21 participants (33%) in the control group were kidney transplant recipients; the most common cause of kidney failure in both groups were congenital anomalies of the kidney and urinary tract (CAKUT), followed by glomerulonephritides including systemic lupus erythematosus. Regarding baseline antihypertensive agent use, 29% ($n = 12$) of the intervention group and 20% ($n = 4$) of the control group were not taking antihypertensive agents at the time of enrollment; 70% of participants in both the intervention and control groups were taking 2 or fewer antihypertensive medications at the time of enrollment, $p = 0.10$.

Feasibility outcomes

Screening-to-enrollment ratio—One hundred fifteen potential participants were screened for participation; 25 did not meet inclusion criteria at the time of enrollment, and 15 were unavailable for study activities when approached. Ultimately, 63 participants were enrolled, which translated to a screening-to-recruitment ratio of 1.8:1.

Retention—After 6 months, 26 (62%) intervention group participants completed the quarterly study visit (compared to 18 control group participants (86%), i.e., those who had not yet received the activity tracker; $p = 0.082$; Fig. 1). At 12 months, 18 (43%) intervention group participants completed the final study visit (compared to 11 control group participants (52%); $p = 0.62$ for the difference in retention between the two groups at month 12).

Although 22/25 (88%) participants who completed a questionnaire post-intervention (or at the time of dropout) reported that the activity tracker was easy to use, the most common reason for dropout was related to the use of the device itself (e.g., technical issues with charging, syncing, or forgetting to wear the device; $n = 10$; see Fig. 1). A total of 65% reported forgetting to wear the activity tracker frequently. No adverse events related to the intervention were cited as the reason for dropout among any participants.

Regarding enrollment, 60 of 63 participants (95%) had completed 6 months of participation, and 48/63 (76%) had completed 12 months of participation, prior to the beginning of March

2020, when a coronavirus pandemic–related state of emergency was declared in the state of California. A small proportion (n = 3, 5%) of participants dropped out either due to logistical concerns related to the COVID-19 pandemic or COVID-related illness.

Clinical outcomes

Primary clinical outcome: change in systolic blood pressure between baseline and month 6—At 6 months, mean change in systolic BP in the intervention group was not statistically significantly different from the control group (− 2.3 mmHg; 95% CI − 6.5, 1.8; + 3.0 mmHg; 95% CI − 2.5, 8.4, respectively; p = 0.12) (see Table 3).

Secondary and exploratory outcomes—Mean change in systolic BP in the intervention group from 6 to 12 months was not statistically significantly different from the control group (− 2.3 mmHg, 95% CI − 7.3, 2.7, vs. + 0.6 mmHg, 95% CI − 6.0, 7.2, p = 0.46). Between baseline and 6 months, the mean change in weight in the intervention group was not statistically significantly different from the control group (+ 3.6 kg, 95% CI 2.1, 5.1; + 3.0 kg, 95% CI 0.3, 5.8, respectively; p = 0.67) (see Table 3).

When we excluded the 5 participants less than age 13 and repeated the primary analysis, results were similar with respect to change in BP at both 6 and 12 months (p > 0.2 at both timepoints) (see Supplemental Table 1).

At 6-month and 12-month follow-up, among those with data available (n = 44 and n = 29, respectively), the between-group differences in the number of new antihypertensive medications were not statistically significant (p = 0.55 at 6 months, p = 0.25 at 12 months).

Adherence to and acceptability of intervention components—Adherence to the use of the physical activity tracker had a bimodal distribution: approximately 28% of participants in the intervention group, averaged across all assessments, wore the device for 0 days/week, while 50% wore the device for 7 days/week. This utilization pattern was like those in the control group who agreed to crossover to intervention during months 6–12: 20% wore the device for 0 days/week, and 51% wore the device for 7 days/week.

Twenty-six of the 42 intervention participants completed a questionnaire on the acceptability of the device post-intervention. Acceptability was high; 25/26 (96%) would recommend the intervention to others. Only 8% felt that the study team’s feedback to prompt an increase in step count was excessive.

Conclusions

In this pilot trial of children and young adults with pre-existing cardiovascular disease risk factors (hypertension, diabetes mellitus, or chronic kidney disease including kidney transplant recipients), randomized assignment to the use of a physical activity tracker coupled with study feedback was feasible, but 6-month trial retention rates were modest (62% completed the 6-month follow-up) though comparable to fitness interventions in similar populations at risk for CVD [11].

No statistically significant changes in the primary clinical outcome of interest (change in systolic BP) or secondary clinical outcomes of interest (change in weight) were observed. The strengths of the intervention included the relatively long study duration compared to prior interventional studies in similar pediatric and young adult populations [11, 20]. The intervention was designed to be pragmatic and feasible within most clinical settings, unlike similar interventions that may be more resource-intensive with mixed efficacy [11, 21].

Feasibility outcomes

Although the vast majority of participants who received the intervention reported that the device was “easy to use” after the study was completed, the most common reason for dropout included technical issues with charging or syncing the device and forgetting to charge or wear the device (see Fig. 1). Dropout was similar to that observed in other interventions for adolescents with chronic health conditions (30% at 6 months, 55% at 24 months in one study [22]; and 60% at 6 months in a separate technology-based study [23]). Given the important role of family support for young individuals living with a chronic condition, the involvement of the family in future interventions may help improve study retention [22].

Although adolescents and young adults with chronic diseases have reported interest in the use of electronic devices and online tools for disease management [24–26], real-world intervention adherence to such devices is lower than desired. To avoid any social desirability bias in responses, better participant engagement with the device is needed, including the design of devices that do not require frequent charging in the setting of busy lifestyles due to school or work.

Clinical outcomes

Physical inactivity is an issue worldwide and contributes to CVD risk. This activity tracker–based intervention did not lead to detectable improvements in the primary or secondary clinical outcomes of interest (change in systolic BP, change in weight). The between-group systolic BP differences of approximately 5 mmHg may hold some clinical relevance; however, this study was not powered to detect this magnitude of change in BP. A larger future trial may enable the detection of smaller statistically significant differences.

Participants’ mean daily step counts, both at baseline and throughout the intervention, were below national age-referenced recommendations for nearly 75% of participants; this was expected given the known high prevalence of physical inactivity among those with chronic kidney disease, diabetes, and kidney transplant recipients internationally [27–29]. Despite the high prevalence of physical inactivity, participants’ step count in our pilot study was generally higher than reported in a similar pedometer-based intervention for children with chronic kidney disease, with our sample having a daily step count of nearly 8000 steps, compared to approximately 6000 steps/day [11].

Participants who had previously used activity trackers were excluded from this study, potentially excluding a highly motivated group for whom similar interventions have been useful [30]. A study of Canadian adolescents involved in an activity tracker–based intervention (with delayed introduction of the activity tracker in the control group) identified

that those in the “action” or “maintenance” stage of behavior change were most likely to increase their minutes of physical activity over the 7-week intervention period, as compared to other stages of change.

Limitations

Because recruitment began in the year prior to the coronavirus pandemic and continued for 2 years, participants may have experienced substantial changes in both active and passive physical activity levels over the intervention period, as has been observed both nationally and globally [31, 32], particularly among those with chronic diseases [33]. However, most participants completed the study prior to stay-at-home directives, and only 3 of the total sample size of 63 participants specifically dropped out due to pandemic-related concerns.

We acknowledge that we did not capture comprehensive data on diet which may have influenced BP and other clinical outcomes of interest, though in a randomized setting, such factors should be balanced. Mechanistically, the lack of difference in step count between groups over time could partially explain the overall null findings. The standard advice provided to participants may not have been individualized enough to effectively motivate changes in physical activity. Our results reinforce that improving measures of cardiovascular health, even with the aid of wearable technology or mobile health applications, remains challenging.

Future directions and opportunities

Despite the increasing popularity of wearable activity trackers, their inconsistent effect (particularly in this population at risk for CVD) highlights the need to identify subgroups for whom these devices work well. Our study showed that although young patients are interested in such interventions, the use of Fitbits and physical activity trackers is difficult to sustain over time, which may explain why blood pressure did not improve significantly in those receiving the intervention. As the popularity of wearable technology increases, newer devices that provide additional capabilities (e.g., communication and camera capabilities, sleep tracking) may be more attractive to young users and integrate better into their daily lives, making behavioral change more sustainable. Additional strategies to increase and sustain the motivation to remain physically active are needed.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Funding

This work was supported by NHLBI (K23HL131023, Dr. Ku).

Data availability

The datasets generated during and/or analyzed during the current study are not publicly available since some participants were minors and did not consent to such data sharing, and this was primarily a feasibility pilot.

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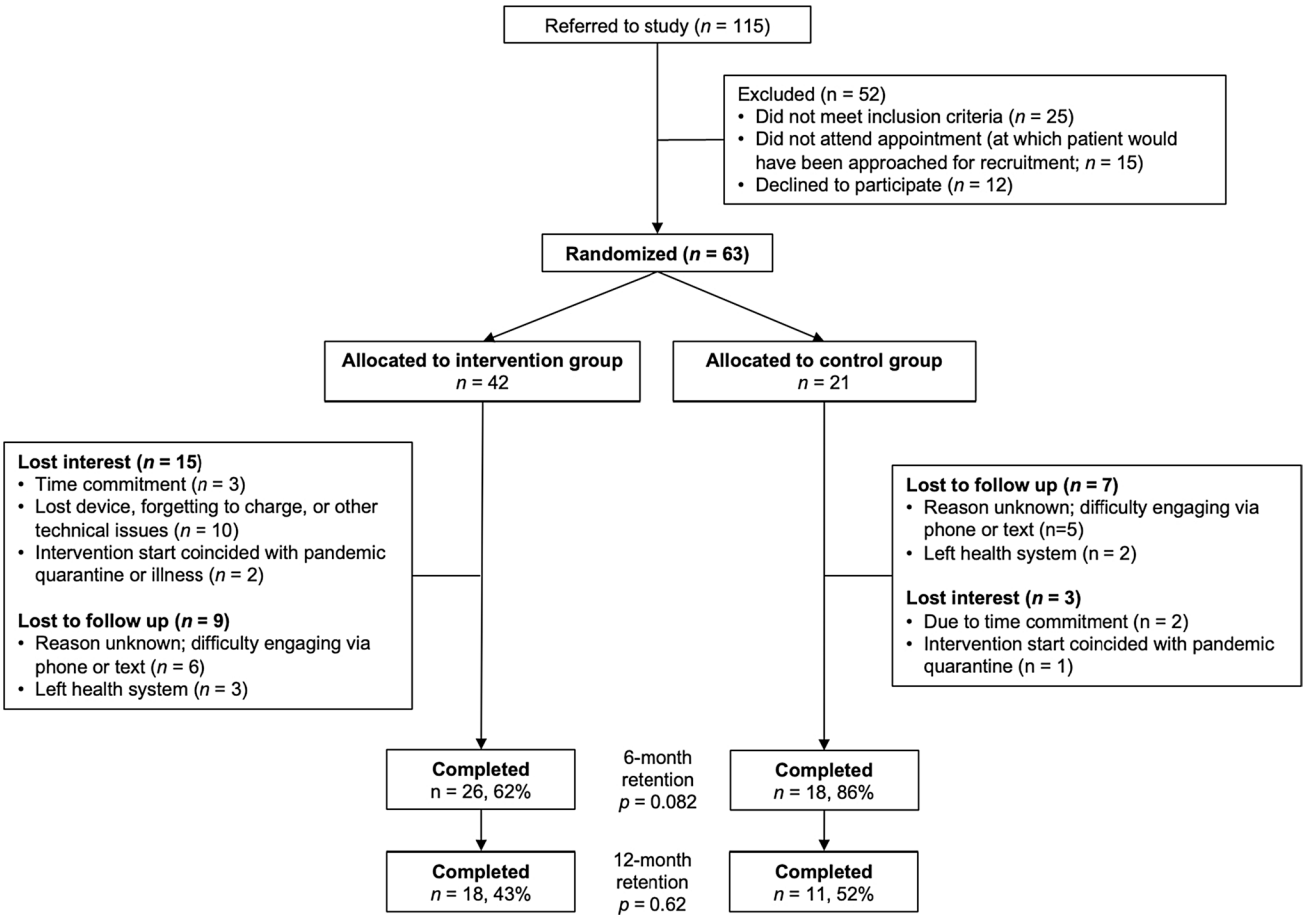

Fig. 1.
CONSORT flow diagram

Table 1

Trial design

	Visit 0 (Baseline)	Month 0–3	Visit 1	Months 3–6	Visit 2	Months 6–9	Visit 3	Months 9–12	Visit 4
Intervention Group	BP & Weight	Received Fitbit and biweekly motivational email or phone call for 6 months				Continued to use Fitbit; stopped receiving email or phone calls			BP & Weight
			BP & Weight		BP & Weight		BP & Weight		
Control Group	BP & Weight	Received usual care				Received Fitbit and biweekly motivational email or phone call for 6 months			BP & Weight
			BP & Weight		BP & Weight		BP & Weight		

Table 2

Demographic and clinical characteristics of children and young adults participating in a randomized controlled pilot study investigating the utility of pedometers in improving blood pressure

	Full sample *n* = 63	**Intervention group *n* = 42**	**Control group *n* = 21**	***p* value***
Median age in years (IQR)	18 (15–20)	18 (15–19)	18 (15–20)	0.82
Male (*n*, %)	36 (57%)	27 (64%)	9 (43%)	0.11
Race/Ethnicity (*n*, %)				0.44†
Hispanic	30 (48%)	19 (45%)	11 (52%)	
Non-Hispanic Asian	12 (19%)	8 (19%)	4 (19%)	
Non-Hispanic White	10 (16%)	7 (17%)	3 (14%)	
Non-Hispanic Black	8 (13%)	5 (12%)	3 (14%)	
Other	3 (5%)	3 (7%)	0 (0%)	
Baseline median systolic blood pressure in mmHg (IQR)	124 (116–130)	125 (117–130)	120 (114–126)	0.19
Baseline median weight in kg (IQR)	77 (60–93)	83 (65–97)	69 (58–89)	0.16
Baseline median daily step count, rounded to nearest 100 (IQR)**	8300 (5000–10,400)	8900 (5000–10,400)	7000 (5100–10,400)	0.76
Baseline mean daily steps at goal (*n*, %)	15 (28%††)	11 (29%)	4 (25%)	0.88

* *p* value for the Wilcoxon rank-sum test, *t*-test, or *z*-test of proportions, where applicable, comparing intervention vs. control group

† *p* value for chi-square test comparing counts between intervention vs. control groups

** Calculated after the first 1 week of Fitbit use (i.e., weeks 1 and 2 of the intervention for the intervention group, and weeks 26 and 27 for the control group)

†† Baseline mean daily step count was calculated over the first 7 days of pedometer use. Four intervention groups and 5 control participants did not utilize the pedometer in the first week; denominator is 54 participants

Table 3

Outcome measures

	Intervention group	Control group	*p* value
Mean change in systolic blood pressure (mmHg) (95% confidence interval)			
Month 0–6 assessment	− 2.3 (− 6.5, 1.8)	3.0 (− 2.5, 8.4)	0.12
Month 6–12 assessment	− 2.3 (− 7.3, 2.7)	0.6 (− 6.0, 7.2)	0.46
Mean change in weight (kg) (95% confidence interval)			
Month 0–6 assessment	3.6 (2.1, 5.1)	3.0 (0.3, 5.8)	0.67
Month 6–12 assessment	2.2 (0.4, 4.0)	1.8 (− 1.4, 4.9)	0.78