ORIGINAL RESEARCH

Effect of pedometer use and goal setting on walking and functional status in overweight adults with multimorbidity: a crossover clinical trial

Paul Y Takahashi[1]
Stephanie M Quigg[1]
Ivana T Croghan[1]
Darrell R Schroeder[2]
Jon O Ebbert[1]

[1]Division of Primary Care Internal Medicine, [2]Division of Biomedical Statistics and Informatics, Mayo Clinic, Rochester, MN, USA

Background: Walking can improve functional status, and a pedometer and goal setting can increase walking and, potentially, gait speed. The efficacy of pedometer use and goal setting for increasing step counts among overweight and obese adults with multiple comorbid conditions has not been evaluated.

Methods: We recruited and randomly assigned obese or overweight adults with multimorbidity to immediate pedometer use with goal setting or delayed pedometer use, using a crossover design. The primary outcome of interest was step count, with secondary outcomes of gait speed and grip strength, with comparison between the intervention and delayed pedometer groups.

Results: Mean (standard deviation [SD]) age of the 130 participants was 63.4 (15.0) years. At 2 months, mean (SD) steps for the immediate pedometer use group (n=64) was 5,337 (3,096), compared with 4,446 (2,422) steps in the delayed pedometer group (n=66) ($P=0.08$). Within-group step count increased nonsignificantly, by 179 steps in the immediate pedometer group and 212 steps in the delayed pedometer group after 2 months of intervention, with no significant difference between the groups. Gait speed significantly increased by 0.08 m/s ($P<0.05$) and grip strength significantly increased by 1.6 kg ($P<0.05$) in the immediate pedometer group.

Conclusion: Pedometer use and goal setting did not significantly increase step count among overweight and obese adults with multimorbidity. The absolute step count was lower than many reported averages. Gait speed and grip strength increased with immediate pedometer use. The use of pedometers and goal setting may have an attenuated response in this population.

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Keywords: chronic disease, muscle strength, obesity, physical activity, pedometer, gait speed, grip strength

Introduction

Walking is important for all people, but is particularly important for older adults. Understanding the importance of gait speed, walking, and exercise in general, primary care providers routinely encourage increased physical activity. One such method to increase activity involves the use of a pedometer. Pedometers provide step count for the day and may record these steps for a week. Pedometers provide feedback that uses theoretical modeling of social cognitive theory. Patients set goals by trying to reach a target for steps and improve self-efficacy by setting and reaching daily goals. In some workplace studies, 70% of people will increase their activity with a 4-week pedometer program.[1] In a 2007 meta-analysis of 27 studies – both randomized controlled trials and observational studies – participants in clinical trials increased their physical activity by 2,183 steps compared with a control group.[2] Other meta-analyses have evaluated step

Correspondence: Paul Y Takahashi
Division of Primary Care Internal Medicine, Mayo Clinic, 200 First St SW, Rochester, MN 55905, USA
Tel +1 507 284 2511
Fax +1 507 266 0036
Email takahashi.paul@mayo.edu

count in patients with specific illnesses. An analysis of seven randomized trials in patients with musculoskeletal disorders showed an average increase in step count of 1,950 steps.[3] In a recent Cochrane analysis of workplace pedometer use in 1,809 employees, only one of four studies showed increased pedometer steps and two studies showed no difference.[4] In younger populations, the use of pedometer may provide health benefits.[2,5]

Both the speed of walking and the absolute number of steps are important. Gait speed is an established biological marker for frailty and a potential predictor of mortality.[6] Gait speed is calculated using traveled distance in meters by the time required to travel that distance in seconds (m/s). Consensus statements and systematic reviews have outlined the deleterious effects of low gait speed. The International Academy on Nutrition and Aging concluded that low gait speed was a risk factor for disability, falls, institutionalization, and mortality.[7] A timed gait speed slower than 1.0 m/s is considered to indicate deficient muscle functional strength.[8] Gait speed in people older than 70 years averages 0.74 m/s (95% confidence interval 0.65–0.83 m/s) in the outpatient clinic[9] and 0.475 m/s in nursing homes.[10] On average, most adults older than 70 years have a gait speed that places them at risk for adverse outcomes.

An increasing proportion of our patient population is overweight or obese and has multimorbidity. These patients are at increased risk for hospitalization and adverse health events.[11] No data exist on whether a pedometer coupled with a goal-setting program will improve step count or gait speed in this population. Obesity or multimorbidity may influence step count. In this study, we aimed to determine the effect of pedometer use and behavioral goal setting, compared with usual care, on walking steps, gait speed, and grip strength in overweight and obese adults with multimorbidity.

Methods
Trial setting and design
The study was approved by the Mayo Clinic Institutional Review Board. We conducted a randomized controlled trial with a crossover design at Mayo Clinic, Rochester, MN, USA. The study participants and staff were not masked to assignment because the intervention group wore the pedometer and the usual care group did not. Randomization was completed with a computerized randomization scheme with blocks of four and given to patients in sealed envelopes. There were no changes to the design or execution of the trial after initiation. Study enrollment occurred from May 1, 2013, through September 10, 2014.

Participants were assigned to pedometer and behavioral goal setting or usual care in a 1:1 ratio. All participants had a baseline visit. Those in the immediate pedometer group then had three intervention visits at Months 1, 2, and 3 and a follow-up visit at Month 4; those in the delayed pedometer group had a follow-up visit at Month 1, with the intervention in Months 2 and 3, and a final follow-up at Month 4. Continuing the intervention in the immediate pedometer group allowed for a longer within-group comparison.

Participants
Patients were eligible for enrollment if they were at least 18 years old, community dwelling, overweight or obese, and had multiple medical comorbid conditions. Overweight was defined as a body mass index (BMI) between 25 and 29.9 kg/m² and obese as a BMI of ≥30.0 kg/m². Potential participants were screened for BMI using the electronic medical record, sampling the previous 12 months of clinical data.

We used Minnesota medical tiering as the basis for determining medical complexity. Minnesota medical tiering is based on the Ambulatory Care Group risk stratification method, which counts both number and severity of illnesses.[12] Trained medical staff not involved with the study calculated Minnesota tiering scores for the medical practice based on medical record billing codes. The International Classification of Diseases-9 codes for the previous year were used and were counted and placed into expanded disease clusters. These clusters were further categorized into 22 major expanded disease clusters, which were then counted, for each patient to be placed into medical tiers. Tiering placed patients into five categories: 0, low (0 medical conditions); 1, basic (one to three conditions); 2, intermediate (four to six conditions); 3, extended (seven to nine conditions); and 4, complex (ten or more conditions). Patients with extended and complex tiering (seven or more conditions or Tiers 3 or 4) were eligible for this study.

Participants were excluded if they were in Tier 2 or lower, had clinically documented dementia, were wheelchair bound, had uncontrolled depression (Patient Health Questionnaire-9 score >10),[13] or were in hospice. They were also excluded if they lived in a skilled nursing facility or were in a correctional facility. Patients who refused medical record review were also excluded.[14]

Study enrollment
Identification numbers for potentially eligible patients were placed in random order, and letters were sent to potential participants. Before distribution of the letters, tiering

scores within the week were checked to ensure continued eligibility. Participants telephoned a study coordinator who used an institutional review board-approved script to discuss the study. Participants met in person with the study coordinator to obtain informed consent and conduct screening procedures.

Age, sex, and race information were obtained at baseline. The study coordinator measured weight (kg), height (cm), blood pressure (mmHg), and pulse rate at baseline and at follow-up visits. The study coordinator measured cognitive status using the Short Test of Mental Status,[15,16] which is scored on a 38-point scale, with 29 points or less considered as possible dementia. The reported sensitivity ranges from 86% to 92% and specificity from 91% to 93%. The study coordinator administered the Patient Health Questionnaire-9;[13] the nine questions are based on the standard criteria for depression and have rankings from 0 to 3, for a total possible score of 27. A score of ≥10 has a sensitivity and specificity for depression of 88%.[13] All data were collected and managed using REDCap electronic data capture tools at Mayo Clinic.[17]

Intervention
The intervention emphasized exercise through pedometer use, as well as SMART (Specific, Meaningful, Action-based, Realistic, and Timely) goal setting.[18] SMART goals follow a transtheoretical model of change in which participants are in contemplation stages of change.[19] This method of goal setting has the participant set realistic goals that are obtainable and helpful at each stage. Participants in the immediate pedometer group received the pedometer, a digital versatile disc on exercise, exercise literature, nutrition literature, and a journal for activity self-entry. The pedometer was an Omron HJ-112 (Omron Healthcare, Inc, Lake Forest, IL, USA), with 7-day recording capability. Omron pedometers have been validated as accurate measures of step count.[20–25] Patients were instructed to wear the pedometer whenever they were up and walking. The participants set their own step goal, which was based on their baseline steps and the SMART goals they set. The pedometer served as the measure of adherence to the walking program.

Each intervention visit (baseline, 1-, 2-, and 3-month) involved brief behavioral goal setting to encourage and outline an increase in walking steps or healthy lifestyle. The initial visit averaged 90 minutes in length, and the follow-up visits were 30 minutes long. The digital versatile disc encouraged patients to start an exercise program in a 43-minute overview, including sample exercises. The exercise booklet

emphasized SMART goals and included strengthening and stretching exercises. The nutritional material emphasized the food pyramid and reducing cholesterol and salt intake. The daily journal had a section to record exercise and a food log. The front of the booklet had a section on SMART goals, with a space for the participant to write down their goals. The study coordinator helped participants set goals, with physical activity and nutritional goal setting, as directed by the patient.

Delayed pedometer group
Participants enrolled in the delayed pedometer group received entrance screening tests with no goal setting or pedometer use. Participants had full access to the video, journal, and education materials; however, this was not given to them at the baseline visit. Participants were given entry into the intervention at the 2-month visit and received the pedometer, educational materials, and behavioral goal setting at that point.

Outcomes
Walking steps were the primary outcome of interest, with comparison between the immediate pedometer group and the delayed pedometer group. Walking steps and functional status were obtained at baseline and at follow-up visits. For baseline steps, the study coordinator called the patient after 1 week to obtain an average number of steps for the initial week using the pedometer. Steps per day were averaged over the first 7 days of intervention and the 7 days before visits at 1, 2, 3, and 4 months.

Grip strength was measured using a Baseline (Medline Industries, Inc, Mundelein, IL, USA) hydraulic hand dynamometer and recorded in kilograms. The study coordinator had the participant tightly squeeze the dynamometer in the dominant hand with an outstretched arm. The study coordinator measured gait speed using a stopwatch, instructing the participant to walk at a normal speed over 4 m, which was measured in seconds and reported as m/s. The 4-m test is used as a standard gait measure.[26] To assess safety, we recorded the total number of adverse events (AEs), defined as any concerns from the participant (such as unplanned doctor visits or injury), and serious AEs (SAEs), defined as death, life-threatening events, hospitalization, and emergency room visits. AEs and SAEs were adjudicated for relationship to the study intervention.[27]

Data analysis
To compare groups at baseline, we used the χ^2 test for dichotomous characteristics and t-tests for continuous

variables. For the primary outcome of walking steps, we used matched *t*-tests to compare the differences between baseline and 2- and 4-month visits for within-group comparisons in both the immediate pedometer and delayed pedometer groups. We also compared between the immediate pedometer and delayed pedometer groups for walking steps at 2 months using a *t*-test. On the basis of step counts, we categorized patients as sedentary (<5,000 steps) or nonsedentary (≥5,000 steps) based on previously published categories for step count for the overall population.[28] For the secondary outcomes of gait speed and grip strength, both outcomes were compared within assigned group at baseline, 2 months, and 4 months and between groups at 1 and 2 months.

We analyzed the data using an intention-to-treat analysis. For patients with incomplete or missing step information, we used the average daily steps from the available data or last observation carried forward. For patients with other types of missing data, we carried forward the last available information using the last observation carried forward method of imputing the data. We performed analysis of covariance for between-group (immediate pedometer vs delayed

pedometer group) evaluation. Significance was determined using a two-tailed test, with *P*<0.05 being considered significant. All analyses were conducted using SAS software version 9.3 (SAS Institute Inc., Cary, NC, USA).

The study power calculation was based on 100 participants to be randomly assigned into the immediate pedometer group (n=50) and delayed pedometer group (n=50). The power calculations were based on the primary outcome of walking steps. The basis for sample size calculations was 7,500 steps on average, with an expected change of 26%. These baseline assumptions were derived from a meta-analysis of clinical trials and observational studies using pedometers.[2] Using these assumptions, we had an 80% power to detect a 30% difference with 90 participants. We did not perform an interim analysis.

Results
Participants
In this study, 130 participants were enrolled, provided consent, and were randomly assigned: 64 participants to the immediate pedometer group and 66 to the delayed pedometer group (Figure 1). The first patient was enrolled
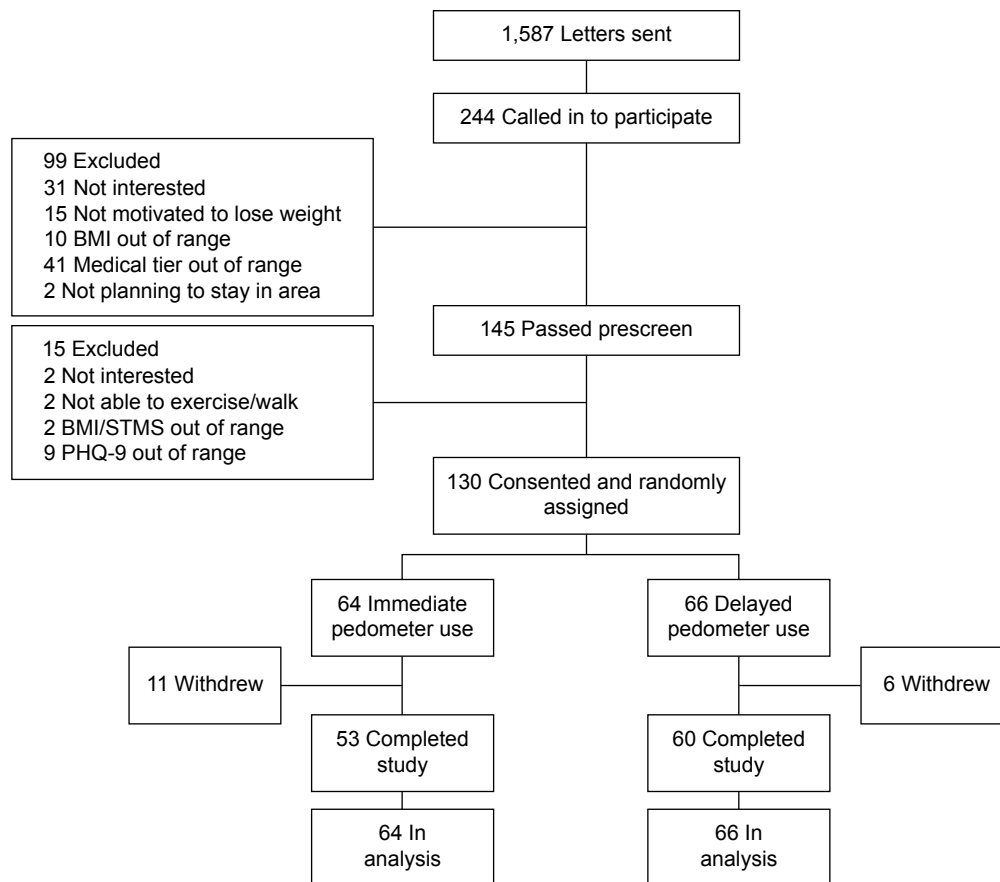
Figure 1 CONSORT flow diagram.
Note: Eleven withdrew in the immediate use and six withdrew in delayed use because they withdrew from the study.
Abbreviations: BMI, body mass index; CONSORT, consolidated standards of reporting trials; PHQ-9, Patient Health Questionnaire-9; STMS, short test of mental status.

Table 1 Baseline characteristics

Characteristic	Overall (N=130)	Pedometer group[a]		P-value
		Immediate (n=64)	Delayed (n=66)	
Age, years	63.4 (15.0)	62.2 (17.3)	65.0 (12.2)	0.30
Women	94 (72%)	43 (67%)	51 (77%)	0.20
White, not Hispanic	127 (98%)	63 (98%)	64 (97%)	>0.99
Blood pressure, mmHg				
Systolic	130.4 (14.2)	130.0 (15.5)	130.8 (12.9)	0.75
Diastolic	74.1 (10.3)	73.8 (10.4)	74.4 (10.3)	0.72
Pulse, beats per minute	70.0 (11.1)	70.2 (11.3)	69.8 (11.0)	0.84
PHQ-9	3.0 (2.6)	2.9 (2.5)	3.0 (2.8)	0.82
Short test of mental status	36.3 (1.7)	36.2 (1.7)	36.3 (1.6)	0.86

Note: [a]Values are mean (standard deviation) or number of patients (%).
Abbreviation: PHQ-9, Patient Health Questionnaire-9.

on May 1, 2013, and the study finished on January 9, 2015. The mean (standard deviation [SD]) age for the cohort overall was 63.4 (15.0) years; 72% were women, and 98% were white. Participant characteristics were similar between groups at baseline (Table 1).

Step count

The mean (SD) number of baseline steps was 5,158 (3,048) steps in the immediate pedometer group. At 2 months, the number was 5,337 (3,096) steps in the immediate pedometer group and 4,446 steps (2,422) in the delayed pedometer group (P=0.08). After 2 months of pedometer use and behavioral goal setting, step count increased nonsignificantly in the immediate pedometer group by 179 steps from baseline. In the delayed pedometer group, the step count also increased nonsignificantly (212 steps) from Months 2 to 4. The proportion of sedentary adults in the immediate pedometer group was 56% at baseline and 57% at 2 months, compared with 61% at baseline vs 60% at 2 months in the delayed pedometer group (Table 2).

Table 2 Step count and sedentary status

Characteristic	Pedometer group[a]		P-value
	Immediate (n=63)	Delayed (n=62)	
Steps			
Baseline	5,158 (3,048)		
1 month	4,842 (2,602)		
2 months	5,337 (3,096)	4,446 (2,422)	0.08
3 months	5,364 (3,193)	4,354 (2,865)	
4 months	5,274 (3,364)	4,658 (3,285)	
Sedentary			
Baseline	35 (56%)		
1 month	34 (54%)		
2 months	36 (57%)	38 (61%)	0.64
3 months	32 (51%)	42 (68%)	
4 months	34 (54%)	37 (60%)	

Notes: No pedometer data were available for one subject in the immediate intervention group and four subjects in the delayed group. Thus the effective sample-sizes are N=63 and N=62 respectively. [a]Values are mean (standard deviation) steps or number of patients (%) who were sedentary (<5,000 steps per day).

Gait speed and grip strength

The mean measured time to walk 4 m at baseline in the immediate pedometer group was 4.31 seconds; meter time was significantly lower (faster gait speed) than baseline at Months 1, 2, and 4 (paired t-test: P=0.02, P=0.02, and P=0.002, respectively) (Table 3). Calculated gait speed was 0.93 m/s vs 1.02 m/s after 4 months (P=0.002). For the delayed pedometer group, meter time was significantly lower than baseline at all follow-up months (all P<0.001). The delayed pedometer group also showed improvement in gait speed from baseline to 4 months (P<0.001). For the immediate pedometer group, grip strength was significantly greater than baseline at Months 2, 3, and 4 (P=0.02, P=0.04, and P=0.01, respectively). Grip strength did not change from baseline at any follow-up in the delayed pedometer group (Table 3).

Safety

Participants in the immediate pedometer group reported 51 AEs and 22 SAEs: 11 hospitalizations and 11 emergency department visits. None of the SAEs were adjudicated as being study related. In the delayed pedometer group, 56 AEs and 26 SAEs (22 emergency department visits and 4 hospitalizations) were reported. None of the SAEs were adjudicated as being study related.

Discussion

In this randomized trial of obese, multimorbid adults, the use of a pedometer with goal setting did not increase step counts at 2 months in the immediate pedometer group compared with the delayed pedometer group. Comparing change from before to after intervention, participants had an increased number of steps, but the change was nonsignificant. There was no change in sedentary status in either the immediate pedometer or delayed pedometer group after starting the pedometer and goal-setting program. Our study reflected an

Table 3 Measured meter time, calculated gait speed, and grip strength

Characteristic	Pedometer group[a]		Treatment effect, estimate (95% CI)[b]	*P*-value
	Immediate (n=64)	Delayed (n=66)		
Meter time, s				
Baseline	4.31 (1.15)	4.72 (1.36)		
1 month	4.15 (1.21)[c]	4.31 (1.20)[c]	0.16 (−0.07 to 0.39)	0.17
2 months	4.09 (1.32)[c]	4.17 (1.13)[c]	0.24 (−0.02 to 0.50)	0.08
3 months	4.11 (1.51)	4.19 (1.12)[c]		
4 months	3.93 (1.39)[c]	4.12 (1.29)[c]		
Gait speed, m/s				
Baseline	0.93	0.85		
1 month	0.96	0.93		
2 months	0.98	0.96		0.64
3 months	0.97	0.95		
4 months	1.02	0.97		
Grip strength, kg				
Baseline	25.73 (9.69)	23.83 (9.39)		
1 month	26.04 (9.44)	23.55 (9.77)	0.66 (−0.28 to 1.60)	0.17
2 months	26.83 (9.66)[c]	23.97 (9.55)	1.06 (−0.10 to 2.23)	0.08
3 months	26.92 (10.05)[c]	23.91 (9.61)		
4 months	27.33 (10.05)[c]	24.26 (9.53)		

Notes: [a]Values are mean (standard deviation) or mean. [b]Treatment effect was estimated using analysis of covariance, with the baseline value of the given variable included as the covariate. [c]$P<0.05$ compared with baseline. For the delayed group, meter time and grip strength at months 3 and 4 did not differ significantly from month 2.
Abbreviation: CI, confidence interval.

effectiveness intervention with a pedometer and available patient education with monthly follow-up.

Our findings contrast with those in the available literature. Several studies have confirmed the utility of pedometers for increasing step count in different populations. In a study from Qatar, 970 adults used a pedometer and online goal setting, with 45% of participants reaching 10,000 steps, compared with 19% at baseline.[29] In 102 older adults with obstructive lung disease, patients randomly assigned to use a pedometer had an increase of 3,080 steps, compared with a 140-step increase in the usual care group ($P<0.001$).[30] A study from Hong Kong of 205 older adults who used a pedometer for 10 weeks found an increase in mean step count from 6,591 to 8,934.[31] In a systematic review of seven articles with 484 total participants with musculoskeletal problems, the use of a pedometer increased the number of steps by an average of 1,950.[3] Finally, a study using intensive counseling and educational intervention and a pedometer in 18 obese women aged >60 years showed an increase of 1,856 steps from baseline to 3 months and a decrease in weight.[32] Our findings may differ from these previous studies because of the multimorbidity and obesity in our population, which may affect mobility. Climate may also have a role in walking steps, with cold weather, ice, and snow potentially changing walking patterns. In survey studies, people who were younger and had a lower BMI had higher step counts.[33]

We observed an increase in gait speed with the immediate pedometer group from baseline to the 4th month. This is an encouraging finding because gait speed is a primary marker for frailty. Other studies with an emphasis on pedometer use and ensuing gait speed showed some differing findings. In a pilot study of eleven patients after stroke who used a step activity monitor, step count increased by 1,100 steps, but gait speed did not change over the 3-month trial.[34] Definition of a clinically meaningful change in gait speed varies; however, in stroke patients, an increase of 0.16 m/s resulted in less disability.[35] It is unclear whether the 0.08 m/s increased gait speed in our study population has any clinical relevance.

We observed a small within-group increase in grip strength in the immediate pedometer group compared from baseline to the 2nd, 3rd, and 4th month. The strength increased by approximately 1 kg, although the clinical significance of a 1 kg change has not been determined. It is possible that patients in the immediate pedometer group undertook further activity that increased their grip strength; however, the difference we identified may represent random chance. In patients with wrist fracture, a change of 6.5 kg of grip strength is noticeable by self-report.[36] Improvement in grip strength with a pedometer program has not been well documented. In a previous study of 36 ambulatory patients in assisted living, the use of a pedometer increased step count by 670 steps, which was significant; however, the investigators did not find a difference in grip strength.[37] Our findings that

grip strength improved in addition to gait speed within group is encouraging but not expected given the nonsignificant change in step count. The findings of improved strength and gait speed may reflect a greater emphasis on physical activity that was not reflected by the step count.

Our study has several limitations. The mean number of steps and the effect of the pedometer on improving step count were lower than expected, and the study was underpowered to detect such a small difference. The study was not masked for practical reasons; however, the observation bias should favor increased steps in the immediate pedometer group, which was not seen. Adherence to the intervention (ie, increased activity and wearing the pedometer) was the primary challenge, and measuring adherence was difficult. However, adherence is the primary challenge in clinical practice, and this study attempts to reflect a practical approach that can be used in a clinical setting. A more intensive intervention may have had a greater effect on step count. The completion rates in both the immediate pedometer group and the delayed pedometer group were 80% and 90%, respectively, with slightly more attrition in the immediate pedometer group. We imputed the data using last observation carried forward, which might introduce bias into the analysis. The generalizability of the study may be restricted because our regional population is predominantly white and highly educated,[38] and our sample was predominantly white.

Conclusion

We did not observe a significant difference in step count between participants with immediate or delayed use of a pedometer with a goal-setting program. We also did not find within-group changes in step count from before to after starting the program in either group. We did note an increase in gait speed and grip strength, but the clinical utility of these findings will have to be determined. The clinical implications involve the recommendations of pedometer use in this population. Pedometers may have much less or no utility in this group. Different interventions may be required to increase activity and step count in this population. Ultimately, patients will continue to use pedometers in the general community, because it is an inexpensive intervention; however, for this overweight, multimorbid population, the effectiveness of this intervention was not demonstrated by our study. Future work may involve a more intensive pedometer regimen with a potential online goal-setting program and potentially a longer period of intervention. Future work may also focus on identifying the population that most benefits from the intervention.

Disclosure

The authors report no conflicts of interest in this work.

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