ORIGINAL ARTICLE

Pedometer Step Count Targets during Pulmonary Rehabilitation in Chronic Obstructive Pulmonary Disease

A Randomized Controlled Trial

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Abstract

Rationale: Increasing physical activity is a key therapeutic aim in chronic obstructive pulmonary disease (COPD). Pulmonary rehabilitation (PR) improves exercise capacity, but there is conflicting evidence regarding its ability to improve physical activity levels.

Objectives: To determine whether using pedometers as an adjunct to PR can enhance time spent in at least moderate-intensity physical activity (time expending ⩾3 metabolic equivalents [METs]) by people with COPD.

Methods: In this single-blind randomized controlled trial, participants were assigned 1:1 to receive a control intervention (PR comprising 8 wk, two supervised sessions per week) or the trial intervention (PR plus pedometer-directed step targets, reviewed weekly for 8 wk). In the randomization process, we used minimization to balance groups for age, sex, FEV_1 percent predicted, and baseline exercise capacity and physical activity levels. Outcome assessors and PR therapists were blinded to group allocation. The primary analysis was based on the intention-to-treat principle.

Measurements and Main Results: The primary outcome was change from baseline to 8 weeks in accelerometer-measured daily time expending at least 3 METs. A total of 152 participants (72% male; mean [SD] FEV_1 percent predicted, 50.5% [21.2]; median [first quartile, third quartile] time expending ⩾3 METs, 46 [21, 92] min) were enrolled and assigned to the intervention (n = 76) or control (n = 76) arm. There was no significant difference in change in time expending at least 3 METs between the intervention and control groups at 8 weeks (median [first quartile, third quartile] difference, 0.5 [−1.0, 31.0] min; $P = 0.87$) or at the 6-month follow-up (7.0 [−9, 27] min; $P = 0.16$).

Conclusions: Pedometer-directed step-count targets during an outpatient PR program did not enhance moderate-intensity physical activity levels in people with COPD.

Clinical trial registered with www.clinicaltrials.gov (NCT01719822).

Keywords: physical activity; rehabilitation; chronic obstructive pulmonary disease

Increasing physical activity levels is a key therapeutic aim in chronic obstructive pulmonary disease (COPD) (1) because physical inactivity is associated with increased risk of mortality and exacerbations, greater decline in lung function, and impaired quality of life (2–4). There is strong evidence for the effectiveness of pulmonary rehabilitation (PR) in improving exercise capacity in COPD (5), but the effect of PR on physical activity levels is modest (6).

Pedometers may help people to become more active. Authors of a metaanalysis of 18 observational studies and 8 randomized

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At a Glance Commentary

Scientific Knowledge on the Subject: Despite the strong evidence base for pulmonary rehabilitation (PR) to improve exercise capacity in people with chronic obstructive pulmonary disease (COPD), the effect on physical activity levels is uncertain. To date, researchers in three small randomized controlled trials have examined the effect of pedometer use by patients with COPD undergoing PR, with conflicting results. Methodologies and intervention strategies used in these studies varied, and the studies were underpowered and had a high risk of effect size error and sample bias.

What This Study Adds to the Field: This trial contributes high-quality evidence demonstrating that the routine use of pedometer feedback and step targets does not augment the effects of PR on physical activity levels, exercise capacity, or health-related quality of life of patients with COPD. Pedometers might limit the effect of PR on some aspects of quality of life in the short term, reflecting the added burden of using the pedometer on a daily basis.

controlled trials involving 2,767 outpatients found pedometer use was associated with a significant increase in physical activity levels (7). In a recent, single-center randomized controlled trial among patients with stable COPD, a pedometer-based physical activity program led to significantly greater improvement in physical activity levels, exercise capacity, and quality of life compared with simple encouragement to be more active (8). In contrast, Burtin and colleagues showed that the addition of simple physical activity counseling alone did not enhance the effects of PR on physical activity levels (9).

We postulated that pedometers could enhance the effects of PR on physical activity levels. To date, three small randomized controlled trials have explored the effect of pedometers as an adjunct to PR (10–12). The results were conflicting, reflecting intervention heterogeneity and trial methodologies. The trials were also underpowered (n = 16–39) and at high risk of effect size error and sample bias (10–12).

The aim of the present trial was to determine the short- and medium-term effectiveness of pedometer-directed step targets as an adjunct to outpatient PR in improving physical activity levels, exercise capacity, and health-related quality of life in people with stable, symptomatic COPD. We hypothesized that the use of pedometers would enhance the short- and medium-term effects of PR on physical activity levels, exercise capacity, and health-related quality of life.

Methods

Trial Design and Participants

We conducted a parallel, two-group, assessor-blinded randomized controlled trial to investigate the effect of a pedometer intervention during and following PR on physical activity levels in people with COPD. Recruitment took place within the Harefield Hospital Pulmonary Rehabilitation Unit (Harefield, UK) between July 2012 and June 2014 with patients undergoing an initial PR assessment. Eligible participants were at least 35 years of age, had a physician's diagnosis of COPD consistent with the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria (13), had a Medical Research Council dyspnea scale score greater than or equal to 2, and consented to undergo supervised PR. Exclusion criteria included contraindications to exercise (e.g., significant cardiovascular comorbidities) or participants choosing a community PR site without access to specialist exercise equipment. All participants provided written informed consent. The trial protocol was preregistered with clinicaltrials.gov (NCT01719822) and approved by the West London Research Ethics Committee (reference 11/LO/1021).

Randomization and Blinding

Following baseline assessment, participants were randomly allocated 1:1 to receive usual care or usual care plus the pedometer intervention. The allocation sequence was computer generated (Minim; Stephen Evans, Simon Day, and Patrick Royston, UK) and accessed by a researcher independent of the recruitment process, PR program provision, trial intervention, and outcome assessment. Minimization was used to balance groups for age ($\leq$65 yr vs. >65 yr), sex (male vs. female), GOLD stage (I–II vs. III–IV), incremental shuttle walk test (ISWT) distance (<170 m vs. $\geq$170 m), oxygen use (yes vs. no), and physical activity level (<1.4 vs. $\geq$1.4) (14). It was not possible to conceal group allocation from participants. Subsequent assessment visits were completed immediately after the PR program (8 wk) and 6 months after the end of the PR program by assessors blinded to group allocation. The statistician undertaking the primary statistical analysis (W.B.) was blinded to group allocation.

Intervention

Usual care was a standardized, twice-weekly, supervised, 8-week outpatient PR program (*see* online supplement). The additional intervention was provision of a pedometer (Yamax Digi-walker CW700; Yamax, Bridgnorth, UK), an individualized daily pedometer step-count target (with weekly review for 8 wk), and a step-count diary provided during the PR program and the following 6 months. During PR, the daily pedometer step-count target was an increase of 5% on the preceding week's average daily pedometer step count, with the first week's target derived from the baseline pre-PR assessment (e.g., 250 additional steps from a mean daily step count of 5,000). At this weekly step-count review, each patient was counseled on the importance of achieving the pedometer step count and given advice on how to increase physical activity levels, focusing on barriers and opportunities arising during daily life. On completion of the PR program, participants in the intervention group received a final step-count target based on a 20% increase in daily step count from the baseline pre-PR assessment and a step-count diary. The detailed intervention protocol is described in the online supplement.

Outcomes

Participants wore an accelerometer (SenseWear; Body Media Inc., Pittsburgh, PA) and a pedometer for 7 days at the baseline, immediate post-PR, and 6-month follow-up assessment visits. Data recorded by the accelerometer included mean daily step count and time spent performing moderate-intensity physical activity (time expending $\geq$3 metabolic equivalents [METs]) (4, 15, 16). The pedometer measured daily step count, and participants noted this number in the trial diary. Further information on the accelerometer and

pedometer is provided in the online supplement.

Additional assessments included spirometry, functional exercise capacity measured using the ISWT (17), and health status assessed with the Chronic Respiratory Questionnaire (CRQ). To gather feedback on pedometer use, participants allocated to the intervention completed a telephone survey after the 6-month assessment. Questions in the survey concerned positive and negative attributes of using the pedometer, physical activity undertaken after the study, and ideas that might motivate participants to exercise.

The primary outcome was change in daily time spent in at least moderate-intensity physical activity (time expending ⩾3 METs) from baseline to immediately following PR. Secondary outcomes were change in time expending at least 3 METs at 6 months following PR and change in accelerometer and pedometer step counts, ISWT, and CRQ domain and total scores. Adverse events, hospitalizations, and deaths were recorded throughout the trial.

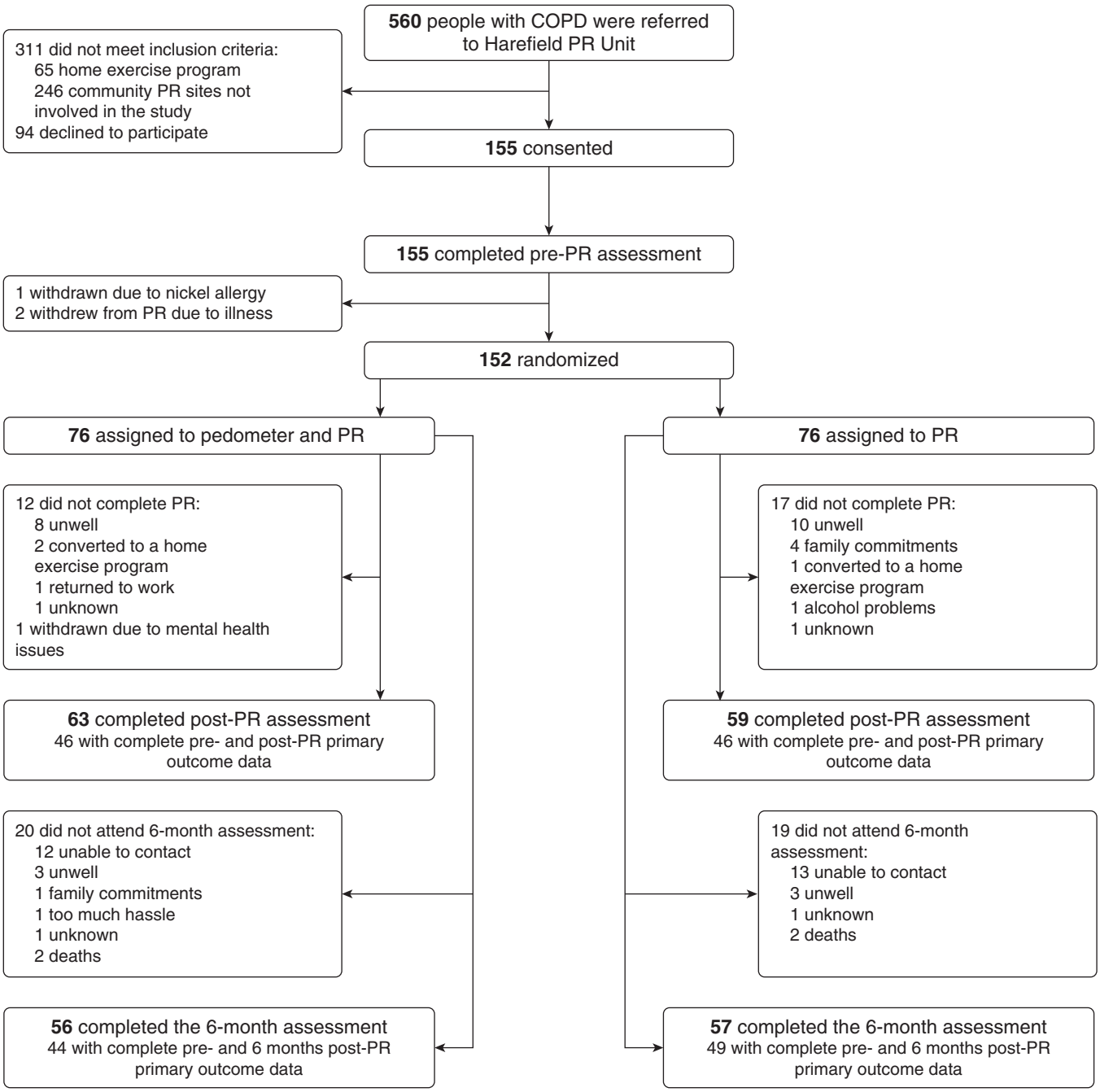

Figure 1. Consolidated Standards of Reporting Trials diagram of the study. COPD = chronic obstructive pulmonary disease; PR = pulmonary rehabilitation.

Statistical Analysis

Our sample size was based on a previous study which demonstrated that a 3-month PR program increased the average daily walking time assessed using an accelerometer by a mean (SD) of 7% (35) (18). We assumed that an additional increase in moderate-intensity physical activity of 20% would represent a clinically relevant improvement. To detect this using a two-sample *t* test with 80% power at the 0.05 significance level (two-sided), assuming equal variances, a total of 50 participants per group was required. On the basis of PR studies of similar duration, we allowed for attrition during PR (22%) and from PR to 6 months post-PR (33%) and planned to recruit 155 participants overall.

Data were exported from a Microsoft Office Access 2010 database (Microsoft, Redmond, WA), and analysis was completed by the trial statistician (W.B.) using Stata 14.1 software (StataCorp LP, College Station, TX). The prespecified primary analysis was based on the intention-to-treat principle. Missing data were explored and reported according to cause (19). Missing data were handled by a Markov chain Monte Carlo method, using multiple imputations (10 datasets). Data were assumed to be from a multivariate normal, and data augmentation was applied to Bayesian inference with missing data. The data were log transformed for multiple imputation and then antilogged.

Continuous data were expressed as means with SDs or 95% confidence intervals and were compared between groups with unpaired Student's *t* tests (20). Nonnormally distributed data were expressed as median (first quartile [Q1], third quartile [Q3]) and compared between groups with the Mann-Whitney *U* test (20). Categorical data were presented as

Table 1. Baseline Characteristics

Variable	Whole Group (*n* = 152)	Intervention Group (*n* = 76)	Control Group (*n* = 76)
Male sex, n (%)	110 (72)	56 (74)	54 (71)
Age, yr	68 (9)	69 (9)	68 (8)
FEV_1, % predicted	50.5 (21.2)	50.6 (20.7)	50.3 (21.8)
FEV_1/FVC	0.50 (0.15)	0.51 (0.15)	0.50 (0.16)
MRC dyspnea scale score	3 (1)	3 (1)	3 (1)
Smoking status			
Never, n (%)	2 (1.3)	1 (1.3)	1 (1.3)
Former, n (%)	123 (80.9)	63 (82.9)	60 (79.0)
Current, n (%)	27 (17.8)	12 (15.8)	15 (19.7)
Pack-year history	40 (23, 60)	40 (20, 65)	40 (27, 53)
ADO index	4.6 (1.6)	4.7 (1.6)	4.6 (1.6)
COTE index	1 (0–2)	1 (0–3)	1 (0–2)
Sp_{O_2} on room air, %	95 (3)	95 (3)	96 (3)
Current medication, n (%)			
Long-acting bronchodilators	101 (66.4)	48 (63.2)	53 (69.7)
Short-acting bronchodilators	120 (78.9)	61 (80.3)	59 (77.6)
Inhaled corticosteroids	106 (69.7)	51 (67.1)	55 (72.4)
Oral steroids (maintenance)	13 (8.6)	7 (9.2)	6 (7.9)
Long-term oxygen therapy	4 (2.6)	1 (1.3)	3 (3.9)
Ambulatory oxygen therapy	16 (10.6)	8 (10.5)	8 (10.5)
Noninvasive ventilation	1 (0.7)	1 (1.3)	0 (0)
BMI, kg/m^2	28.1 (5.8)	28.7 (6.6)	27.6 (4.7)
Walking aid, n (%)			
None	136 (89.5)	69 (90.8)	67 (88.2)
Walking stick	12 (7.9)	5 (6.6)	7 (9.2)
Walking frame	4 (2.6)	2 (2.6)	2 (2.6)
4MGS, ms^{-1}	0.96 (0.24)	0.96 (0.21)	0.96 (0.26)
ISWT distance, m	259 (145)	267 (156)	248 (138)
CRQ*			
Dyspnea	13.4 (5.7)	14.1 (6.3)	12.7 (4.9)
Fatigue	13.9 (5.9)	14.6 (6.4)	13.1 (5.3)
Emotion	31.4 (9.4)	33.5 (9.5)	29.3 (8.8)
Mastery	18.2 (5.8)	19.2 (5.9)	17.1 (5.5)
Total	76.8 (22.8)	81.4 (23.9)	72.2 (20.9)
Accelerometer			
Moderate intensity physical activity (⩾3 METs), min	46 (19, 85)	45 (20, 81)	47 (18, 103)
Daily accelerometer step count	3,323 (1,654, 5,535)	3,293 (1,717, 5,502)	3,456 (1,567, 5,925)
Daily pedometer step count	2,418 (1,440, 4,261)	2,329 (1,416, 4,449)	2,531 (1,440, 4,062)

Definition of abbreviations: 4MGS = 4-m gait speed; ADO = age, dyspnea, airflow obstruction; BMI = body mass index; COTE = chronic obstructive pulmonary disease–specific comorbidity test; CRQ = Chronic Respiratory Questionnaire; ISWT = incremental shuttle walk test; METs = metabolic equivalents; MRC = Medical Research Council; Sp_{O_2} = oxygen saturation as measured by pulse oximetry.

Data are mean (SD) or median (first quartile, third quartile) unless stated otherwise.

*The CRQ domain score ranges are as follows: dyspnea, 5–35; fatigue, 4–28; emotion, 7–49; and mastery, 4–28. The total score of the self-administered version of the CRQ ranges from 20 to 140, with higher scores representing better health status.

percentages and were compared between groups with Pearson's χ^2 test (20). Outcomes were summarized as change from baseline. We used independent samples Student's *t* tests (two-sided) or the Mann-Whitney *U* test to compare change in time expending at least 3 METs in physical activity (primary outcome) and secondary outcomes immediately and 6 months following PR, by trial group (20). In sensitivity analysis, we considered complete cases only (i.e., with paired observations) to account for the possible impact of data imputation (Table E1 in the online supplement) and participants' not achieving at least 150 minutes of moderate-intensity physical activity each week at baseline. A *P* value less than 0.05 indicated statistical significance. Telephone survey data were handled using the Microsoft Office Excel 2010 database, and content analysis was used to explore participants' experience of the intervention. We identified categories inductively from the interview data, with attention to terms and content.

Results

Patient Flow

Figure 1 shows the Consolidated Standards of Reporting Trials flowchart. In total, 155 people provided consent, and 152 were randomized. Their baseline characteristics are shown in Table 1.

Outcomes were obtained for 122 (80.3%) and 113 (74.3%) participants at the immediate post-PR and 6-month follow-up assessments, respectively, with similar attrition rates across groups (Figure 1). The planned intervention offered eight opportunities (each week of PR) for a new step-count target to be set using 5% increments. In the intervention group, participants did not increase their target by 5% on a mean (SD) of 5 (10) occasions during PR, because these participants missed their PR session, could not be contacted by telephone, or the previous week's target was not met.

Valid accelerometer data for the primary outcome measure were available for 92 participants at the immediate post-PR assessment (intervention group, n = 46; control group, n = 46) and for 93 participants at the 6-month follow-up assessment (intervention group, n = 44; control group, n = 49). The reasons for missing accelerometer data are provided in Table E1. Missing data and dropouts were not associated with baseline age, sex, FEV_1 percent predicted, exercise capacity, CRQ score, or group allocation, and they were considered missing at random. Consequently, multiple imputation was performed for the primary outcome, and analyses involved all randomly assigned participants.

Primary Outcome

Table 2 and Figure 2 show change in time expending at least 3 METs from baseline to 8 weeks and from baseline to 6 months following the PR program. We found no significant between-group differences in time expending at least 3 METs from baseline to 8 weeks (median [Q1, Q3] change in intervention group, 11 [−1, 33] min; vs. control group, 11 [−2, 28] min; $P = 0.62$). Similarly, no significant between-group differences in change in time expending at least 3 METs were observed at 6 months (intervention group, 2 [−12, 25] min; vs. control group, 12 [−7, 31] min; $P = 0.16$) (Table 2 and Figure 2). This finding was consistent when only complete cases were considered (Table E2).

Secondary Outcomes

Figure 3 shows the overall progression in daily pedometer step count achieved during PR in the intervention group. The median (Q1, Q3) step-count target for the final week of PR was 36% (0, 76) higher than participants' baseline step count.

Consistent with the findings for the primary outcome measure, there were no significant between-group differences for accelerometer-recorded step count, pedometer-recorded step count, or ISWT at either time point (Table 2). At all time points, the median accelerometer-recorded daily step count was greater than the pedometer-recorded step count, with the

Table 2. Changes in Primary and Secondary Outcome Measures in Intervention and Control Groups

	Change from Baseline to Immediately following PR			Change from Baseline to 6 mo following PR		
	Intervention Group (*n* = 63)	Control Group (*n* = 59)	*P* Value	Intervention Group (*n* = 56)	Control Group (*n* = 57)	*P* Value
Primary outcome: time spent expending ⩾3 METs, min/d	11 (−1, 33)	11 (−2, 28)	0.62	2 (−12, 25)	12 (−7, 31)	0.16
Secondary outcomes						
Accelerometer step count, steps/d	272 (−342, 782)	155 (−438, 867)	0.99	−263 (−778, 197)	−461 (−1,168, −62)	0.09
Pedometer step count, steps/d	727 (−1,493, 3,119)	892 (−1,187, 2,534)	0.55	116 (−1,698, 3,200)	481 (−1,931, 1,781)	0.85
ISWT distance, m	60 (20, 90)	50 (10, 90)	0.83	30 (0, 70)	10 (−30, 70)	0.25
CRQ						
Dyspnea	3.7 (2.1 to 5.2)	5.6 (4.2 to 7.0)	0.07	1.8 (−0.1 to 3.6)	3.7 (2.1 to 5.3)	0.10
Fatigue	2.0 (0, 5.0)	4.0 (2.0, 6.0)	0.008	1.0 (−0.3 to 2.0)	2.0 (0.7 to 3.4)	0.19
Emotion	3.1 (1.9 to 4.4)	5.3 (3.3 to 7.3)	0.07	0.5 (−3.0, 4.0)	2.0 (−1.0, 6.0)	0.12
Mastery	1.8 (1.0 to 2.7)	3.4 (2.1 to 4.7)	0.047	0.5 (−1.0, −3.0)	2.0 (−2.0, 5.0)	0.29
Total	11 (3.0, 20.0)	20 (8.0, 27.0)	0.008	3.0 (−8.0, 16.0)	10 (−2.0, 19.0)	0.07

Definition of abbreviations: CRQ = Chronic Respiratory Questionnaire; ISWT = incremental shuttle walk test; METs = metabolic equivalents; PR = pulmonary rehabilitation.
Data are mean (95% confidence interval) (if normally distributed) or median (first quartile, third quartile) (if not normally distributed).

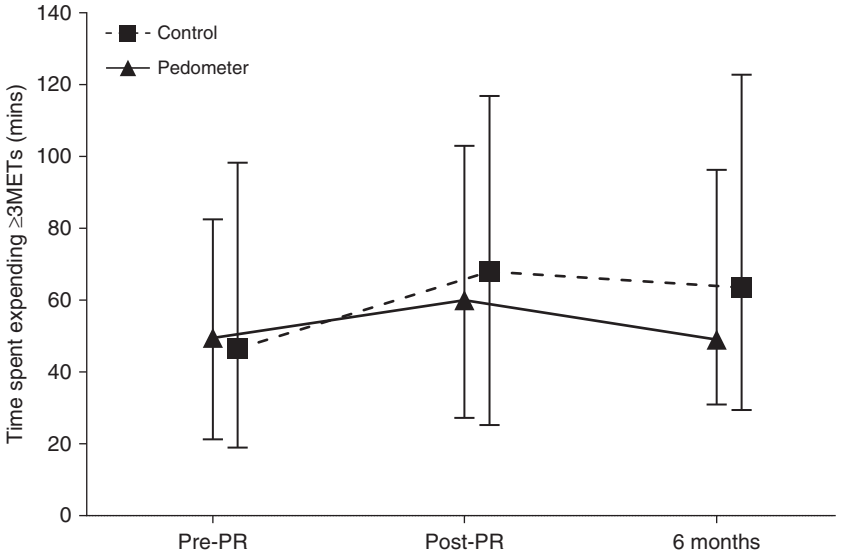

Figure 2. Daily time spent expending at least 3 metabolic equivalents before, after, and 6 months following pulmonary rehabilitation in the control and intervention groups. Data are presented as medians, with *error bars* representing first quartile and third quartile. METs = metabolic equivalents; PR = pulmonary rehabilitation.

discrepancy potentially arising from the poor accuracy of pedometers at slow walking speeds (21).

Unexpectedly, short-term improvements in CRQ scores following PR were significantly greater in the control group than in the intervention group for the fatigue ($P < 0.01$) and mastery ($P = 0.047$) domains as well as the total score ($P < 0.01$). We also adjusted for baseline CRQ values, and the group effect for differences in the fatigue domain and total scores remained significant (Table E3). However, between-group differences in CRQ did not persist at 6 months.

Given recent insights suggesting that the effects of adjunct interventions during PR depend on their being offered in a targeted manner (22), we undertook a *post hoc* sensitivity analysis considering only the 38 (25%) of 152 participants with low baseline physical activity levels (≤150 min of moderate-intensity physical activity each week), as per international guidelines (23, 24). The finding for the primary outcome did not change at 8 weeks (median [Q1, Q3] change, 10 [2, 18] min vs. 10 [6, 15] min; $P = 0.20$) or at the 6-month follow-up (2 [−1, 25] min vs. 14 [5, 31] min; $P = 0.52$) (Table 3). There were no longer significant differences in CRQ scores following PR, suggesting that the pedometer intervention blunts CRQ response to PR principally in those with higher levels of physical activity at trial entry (Table 3). Data for patients achieving at least 150 minutes of moderate-intensity physical activity per week are presented in Table E4.

The survey feedback on the pedometer was mixed. Some participants felt positive about the intervention. For example, respondents stated that "it was interesting to get feedback … good to push myself" and that the pedometer provided "an incentive to go walking," whereas others reported issues with its use, such as that "it needed to be clipped onto a waistband and so it was impossible to wear a dress" and "it didn't pick up all of my steps." Others revealed that they could "alter [the step count] by shaking [the pedometer]." Some participants reported that they stopped using the pedometer following PR owing to a change in clinical condition, such as after an exacerbation ("I had a really bad chest infection.… as I couldn't leave the house, I didn't see the point in wearing it") or perception of its role ("I stopped because I became obsessed with the step count target"). On completion of PR, participants reported that their physical activity levels tended to decline because of lack of incentive to exercise or becoming unwell with a chest infection.

The proportion of participants experiencing adverse events during and following PR was similar between groups. One participant experienced an allergic reaction to the nickel baseplate of the accelerometer during baseline assessments and as a result was not randomized. In total, there were 56 hospital admissions (intervention group, n = 23; control group, n = 33; $P = 0.50$). Thirty of these admissions were for COPD (intervention group, n = 14; control group, n = 16 ; $P = 0.29$). Four deaths (two in each group) were recorded during the study period.

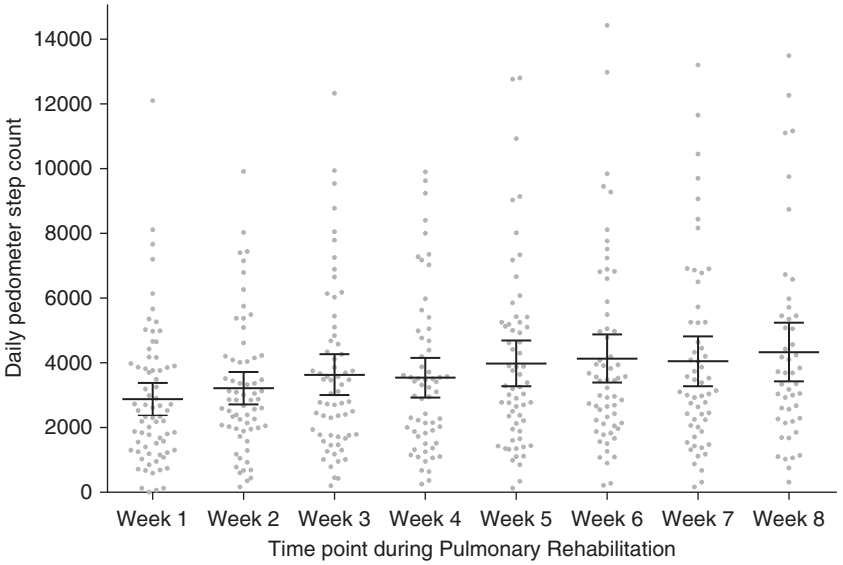

Figure 3. Progression of daily pedometer step-count targets during PR among participants allocated to the pedometer intervention. The *horizontal bars* represent the median, the *error bars* represent the first and third quartiles, and each *dot* represents a data point.

Discussion

Contrary to our hypothesis, this single-blind randomized controlled trial demonstrated that pedometer-directed step-count targets did not

Table 3. Baseline Characteristics and Changes in Outcome Measures among Participants Achieving Less Than 150 Minutes of Moderate-Intensity Physical Activity*

Variable	Baseline (*n* = 38)	
	Intervention Group (*n* = 19)	Control Group (*n* = 19)
Male sex, n (%)	14 (74)	14 (74)
Age, yr	70 (7)	69 (8)
FEV_1, % predicted	49.1 (20.2)	47.1 (23.8)
FEV_1/FVC	0.52 (0.16)	0.47 (0.18)
MRC dyspnea scale score	3 (1)	4 (1)
BMI, kg/m^2	32.6 (7.8)	29.1 (3.8)

	Change from Baseline to Immediately following PR (*n* = 38)			Change from Baseline to 6 mo following PR (*n* = 38)		
	Intervention Group (*n* = 19)	Control Group (*n* = 19)	*P* Value	Intervention Group (*n* = 19)	Control Group (*n* = 19)	*P* Value
Primary outcome: time ⩾3 METs, min/d	10 (2 to 18)	10 (6 to 15)	0.20	2 (−1, 25)	14 (5, 31)	0.52
Secondary outcomes						
Accelerometer step count, steps/d	229 (131 to 588)	206 (186 to 599)	0.60	1 (−436, 655)	−530 (−933, −292)	0.05
Pedometer step count, steps/d	285 (−20, 779)	461 (35, 1,170)	0.72	505 (−744, 1,128)	258 (−243, 1,236)	1.0
ISWT distance, m	32 (4 to 60)	46 (4 to 96)	0.59	10 (−25 to 45)	−3 (−53 to 59)	0.82
CRQ						
Dyspnea	3.8 (−0.3 to 7.2)	6.0 (2.8 to 9.0)	0.34	0.9 (−2.0 to 3.9)	4.2 (−0.8 to 7.5)	0.09
Fatigue	2.2 (−0.2 to 4.3)	3.6 (1.8 to 5.4)	0.31	1.3 (−1.6 to 4.2)	1.8 (−1.3 to 4.9)	0.57
Emotion	3.5 (−0.3 to 6.7)	3.4 (0.1 to 6.9)	0.96	−2.2 (−9.6 to 5.2)	1.6 (−2.8 to 6.0)	0.27
Mastery	2.6 (−0.5 to 4.6)	2.7 (0.1 to 5.3)	0.94	−1.1 (−6.4 to 4.2)	0.7 (−2.3 to 3.7)	0.50
Total	11.6 (3.6 to 19.5)	15.6 (6.7 to 24.5)	0.52	−1.1 (−16.6 to 14.5)	8.0 (−3.9 to 20.2)	0.23

Definition of abbreviations: BMI = body mass index; CRQ = Chronic Respiratory Questionnaire; ISWT = incremental shuttle walk test; METs = metabolic equivalents; MRC = Medical Research Council; PR = pulmonary rehabilitation.
Data are mean (SD), mean (95% confidence interval) (if normally distributed), or median (first quartile, third quartile) (if not normally distributed).
*Per week at baseline.

enhance the short- or medium-term effects of PR on moderate-intensity physical activity levels, daily step count, exercise capacity, or health-related quality of life in people with COPD. Indeed, there was evidence that the intervention was associated with a reduced improvement in some aspects of health-related quality of life with PR, though this difference did not persist at 6 months.

To our knowledge, in two previous trials (10, 12) and a substudy of a larger trial (11), researchers have examined the use of pedometers as an adjunct to PR. Findings have been conflicting, which may reflect intervention heterogeneity and small sample sizes. Our study bears similarities to that described by Kawagoshi and colleagues (12). Pedometer feedback was the main intervention in their study, whereas an accelerometer was used to objectively measure physical activity levels. There was limited physical activity counseling other than simple monthly verbal reinforcement to increase physical activity. Unlike us, Kawagoshi and colleagues were able to demonstrate a significant between-group difference in walking time in favor of the intervention group at 1 year (12). However, only 27 patients completed the study, no attempt was made to impute missing data, and the PR program was home based, of low intensity, and minimally supervised. In the study by de Blok and colleagues, the intervention consisted primarily of four individual exercise-counseling sessions, with pedometers used as motivational and feedback tools (10). This study was very underpowered (only 16 patients in total completed it), and the randomization process was not well described. Although both intervention and control groups showed a significant increase in daily step count, there were no statistically significant between-group differences (10). In a larger trial, Altenburg and colleagues also studied the effects of a lifestyle physical activity counseling program in outpatients with stable COPD (11). The intervention included pedometers used as motivational and feedback tools. In a subgroup analysis of patients undergoing PR, the authors demonstrated a short-term additive improvement in daily step count with the intervention, but this did not persist at 15 months (11). There are marked differences between their study and ours. First, the Altenburg study cohort was considerably younger (mean age, 54 yr vs. 68 yr) and had more severe airway obstruction (mean FEV_1 percent predicted, 43% vs. 50%). Second, the PR substudy population was considerably smaller, with only 37 and 23 patients providing data at 3 months and 15 months, respectively, and no attempt to impute missing data. Third, the primary outcome in the Altenburg study was pedometer step count, which has significant limitations; our choice of a multisensory accelerometer is considered a

more accurate measure of physical activity. Finally, there were differences in baseline physical activity parameters between the control and intervention groups of the PR substudy. This was not corrected for in the between-group difference analysis.

Four randomized controlled trials and two uncontrolled interventional studies outside of PR, using pedometers and either a physical activity counseling program (8, 11, 25) or an Internet-mediated, pedometer-based program (26–28), have generally been positive by showing improvements in daily pedometer step count. A number of possibilities may account for the difference in physical activity outcomes between our study and these other studies. Our study used an accelerometer to assess the impact of the intervention on physical activity, whereas the aforementioned studies employed pedometers. The capacity of pedometers to reliably measure physical activity is disputed, owing to inconsistent construct and convergent validity and reliability at slow walking speeds, as well as the ability to manipulate the step count by shaking the device (21, 29–32). Three of the studies (25, 27, 28) were small (range, 24–35 participants), and only two of the studies provided a sample size calculation (8, 11). The contact time with healthcare professionals was greater in the aforementioned studies, with time periods ranging from 12 to 52 weeks (25, 26) in contrast to 8 weeks in our study. Furthermore, only one study in addition to ours assessed the medium-term impact of the intervention on physical activity levels (33).

There were a number of important secondary findings in the present study. The use of a pedometer appeared to blunt the effects of PR on some health-related quality-of-life domains. This may reflect the added burden of using a pedometer and step-count diary, as evidenced by some negative feedback in the qualitative interviews. The reduction in pedometer step count from Week 8 of the PR program to post-PR assessment is noteworthy because it suggests that participants rapidly became more sedentary on stopping PR. This was further compounded by the consistent drop in physical activity levels from immediately after PR to 6 months post-PR in both groups, which may indicate that an 8-week outpatient PR program is insufficient to elicit long-term behavior change (34).

Strengths of our study include the use of randomization and an intention-to-treat analysis to limit the risk of bias, as well as an adequate sample size to test our *a priori* hypothesis. Our study is the largest trial done to explore the adjunct use of pedometers during PR. Outcome assessors and PR staff were blinded to group allocation, and, although owing to the nature of the intervention it was not possible to do this with the trial participants, the primary outcome of objective, accelerometer-recorded physical activity parameters partly mitigated this source of bias (35). Importantly, these data were measured independently of the intervention device. Our assessment of outcomes immediately and 6 months following PR was rigorous, allowing us to examine both short- and medium-term effects of the intervention.

There are limitations to consider. Our *a priori* sample size calculation required 50 subjects in both the intervention and control groups to complete at the immediate post-PR time point. There was an unexpectedly great amount of invalid or missing data from the accelerometer, and primary outcome measure data were available for only 46 pedometer and 46 control subjects, so the study may be underpowered. However, imputation of accelerometer data partly mitigated this problem. In addition, there was wide variability in physical activity levels measured using the accelerometer. A number of different methods of analyzing physical activity data exist. At the time of study planning, we prespecified the then-recommended method of Watz and colleagues (4), which involves analyzing 5 days of data: 3 weekdays and 2 weekend days. However, recent data from Demeyer and colleagues (36) recommend analyzing 4 weekdays with at least 8 hours of data and considering daylight time to help reduce variability. With hindsight, a greater focus on the behavioral aspects may have produced more positive results in our trial, but we note a recent trial by Burtin and colleagues (9), who used a comprehensive physical activity behavioral program (eight individual activity counseling sessions without pedometer feedback) alongside PR as their intervention. Like our study, this study failed to show an additional benefit regarding physical activity levels compared with PR alone. In the PR setting, de Blok and colleagues also failed to augment the benefits of PR with a combined approach of physical activity counseling with pedometer feedback (10). However, our intention was to design an intervention that is pragmatic and feasible to implement easily within a standard PR program without a significant increase in staff time, and that would encourage patient self-management.

Conclusions

The study findings indicate that pedometer-directed step targets do not enhance the effects of PR on short- or medium-term physical activity levels, exercise capacity, or health-related quality of life. These data do not support the routine use of pedometers to augment physical activity during PR programs. In light of this, studies investigating alternative methods to enhance physical activity are necessary to realize physical activity–associated health and economic benefits for people with COPD attending PR. ■

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