Pedometers to enhance physical activity in COPD: a randomised controlled trial

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ABSTRACT   Physical inactivity is a cardinal feature of chronic obstructive pulmonary disease (COPD), and is associated with increased morbidity and mortality. Pedometers, which have been used in healthy populations, might also increase physical activity in patients with COPD.

COPD patients taking part in a 3-month individualised programme to promote an increase in their daily physical activity were randomised to either a standard programme of physical activity encouragement alone, or a pedometer-based programme. Assessments were performed by investigators blinded to treatment allocation. Change in average 1-week daily step count, 6-min walking distance (6MWD), modified Medical Research Council scale, St George's respiratory questionnaire (SGRQ) and COPD assessment test (CAT) were compared between groups.

102 patients were recruited, of whom 97 completed the programme (pedometer group: n=50; control group: n=47); 60.8% were male with a mean$\pm$SD age of 68.7$\pm$8.5 years, and forced expiratory volume in 1 s (FEV1) 66.1$\pm$19.4% and FEV1/forced vital capacity 55.2$\pm$9.5%. Both groups had comparable characteristics at baseline. The pedometer group had significantly greater improvements in: physical activity 3080$\pm$3254 steps·day^{-1} *versus* 138.3$\pm$1950 steps·day^{-1} (p<0.001); SGRQ -8.8$\pm$12.2 *versus* -3.8$\pm$10.9 (p=0.01); CAT score -3.5$\pm$5.5 *versus* -0.6$\pm$6.6 (p=0.001); and 6MWD 12.4$\pm$34.6 *versus* -0.7$\pm$24.4 m (p=0.02) than patients receiving activity encouragement only.

A simple physical activity enhancement programme using pedometers can effectively improve physical activity level and quality of life in COPD patients.

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Introduction

Physical inactivity is a cardinal feature of chronic obstructive pulmonary disease (COPD) [1]. Patients with the condition display a significant reduction in their level of physical activity even at relatively early stages [2–5], and there is evidence that physical inactivity is independently associated with dyspnoea, quality of life, lung function decline, muscle strength and endurance, the frequency of acute exacerbations and mortality in COPD [1, 6–10]. International guidelines recommend that all COPD patients should receive advice to walk for 30 min each day [11], but advice alone has limited impact on sedentary behaviour [12]. Pulmonary rehabilitation is known to improve exercise capacity [13, 14], but there are two important issues. First, access to this form of treatment remains limited because of resource constraints that particularly limit its possible application in patients with less severe disease and secondly, its effects on daily physical activity may be limited and short lived [15]. Therefore, there is a need to find additional effective and scalable interventions that are cheap to implement and which can improve physical activity level in COPD patients [9].

Pedometers can provide feedback to patients about their daily activity, and have been promoted as effective tools to monitor and increase physical activity levels in healthy populations [12], but it is not known if they are effective tools to improve physical activity levels in COPD patients. The aim of this randomised controlled trial was, therefore, to determine if a 3 month pedometer-based programme could be useful to increase daily step count in stable outpatients with COPD. Secondary outcomes were health status and exercise capacity.

Methods

Subjects

The study was a parallel group, assessor-blind, randomised controlled trial conducted at Hospital Clínico Universidad de Chile (Santiago, Chile) between December 2010 and January 2012. Patients with COPD, diagnosed according to the 2006 Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines [16], aged $\geqslant 40$ years, with a smoking history of $\geqslant 10$ pack-years and who had quit at least 2 months prior to recruitment and who had had no exacerbation in the preceding 4 weeks were recruited from the outpatient clinics at private and public hospitals, private clinics and from public primary health centres in Santiago. Patients were excluded if they had any other chronic condition that significantly interfered with their ability to walk or if they had participated in a pulmonary rehabilitation programme in the previous year. The institutional ethics committee approved the protocol and subjects provided written informed consent prior to participation. The study was registered at clinicaltrials.gov (identifier NCT01739751) and a preliminary report including 55 subjects has been published in Spanish [17].

Protocol

All study visits were conducted at the Hospital Clínico Universidad de Chile. Following their baseline assessments, patients attended monthly for 3 months. Counselling was delivered by the patients' physicians and a physiotherapist and each session lasted ~30 min. Consecutive patients who consented to participate were randomly assigned to one of two groups, "control" or "pedometer", by the investigators based on a random number sequence generated in Excel (Microsoft, Redmond, WA, USA) before enrolment commenced.

Patients assigned to the control group received counselling at each visit to increase their physical activity level and were advised to walk for at least 30 min per day. They were provided with a diary and instructed to record information related to their condition each day (see supplementary material). Patients brought the diary to each monthly appointment.

Patients allocated to the pedometer group received a PD724 Triaxial pedometer (Tanita, Tokyo, Japan) and were instructed how to use it. They were encouraged to be more active by using the pedometer to measure the number of steps walked daily and to record this in the diary provided, together with any information related to their clinical condition. This diary was the same as for the control group with the exception of an additional column for the step count. Patients were asked to bring both the pedometer and the diary to each monthly appointment. The Tanita PD724 pedometer displays a cumulative step count for each day and also retains the step counts from the preceding 7 days in its memory allowing the average step count for the preceding week to be evaluated. Based on this, patients then received a task to increase their steps per day by the next appointment following a specific protocol (table 1). This continued for each of the 3 months of follow-up.

On each occasion, all participants were advised to continue with non-pharmacological and pharmacological treatments provided by their own health centres.

TABLE 1 Protocol used in the study for the pedometer group

Step count at the monthly visit	Instructions
<6000 steps·day^{-1}	Increase by 3000 steps·day^{-1}
⩾6000 and <9000 steps·day^{-1}	Reach 9000 steps·day^{-1}
>9000 steps·day^{-1}	Maintain or increase steps

Assessments

At the beginning and end of the study, the following were assessed: anthropometrics; spirometry [18]; dyspnoea using the modified Medical Research Council dyspnoea scale [19]; quality of life according to the St George's respiratory questionnaire (SGRQ) [20] and the COPD assessment test score (CAT) [21]; and exercise capacity according to the 6-min walking test (6MWT) [22]. The primary end-point in the study was change in the daily step count, based on an average step count of 7 days obtained using the same Tanita PD724 pedometer, which was given to patients after their baseline and 3-month visit. For this baseline and final assessment period only, the screen was obscured by masking tape, so that the number displayed would not influence behaviour. The tape was signed so that it would be obvious if it had been tampered with. Secondary end-points were change in health status (SGRQ and CAT) and change in exercise capacity (6MWT) compared between groups.

Using data from the patient diaries, the incidence of acute exacerbations of COPD (AECOPD), defined as an acute event with a change in respiratory symptoms that required treatment with antibiotics and/or systemic steroids, was determined [11]. All assessments were made by technicians of the pulmonary function laboratory at Hospital Clínico Universidad de Chile, who were blinded to the allocation of the patients.

Statistical analysis and sample size

Sample size calculation determined that 40 patients would be required in each treatment arm, based on an estimated baseline step count of 7300 ± 3274 steps·day^{-1} taken from patients in a previous study with moderate COPD [3], a 25% difference between the two arms at follow up, with the same SD assumed a statistical power of 80% and a significance level of $p=0.05$. Results are presented as mean $\pm$ SD for quantitative variables or as absolute values and frequency for qualitative variables. Unpaired t-tests or Chi-squared tests were used to compare changes over the course of the study between both groups, and a p-value <0.05 was considered significant. All analyses were performed using Stata v 12.1 (Stata Corporation, College Station, TX, USA).

Results

102 patients were recruited, of whom 97 completed the follow-up (fig. 1). The majority of patients had mild or moderate COPD [16] and the baseline characteristics of the pedometer and control groups did not differ significantly (table 2).

The pedometer group had significantly greater improvements in physical activity compared to the controls: 3080 ± 3254 steps·day^{-1} *versus* 138.3 ± 1950 steps·day^{-1} ($p<0.001$) (table 3 and fig. 2). The pedometer group also experienced significantly greater benefit in exercise capacity ($p=0.03$) and health status measured with the SGRQ ($p=0.02$) and the CAT ($p=0.001$). The differences in health status between groups exceeded the accepted minimum clinically important differences [13, 23–25]. Data in the pedometer group showed a progressive increase in the average steps per day through the course of the study, with the most substantial increase occurring in the first and second months of follow-up (fig. 3). All patients in both groups stated that they had used the pedometer as instructed. In all cases, the tape obscuring the step count was intact, confirming that blinding had been maintained. In the control group there were a total of five missing days of data at baseline and 19 days at follow-up. In the treatment arm there were 14 missing days at baseline and nine at follow-up. In the pedometer group there were strong correlations between the step counts entered in the diary and the step counts available in the device memory at each visit (r^2 0.996, 0.999, 0.975 at 1, 2 and 3 months, respectively) suggesting a high degree of compliance with the programme.

An additional finding was that a significantly higher proportion of COPD patients in the control group (38%) than in the experimental group (19.2%) experienced one or more AECOPD during the course of the study ($p=0.03$).
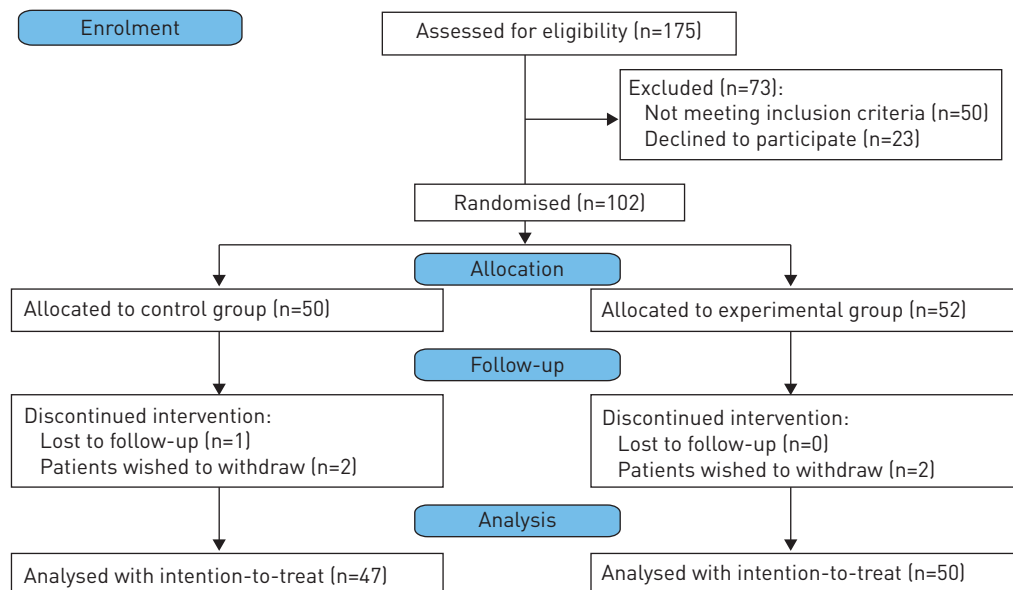
FIGURE 1 CONSORT (Consolidated Standards of Reporting Trials) flow diagram of the study participants.

TABLE 2 Baseline characteristics of patients in the control and pedometer groups

	Control group	Pedometer group	p-value
Patients n	50	52	
Age years	68.4 ± 7.5	68.9 ± 9.5	0.36
Male/female n	33/17	29/23	0.19
BMI kg·m^{-2}	26.5 ± 3.7	27.2 ± 5.1	0.57
Pack-years smoked	41.5 ± 21.1	39.9 ± 20.3	0.76
FEV1/FVC %	53.9 ± 8.2	56.5 ± 10.6	0.16
FEV1 % predicted	66.0 ± 20.8	66.1 ± 18.2	0.49
Step count steps·day^{-1}	3956 ± 2723	4008 ± 2253	0.46
6MWD m	469.7 ± 71.6	463.1 ± 83.2	0.66
mMRC dyspnoea scale points			0.28
0	6 (12)	8 (15.4)	
1	16 (32)	22 (42.3)	
2	20 (40)	14 (26.9)	
3	8 (16)	8 (15.4)	
GOLD classification			0.87
I	15 (30)	13 (25.0)	
II	24 (48)	29 (55.8)	
III	9 (18)	9 (17.3)	
IV	2 (4)	1 (1.9)	
SGRQ points	43.7 ± 16.7	41.9 ± 19.8	0.31
CAT points	16.5 ± 7.3	15.5 ± 8.9	0.27
Treatment			
ICS	34 (68)	36 (69)	0.53
LABA	32 (64)	32 (62)	0.48
LAMA	8 (16)	6 (12)	0.26
Prednisone	2 (4)	1 (2)	0.49
Oxygen	1 (2)	2 (4)	0.52
Salbutamol	30 (60)	37 (71)	0.16
Ipratropium	32 (64)	30 (58)	0.33

Data are presented as mean $\pm$ SD or n (%), unless otherwise stated. BMI: body mass index; FEV1; forced expiratory volume in 1 s; FVC: forced vital capacity; 6MWD: 6-min walking distance; mMRC: modified Medical Research Council; GOLD: Global Initiative for Chronic Obstructive Pulmonary Disease; SGRQ: St George's Respiratory Questionnaire; CAT: chronic obstructive pulmonary disease assessment test; ICS: inhaled corticosteroid; LABA: long-acting β_2-agonist; LAMA: long-acting muscarinic antagonist.

TABLE 3 Change in step count, exercise capacity and health status in the control and pedometer groups at 3 months

	Control group	Pedometer group	p-value
ΔStep count steps·day^{-1}	138.3 ± 1950.4	3080 ± 3254.8	<0.001
ΔSGRQ points	-3.8 ± 10.9	-8.8 ± 12.2	0.02
ΔCAT points	-0.6 ± 6.6	-3.5 ± 5.5	0.001
Δ6MWD m	-0.7 ± 24.4	12.4 ± 34.6	0.03
ΔmMRC dyspnoea scale points	0.0 ± 0.9	0.2 ± 0.7	0.10

Data are presented as mean ± SD, unless otherwise stated. SGRQ: St George's Respiratory Questionnaire; CAT: chronic obstructive pulmonary disease assessment test; 6MWD: 6-min walking distance; mMRC: modified Medical Research Council.

Discussion

The main finding of this randomised controlled trial was that, in patients with COPD, a programme of advice alone had no impact on physical activity, whereas a pedometer-based programme produced significant increases in daily step count which were accompanied by clinically significant improvements in health status. This supports the concept that a simple consumer device, combined with a relatively low level of face to face support, can have an important impact on this key determinant of outcome in COPD [1].
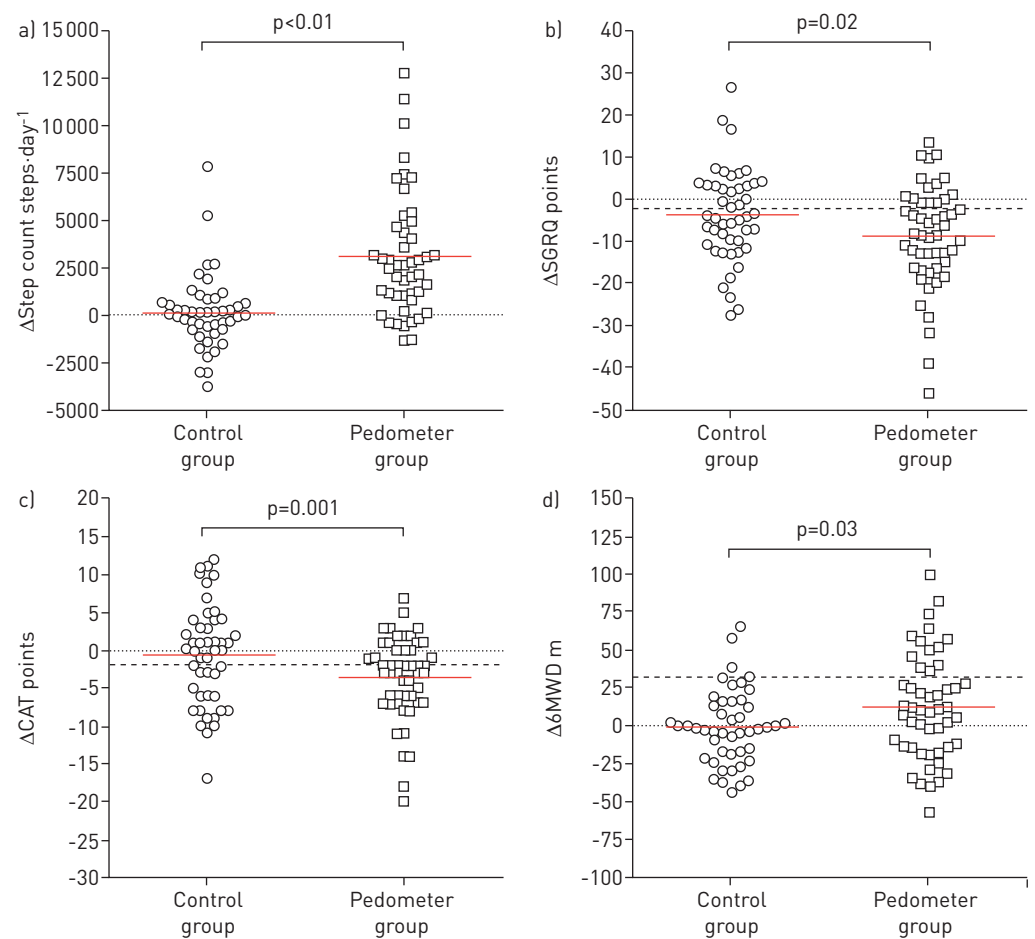

FIGURE 2 Significant differences in a) step count, b) health status, c) chronic obstructive pulmonary disease assessment test (CAT) and d) 6-min walking distance (6MWD) response between the control group and the pedometer group. SGRQ: St George's Respiratory Questionnaire. ——: mean; ······: zero values; - - -: level of minimal clinical difference for each variable [13, 23–25].
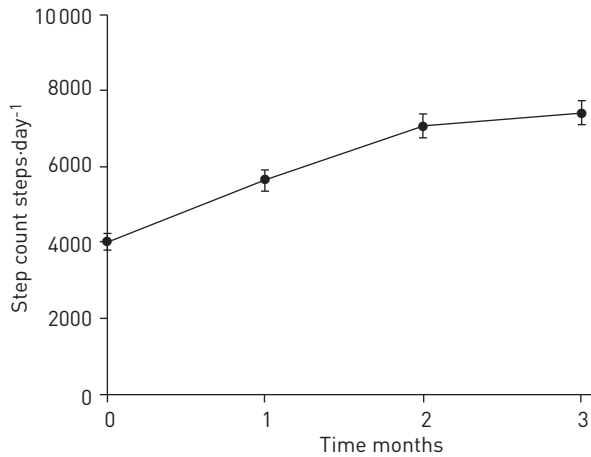
FIGURE 3 Monthly increase in step count for patients in the pedometer group. Data are presented as mean with error bars representing SEM of the daily steps obtained at each monthly visit during follow-up. ANOVA: $p<0.001$. Comparison between basal and 1 month of follow-up ($p=0.026$, CI= -3110–-125), 1–2 months of follow-up ($p=0.071$, CI= -2930–69.8) and 2–3 months of follow-up ($p=0.20$, CI= -1850–1160).

Significance of findings

Formal pulmonary rehabilitation programmes have a strong evidence base for improving exercise capacity and health status in COPD [13, 14], but the evidence that they lead to sustained improvements in physical activity level is not as strong [1, 15, 26] and the benefits are known to wane with time [27]. Moreover, resource considerations mean that access to pulmonary rehabilitation is limited for many patients with COPD [28], as it involves an interdisciplinary professional team [29] and requires facilities to exercise two to three times per week for 6–12 weeks, with estimated costs of $1000 per patient [30]. The present study supports the hypothesis that a pedometer-based programme could be a useful intervention for achieving an improvement in physical activity level in COPD, a determinant of a range of outcomes in the condition [1]. In general, pedometers are developed as consumer devices and are therefore cheap and user-friendly. The programme described required only monthly appointments at the health centre. Pedometers could of course be used as an adjunct to pulmonary rehabilitation and a recent published study found some benefit of adding pedometers as an incentive to exercise in the context of a formal pulmonary rehabilitation programme [31]. PUENTE-MAESTU et al. [32] compared supervised training on a treadmill four times per week or walking 3 or 4 km in 1 h 4 days per week, self-monitored with a pedometer, with weekly visits to encourage adherence in 42 patients (mean forced expiratory volume in 1 s (FEV1) 41% predicted) and found an improvement in health status in both arms, but that supervised exercise had a greater impact on exercise capacity. This study differed from ours in having a much more intense intervention with weekly visits and because the pedometers were used to confirm compliance with the prescribed walks only, rather than as an incentive to influence day to day activity more generally. HOSPES et al. [33] randomised 35 patients (mean FEV1 65% predicted) to usual care or a pedometer-based activity programme combined with five exercise counselling sessions over 12 weeks, which led to an improvement in daily step count of ~10%. Regular phone calls have also been shown to be effective in motivating patients with more severe COPD to increase their level of home-based physical activity [34]. New technologies may have a role. A pilot study showed that pedometer use combined with web-based support is feasible [35], although a recent study by TABAK et al. [36] used a smartphone-based activity coach in a randomised trial against usual care in 30 patients (mean FEV1 48.7% predicted) and found that it had no effect on daily step counts.

n our study, most of the patients had mild or moderate COPD based on airflow obstruction, so caution is needed when extrapolating the findings to more severe disease. The demonstration that behaviour change is possible does support the importance of case finding for COPD to identify people at an earlier stage [5, 37]. Patients with COPD often present with advanced disease [27] and, as well as having more severe respiratory compromise, by this point their physical condition is also impaired due to the cumulative effects of years of physical inactivity.

An interesting observation, although not the focus of the study, was the finding that there were significantly fewer exacerbations in the pedometer group. An association between physical activity level and exacerbations has been noted previously, with possible mechanisms including anti-inflammatory and anti-oxidant effects, as well as change in perceived symptom thresholds [1, 9, 38–40]. If future studies confirm this it would provide further evidence of the value of this form of intervention and could support the concept that relatively early intervention to increase physical activity in COPD patients is disease modifying [9].

Methodological issues

Although patients could not be blinded to their treatment allocation, a strength of this study was that the technicians responsible for the baseline and final measurements were blinded to patient allocation. In addition, for the primary end-point, the pedometer display was covered to ensure that it did not influence behaviour. Both groups received the same amount of face to face contact, meaning that differences between groups were not due to different levels of input from health professionals but rather were related to the specific nature of the intervention; a pedometer and instructions to increase daily step count rather than general advice to be more active with the aim of walking for at least 30 min per day. We speculate that the substantial effect on step count was due to this combination of the face to face nature of the intervention with time taken to demonstrate and reinforce device use, together with explaining the rationale for increased physical activity and the daily reinforcement offered by the device.

The Tanita PD724 pedometer was chosen based on the research team's practical experience of its usability. It is tri-axial so can be worn in the pocket. On board processing requires movement to persist for 7 s before it is accepted as walking and added to the step total. It has not been formally validated in COPD and like other commercial devices it may not record low intensity steps as effectively. Since our intention was to increase purposeful, sustained walking this is not a significant issue.

Although statistically significant, changes observed in the 6MWD between groups did not reach the minimum clinically important difference, in contrast to the effect on health status. This could be due to a ceiling effect. There were a high proportion of patients in GOLD stage I and II which meant that the average 6MWD was >460 m in both groups, above the threshold in the BODE (body mass index, airflow obstruction, dyspnoea, exercise capacity) score classification [41], which has no impact on prognosis. In addition, researchers did not give instructions about the speed of walking; the task was focused to only gradually increase the number of steps walked daily. This underlines that this sort of intervention should be considered complementary to exercise training and pulmonary rehabilitation rather than an alternative, particularly in those with more severe disease. Essentially, a pedometer-based physical activity programme could have a role in patients with disease usually not considered to be severe enough for pulmonary rehabilitation, for patients where pulmonary rehabilitation programmes are not available or have long waiting lists and also as an adjunct to pulmonary rehabilitation in order to enhance and sustain behaviour change.

The data presented here only describe the effect of a 3-month programme so longer term studies are necessary. Patients rapidly became used to the programme, and based on the pattern of increase in step count, which appeared to be plateauing by 3 months (fig. 3), we speculate that over the longer term less frequent visits for reinforcement would be needed.

Conclusion

This study demonstrates that a pedometer-based programme can have a dramatic impact on patients with early COPD, increasing physical activity level and enhancing quality of life.

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