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Walk2Bactive: A randomised controlled trial of a physical activity-focused behavioural intervention beyond pulmonary rehabilitation in chronic obstructive pulmonary disease

Joana Cruz[1,2], Dina Brooks[3] and Alda Marques[1,2]

Abstract

The aim of this study was to investigate the impact of a physical activity (PA)-focused behavioural intervention during and after pulmonary rehabilitation (PR) on PA levels (primary aim), health-related outcomes and self-efficacy (secondary aims) of patients with COPD. Thirty-two patients were randomly assigned to an experimental group (EG) or control group (CG). The EG received a PA-focused behavioural intervention during PR (3 months) and follow-up support (3 months). The CG received PR (3 months). Daily PA was collected: number of steps; time spent in moderate-to-vigorous PA (MVPA), total PA and sedentary activities (SA). Secondary outcomes comprised exercise capacity, muscle strength, health-related quality of life (HRQOL) and self-efficacy. Measures were collected at baseline, 3 and 6 months. Compared with the CG, the EG improved the number of steps ($p = 0.006$) and time spent in MVPA ($p = 0.007$), total PA ($p = 0.014$) and SA ($p = 0.018$) at 3 months. Differences were maintained after follow-up support ($0.025 \leq p \leq 0.040$), except for SA ($p = 0.781$). Exercise capacity, muscle strength and HRQOL were increased at 3 and 6 months ($p \leq 0.002$) with no between-group differences ($0.148 \leq p \leq 0.987$). No changes were observed in self-efficacy ($p = 0.899$). A PA-focused behavioural intervention during and after PR may improve patients' PA levels. Further research is warranted to assess the sustainability of the findings.

Keywords

Chronic obstructive pulmonary disease, daily activity, exercise, monitoring, pedometer social cognitive theory

Introduction

Patients with chronic obstructive pulmonary disease (COPD) are markedly inactive during daily life.[1] Low physical activity (PA) levels have been associated with adverse outcomes, including hospitalisation and all-cause mortality;[2,3] therefore, increasing patients' PA has become a desirable outcome.[4]

Pulmonary rehabilitation (PR) is the cornerstone of COPD management with well-documented effects on exercise capacity and health-related quality of life (HRQOL).[5] Hence, it would seem the ideal intervention to promote PA behaviours in patients with COPD.[4] However, previous studies assessing the impact of PR on PA levels have shown that an

[1] Respiratory Research and Rehabilitation Laboratory (Lab 3R), School of Health Sciences, University of Aveiro (ESSUA), Campus Universitário de Santiago, Aveiro, Portugal
[2] Center for Health Technology and Services Research (CINTESIS), School of Health Sciences, University of Aveiro (ESSUA), Campus Universitário de Santiago, Aveiro, Portugal
[3] Rehabilitation Science Institute and Department of Physical Therapy, University of Toronto, Toronto, ON, Canada

Corresponding author:
Alda Marques, Respiratory Research and Rehabilitation Laboratory (Lab 3R), School of Health Sciences of the University of Aveiro (ESSUA), Campus Universitário de Santiago, Agras do Crasto, Edifício 30, Aveiro 3810-193, Portugal.
Email: amarques@ua.pt

increase in exercise capacity does not necessarily translate into significant improvements in patients' PA.[6–8] Alternative methods to produce PA behaviour change within PR are therefore needed.

In the last decade, several PA-focused interventions complementary to PR have been developed.[9] Those including self-monitoring using activity monitors, behaviour change approaches and goal setting showed the most promising results.[10,11]However, to date, only a few randomised controlled trials have studied the effectiveness of these interventions along with PR in improving patients' PA.[10,12,13]

The aim of this randomised controlled trial was to investigate the impact of a PA-focused behavioural intervention during and after a PR programme on PA levels of patients with COPD. Secondary aims were to evaluate its effects on health-related outcomes and self-efficacy.

Methods

Study design

This was a randomised controlled trial. Patients were randomly assigned to receive a PA-focused behavioural intervention during and after PR (experimental group (EG)) or PR alone (control group (CG)), using a computer-generated schedule in random blocks of two. One researcher kept the allocation sequence in sealed opaque envelopes, drew the envelopes and scheduled patients. Patients knew about the existence of two groups but not the differences between interventions. Ethical approval was obtained from the Central Regional Health Administration (2011-02-28), Hospital Centre (34428) and National Data Protection Committee (9250/2012). Written consent was obtained from each participant. The trial was registered at ClinicalTrials.gov (NCT02122614) and was reported according to CONSORT guidelines.[14]

Participants

Patients were recruited from 3 primary care centres and a district hospital. Patients were included if they were 18 years or older, diagnosed with COPD according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria,[15]clinically stable in the last month (i.e., no hospital admissions or exacerbations) and able to provide informed consent. Exclusion criteria consisted of the presence of severe neurologic, musculoskeletal or psychiatric disorders, unstable cardiovascular disease or severe visual impairment and participation in PR in the previous 6 months or in regular strenuous exercise.

Intervention

Patients of both groups underwent 12 weeks (3 months) of PR between April and July 2014. Additionally, the EG received a PA-focused behavioural intervention (3 plus 3 months).

Pulmonary rehabilitation

PR consisted of exercise training and psychosocial support and education sessions. Exercise training was held 3 times/week (60 minutes/session) by physiotherapists with expertise in the field and comprised warm-up, aerobic training, resistance training, balance training and cool-down (as described elsewhere).[11] Psychosocial support and education sessions were conducted once a week (90 minutes) by a multidisciplinary team. Topics included information about COPD, promotion of healthy lifestyles (PA, nutrition) and self-management strategies. PR programmes were conducted at different times to avoid group contamination.

PA-focused behavioural intervention

The PA-focused behavioural intervention was implemented by one physiotherapist during the PR programme (3 months) and continued for 3 months after its completion. It was specifically designed to achieve a sustained increase in patients' PA levels and was based on the Social Cognitive Theory (SCT),[16] which acknowledges the role of self-efficacy, goal setting and performance feedback as core elements of behaviour change. The present intervention incorporated these concepts using the Health contract technique[17,18] and objective feedback provided by pedometers. The intervention is described in detail below.

In the first psychosocial support and education session, participants in the EG were given a piezoelectric pedometer (Yamax Power Walker EX-510, Yamasa Tokey Keiki Corporation, Tokyo, Japan) and a log diary to record daily steps in order to establish their baseline steps. These pedometers have shown good accuracy results at slow (absolute percent error (APE) 4.5–9.1%), self-preferred/normal and fast (APE < 3%) speeds, particularly when worn at the front right or left sides of the waist or inside the front pockets of the trousers.[19] In the following session, participants received a Health contract,[17] that is, a written

agreement between each patient and the physiotherapist. The physiotherapist assisted patients in completing the Health contract: they had to formulate an individualised long-term step-count goal to achieve by the end of the PR programme, based on their baseline steps and international PA recommendations (7000–10,000 steps/day),[20] and identify potential facilitators (e.g., walking with family/friends, planning a daily schedule). Participants also received a calendar to register their short-term step-count goals and daily steps, which were self-monitored with the pedometer. Short-term goals were defined on a weekly basis and consisted of the previous short-term goal plus approximately 800 additional steps (if the goal of the previous week was met)[21] or the previous goal (if it was not met). The final aim was to achieve the long-term goal. In each psychosocial support and education session, the physiotherapist provided individual feedback on patients' performance and helped them to define the next short-term goal (approximately 20–30 minutes/session). In the last session, the long-term goal was reassessed. If achieved, participants were praised and asked to readjust it for the next 3 months. After PR, patients continued registering their steps in the calendar and received the physiotherapist's support on a weekly (in the first month) and fortnightly (in the second and third months) basis by telephone calls.

Measures

Participants' characteristics were assessed at baseline. Outcome measures were collected at baseline, 3 months (i.e., post-PR) and 6 months (i.e., after the PA-focused behavioural intervention).

Participants' characteristics

Sociodemographic and anthropometric data were collected using a structured questionnaire and dyspnoea using the Modified Medical Research Council dyspnoea scale.[22] Lung function was assessed with a portable spirometer (MicroLab 3500, CareFusion, Kent, San Diego, California, USA)[23] and GOLD grades and exacerbation risk groups were determined.[15]

Primary outcome measure

Daily PA levels were assessed using activity monitors GT3X+ (ActiGraph, Pensacola, Florida, USA), already validated in COPD.[24,25] Participants wore the device for 4 consecutive weekdays during waking hours (except when bathing or swimming).[26] Data were downloaded using Actilife v6.10.4 (ActiGraph). A valid day was defined as $\geq$8 h of wearing time.[26] Daily PA included the time spent in moderate-to-vigorous PA (MVPA, 1952–∞ counts-per-minute (CPM)), total PA (100–∞ CPM)[27] and number of steps. Time spent in MVPA was calculated considering the total time (overall MVPA) and the internationally recommended duration of $\geq$30 min of daily MVPA, either continuous or in blocks of $\geq$10 min (recommended MVPA).[28] Time spent in sedentary activities (SA, 0–99 CPM) was also calculated.[27]

Secondary outcome measures

Secondary outcomes comprised exercise capacity (six-minute walk test),[29] quadriceps muscle strength (one repetition maximum),[28] HRQOL (St. George's Respiratory Questionnaire (SGRQ) – three domains and global score)[30] and self-efficacy (Self-Efficacy Scale).[31] The questionnaires presented good internal consistency (SGRQ: $0.695 \leq$ Cronbach's $\alpha \leq 0.877$; Self-Efficacy Scale: Cronbach's $\alpha = 0.696$).

Statistical analysis

Sample size was estimated using the primary outcome measure based on a pilot study.[11] It was found that 12 patients with COPD would be required in each group to provide 80% power ($\alpha = 0.05$) to detect significant between-group differences in MVPA (using the effect size, $\eta^2 = 0.139$). However, as PR programmes have a considerable dropout rate (approximately 30%),[32,33] 16 patients per group were recruited. Power analyses were performed using G*Power v3.1.3 (Franz Faul, Kiel University, Germany).

Baseline characteristics were compared between groups and between completers and dropouts with independent *t*-tests for normally distributed data, Mann Whitney *U*-tests for ordinal data and χ^2 tests for categorical data. For each outcome, a mixed-model analysis of variance was used to determine the effects of time and time $\times$ group interaction considering a level of significance of 0.05. Effect sizes were computed using the partial η^2 (η^2_{partial}), interpreted as: $\eta^2_{\text{partial}} \geq 0.01$ small, $\eta^2_{\text{partial}} \geq 0.06$ medium and $\eta^2_{\text{partial}} \geq 0.14$ large effect.[34] Observed power was also calculated. If interaction was significant, a simple effects analysis was performed using independent *t*-tests to assess between-group differences at each time point. Data were analysed using SPSS v20.0

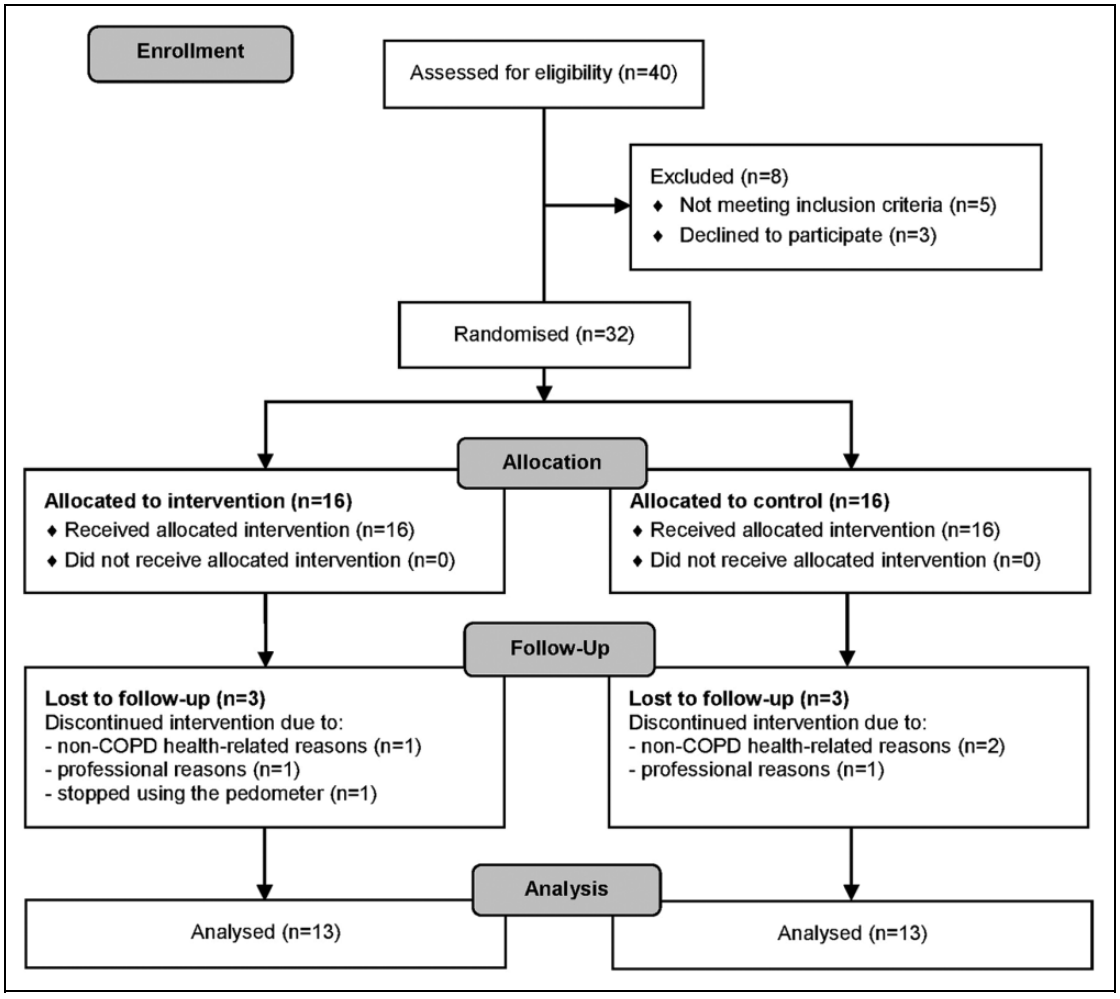

Figure 1. Flow diagram.

(IBM, Armonk, New York, USA) and GraphPad Prism v5.0 (GraphPad, La Jolla, California, USA).

Results

Participants

Forty patients were screened (Figure 1); however, eight were excluded for not meeting the inclusion criteria ($n = 5$) or declining to participate ($n = 3$). Therefore, 32 patients were allocated to the EG ($n = 16$) or CG ($n = 16$). Participants (27 males) had a mean age of 66.4 $\pm$ 8.4 years and a forced expiratory volume in one second of 67.1 $\pm$ 20.1% predicted. No significant between-group differences were found in baseline characteristics ($0.121 \leq p \leq 0.855$, Table 1).

Twenty-six participants completed the intervention and post-test assessments and thus were included in the analysis. Baseline characteristics were not significantly different between completers and dropouts ($0.143 \leq p \leq 0.817$).

Physical activity

Figure 2 and Table 2 present the main PA findings. A significant time $\times$ group interaction was found for time spent in overall MVPA ($p = 0.030$, $\eta^2_{\text{partial}} = 0.21$, power $= 0.89$), recommended MVPA ($p = 0.012$, $\eta^2_{\text{partial}} = 0.17$, power $= 0.78$) and total PA ($p = 0.047$, $\eta^2_{\text{partial}} = 0.12$, power $= 0.59$) and for the number of steps ($p = 0.001$, $\eta^2_{\text{partial}} = 0.27$, power $= 0.96$).

Patients in the EG spent significantly more time in overall MVPA (3 months: EG = 57.8 $\pm$ 32.8 minutes/day CG = 26.7 $\pm$ 19.6 minutes/day, $p = 0.007$; 6 months: EG = 51.6 $\pm$ 29.4 minutes/day CG = 28.0 $\pm$ 26.0 minutes/day, $p = 0.040$), recommended MVPA (3 months: EG = 23.3 $\pm$ 28.6 minutes/day CG = 4.3 $\pm$ 7.3 minutes/day, $p = 0.036$; 6 months: EG = 20.3 $\pm$ 24.2 minutes/day CG = 3.8 $\pm$ 7.4 minutes/day, $p = 0.033$) and total PA (3 months: EG = 279.5 $\pm$ 74.0 minutes/day CG = 212.0 $\pm$ 53.9 minutes/day, $p = 0.014$; 6 months: EG =

Table 1. Characteristics of participants from both groups ($n = 32$).[a]

	EG ($n = 16$)	CG ($n = 16$)	p
Age (years)	68.8 ± 8.2	64.1 ± 8.2	0.121
Sex (male), *n* (%)	13 (81.2)	14 (87.5)	0.626
Current occupation, *n* (%)			
Retired	14 (87.5)	11 (68.8)	0.303
Employed	2 (12.5)	2 (12.5)	
Unemployed	0	3 (18.8)	
BMI (kg m^{-2})	29.3 ± 3.6	29.6 ± 6.3	0.855
mMRC, *M*[IQR]	1.5 [1.0–2.0]	2.0 [1.0–2.5]	0.423
FEV_1 (L)	1.9 ± 0.8	2.0 ± 0.7	0.699
FEV_1 (% predicted)	65.5 ± 21.1	68.4 ± 19.7	0.697
GOLD grade, *n* (%)			
Mild	6 (37.5)	6 (37.5)	0.623
Moderate	4 (25.0)	6 (37.5)	
Severe to very severe	6 (37.5)	4 (25.0)	
Exacerbation risk, *n* (%)			
A	5 (31.2)	5 (31.2)	0.776
B	4 (25.0)	6 (37.5)	
C	3 (18.1)	1 (6.2)	
D	4 (25.0)	4 (25.0)	

BMI: body mass index; CG, control group; EG, experimental group; FVC: forced vital capacity; FEV_1: forced expiratory volume in one second; GOLD: Global Initiative for Chronic Obstructive Lung Disease; IQR, interquartile range; *M*: median; mMRC: Modified British Medical Research Council dyspnoea scale.

[a]Data are presented as mean ± standard deviation, unless otherwise indicated.

269.3 ± 61.5 minutes/day CG = 202.9 ± 82.5 minutes/day, $p = 0.029$). In addition, the EG walked on average more 4010.0 steps/day at 3 months ($p = 0.006$) and 3266.7 steps/day at 6 months ($p = 0.025$) more than the CG (Figure 2).

A time × group interaction was also found for SA ($p = 0.031$, $\eta^2_{\text{partial}} = 0.14$, power = 0.66). At 3 months, the EG spent significantly less time in SA (EG = 536.4 ± 86.6 minutes/day CG = 625.9 ± 93.3 minutes/day, $p = 0.018$). No between-group differences were found at 6 months ($p = 0.781$).

Secondary outcomes

Both EG and CG experienced significant improvements in exercise capacity, muscle strength and HRQOL during the study ($p \leq 0.002$ – except for SGRQ symptoms score, $p = 0.051$), with no between-group differences ($0.148 \leq p \leq 0.987$). Self-efficacy remained constant throughout the study in both groups ($p = 0.899$, Table 3).

Discussion

This was the first randomised controlled trial that evaluated the impact of a PA-focused behavioural intervention comprising a Health contract and pedometer feedback on PA levels of patients with COPD during and after PR. The addition of this novel approach to PR was effective in improving patients' PA levels at 3 months, which remained improved after follow-up support. Nevertheless, it did not produce further improvements in exercise capacity, muscle strength or HRQOL.

The addition of the PA-focused behavioural intervention to PR led to significant PA improvements in the EG, which remained improved after follow-up support. Findings suggest that this intervention is feasible and enhances patients' PA levels. A previous study implementing a PA-focused intervention with goal setting and pedometer feedback during PR found only modest (non-significant) improvements in patients' daily steps.[12] Differences between studies may be explained by the different duration of the PR programme (9 weeks vs. 12 weeks) and professional support (five 30-minute individual sessions vs. weekly 20–30 minute group sessions). When that intervention was implemented in a 3-month period, significant results were observed albeit the improvement was less pronounced than in the present study (547 steps/day vs. 3278.6 steps/day, respectively).[10] Disease severity and baseline PA levels may explain in part these discrepancies. Nevertheless, the type of PA-focused intervention may have also played a role, as in the present study a formal commitment was encouraged by the use of the Health contract. This technique has been applied with varied degrees of success in interventions conducted with other populations and health behaviours.[18,35,36] It has advantages over verbal communication alone, since formal commitment enhances the individual–clinician relationship and stimulates the active participation of the individual in identifying an achievable health goal and creating a behaviour change plan.[37]

The costs associated with the addition of the PA-focused behavioural intervention to PR were relatively small and related to the purchase of pedometers and printed material (Health contract and calendar), the telephone calls and the time needed by the physiotherapist to provide support (approximately 20–30 minute/session). Thus, this intervention can be implemented in various healthcare settings without

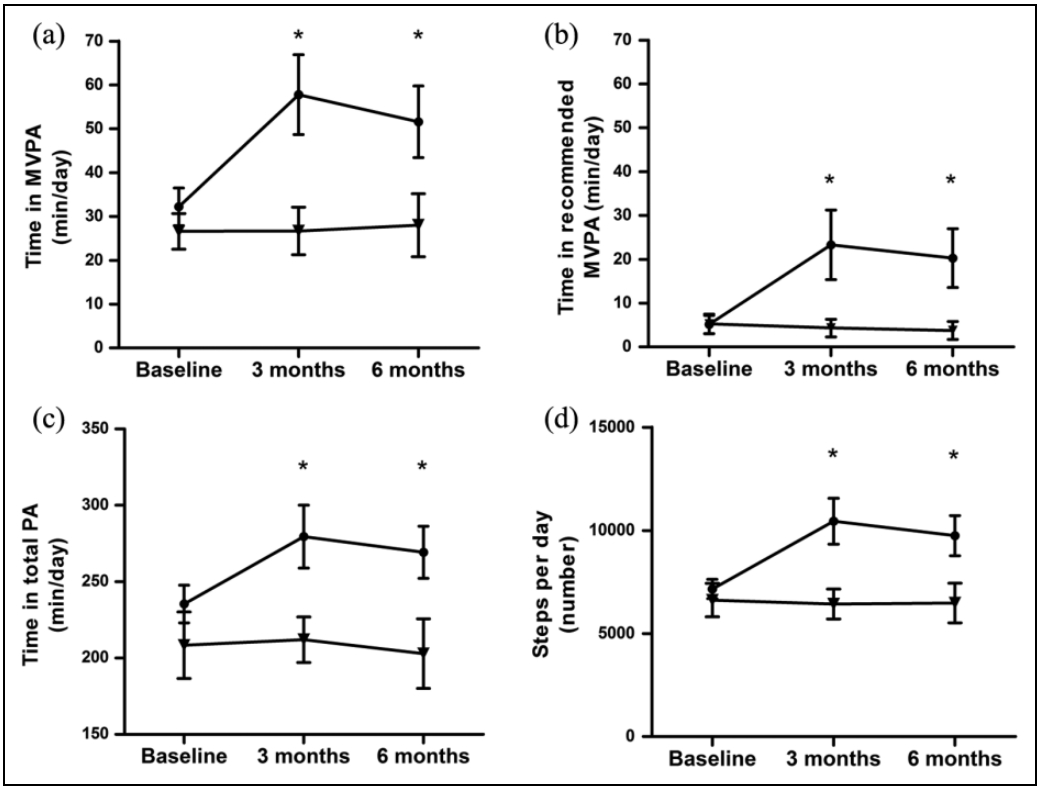

Figure 2. PA levels of participants in the EG (•) and CG (▾) at baseline, 3 and 6 months. Data are presented as mean and standard error of the mean. Significant differences between groups in each time point are identified with an *. (a) Time in MVPA. (b) Time in MVPA according to the international recommendations (i.e., ≥30 minutes of MVPA either continuous or in blocks of ≥10 minutes). (c) Time in total PA. (d) Number of daily steps. CG: control group; EG: experimental group; MVPA: moderate-to-vigorous physical activity; PA: physical activity.

Table 2. Daily PA levels of participants in the EG ($n = 13$) and CG ($n = 13$) groups at baseline, 3 months and 6 months.[a]

		Baseline	3 months	6 months	p[b]	$\eta^2_{partial}$[c]	Observed power[d]
Overall MVPA (min/day)	EG	32.2 ± 15.4	57.8 ± 32.8	51.6 ± 29.4	0.030[e]	0.21	0.89
	CG	26.6 ± 14.6	26.7 ± 19.6	28.0 ± 26.0			
Recommended MVPA (min/day)	EG	5.2 ± 7.5	23.3 ± 28.6	20.3 ± 24.2	0.012[e]	0.17	0.78
	CG	5.3 ± 8.2	4.3 ± 7.3	3.8 ± 7.4			
Total PA (min/day)	EG	235.4 ± 44.6	279.5 ± 74.0	269.3 ± 61.5	0.047[e]	0.12	0.59
	CG	208.4 ± 78.9	212.0 ± 53.9	202.9 ± 82.5			
Steps (number/day)	EG	7161.5 ± 1708.1	10,440.0 ± 4012.9	9747.9 ± 3511.8	0.001[e]	0.27	0.96
	CG	6617.1 ± 2914.2	6430.0 ± 2613.1	6481.3 ± 3454.4			
SA (min/day)	EG	600.2 ± 66.1	536.4 ± 86.6	578.8 ± 102.8	0.031[e]	0.14	0.66
	CG	611.7 ± 77.5	625.9 ± 93.3	566.8 ± 116.5			

CG: control group; EG: experimental group; MVPA: moderate-to-vigorous physical activity; PA: physical activity; SA: sedentary activities.

[a]Data are presented as mean ± standard deviation.

[b]p of time × group interaction.

[c]$\eta^2_{partial}$ of time × group interaction.

[d]Observed power of time × group interaction.

[e]Significant differences.

Table 3. Outcome measures of patients of the EG ($n = 13$) and CG ($n = 13$).[a]

		Baseline	3 months	6 months	p^b	p^c	$\eta^2_{partial}$[d]	Observed power[e]
6MWD (m)	EG	493.8 ± 63.0	547.9 ± 47.9	540.4 ± 31.1	0.962	<0.001[f]	0.53	0.99
	CG	476.2 ± 54.9	529.7 ± 57.2	519.4 ± 50.8				
Quadriceps muscle strength (kg)	EG	37.0 ± 7.4	47.2 ± 11.4	43.7 ± 11.6	0.148	<0.001[f]	0.68	0.99
	CG	40.7 ± 8.0	51.0 ± 10.8	43.8 ± 8.2				
SGRQ Global score	EG	31.5 ± 15.7	24.0 ± 13.6	23.1 ± 10.3	0.987	<0.001[f]	0.41	0.99
	CG	34.9 ± 14.7	26.9 ± 15.2	26.2 ± 15.3				
SGRQ symptoms score	EG	40.2 ± 23.0	32.1 ± 18.4	27.2 ± 16.9	0.773	0.051	0.13	0.58
	CG	41.2 ± 22.7	35.9 ± 21.6	34.0 ± 26.3				
SGRQ activities score	EG	48.7 ± 20.2	38.2 ± 20.4	41.9 ± 17.3	0.882	0.002[f]	0.25	0.92
	CG	49.2 ± 16.7	38.8 ± 22.2	40.0 ± 17.3				
SGRQ impact score	EG	18.4 ± 13.2	13.1 ± 11.6	10.8 ± 7.8	0.833	<0.001[f]	0.36	0.99
	CG	24.8 ± 13.8	17.5 ± 12.8	15.7 ± 14.0				
Self-efficacy	EG	77.0 ± 12.0	75.3 ± 12.7	79.5 ± 11.4	0.068	0.899	0.05	0.07
	CG	82.4 ± 10.4	85.7 ± 11.1	79.6 ± 13.0				

CG: control group; EG: experimental group; SGRQ: St. George's Respiratory Questionnaire; 6MWD: six-minute walking distance.
[a]Data are presented as mean ± standard deviation.
[b]p of time × group interaction.
[c]p of time.
[d]$\eta^2_{partial}$ of time.
[e]Observed power of time.
[f]Significant differences.

the need for significant additional costs or human resources. Further research is needed to study the cost-effectiveness of this PA-focused behavioural intervention.

Despite the PA improvements found in the EG, there were no significant between-group differences in exercise capacity, muscle strength and HRQOL, similar to a previous study.[10] Therefore, the hypothesis that a more active lifestyle after the intervention translates into improved health-related measures could not be shown. One possible explanation is that PA improvements may not have been enough to promote changes in patients' daily life, as the minimum clinically important difference of PA has not been established in COPD.[9] Other health-related measures that were not explored in this study but have been related to patients' PA (e.g., exacerbations)[38,39] may have improved as a result of the intervention. This should be explored in further research. The fact that patients receiving the PR programme alone did not improve their PA levels despite having similar exercise capacity levels to those in the EG also supports the idea that low PA levels, as frequently found in patients with COPD, have a strong behavioural component. This means that some patients may opt to limit their PA levels rather than be restricted by their symptoms or impairments.[4]

No significant differences were found for self-efficacy over time in either group. Since self-efficacy is the main construct of the SCT,[16] it was expected that a SCT-based behavioural intervention would improve patients' self-efficacy. However, studies conducted in COPD have shown conflicting results regarding the relationship between PA and self-efficacy,[40–42] which may in part explain the non-significant findings obtained in this study. These findings may also be attributable to the use of a global self-efficacy scale instead of a specific scale to assess PA behaviour, given that self-efficacy is a task-specific domain.[43] Future research should apply a PA self-efficacy scale.

Limitations

Findings from the present study must be interpreted in light of the limitations. First, this was a small-scale trial, therefore, the generalisability of the results to clinical practice is limited. Nevertheless, the sample size calculation and the large effect sizes found for PA levels added strength to the results. Second, patients had high functioning levels at baseline (mean baseline step counts 6600–7200 steps/day, mean baseline 6-mintute walking distance 493.8–476.2 m). Future research is warranted to explore whether

patients with lower performance levels present similar results after the intervention. Third, the PA-focused behavioural intervention comprised asking patients to walk 800 additional daily steps; however, not all patients achieved the step target throughout the duration of the study (data not shown). Therefore, future research should define the step-count goals according to each patient's performance, for example, by increasing a percentage of the total steps achieved. Fourth, all measures were administrated in a face-to-face interview conducted by the same researchers who implemented the intervention. Thus, assessor blinding was not possible. Fifth, the short- and long-term effects of the intervention were not studied, therefore the sustainability of the results could not be determined. Finally, both groups received the PR during the same timeframe and hence seasonal variations were not taken into account, although they may influence PA.[26]

Conclusions

A PA-focused behavioural intervention during and after PR may improve patients' PA levels. Further research with larger samples and follow-up assessments is warranted to support these preliminary findings and assess the short- and long-term impact of this intervention in COPD.

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Declaration of Conflicting Interests

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