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Promotion of physical activity after hospitalization for COPD exacerbation: A randomized control trial

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Abstract

Background and Objective: Physical activity worsens during exacerbations of chronic obstructive pulmonary disease (COPD) and notably after hospitalizations. Pedometer-based interventions are useful to increase physical activity in stable patients with COPD. However, there is little information concerning the implementation of such programs following severe exacerbation. This study assessed the efficacy of a physical activity program after hospitalization for a COPD exacerbation.

Methods: We performed a prospective, 12-week, parallel group, assessor-blinded, randomized control trial in COPD patients hospitalized for an exacerbation. After discharge, physical activity and other secondary variables were assessed. Patients were allocated (1:1) to a physical activity promotion program (intervention group, IG) or usual care (control group, CG). Based on a motivational interview and accelerometer physical activity assessment, a patient-tailored, pedometer-based, progressive and target-driven program was designed. Linear mixed effect models were used to analyse between-group differences.

Results: Forty-six out of 61 patients recruited were randomized and 43 (IG = 20, CG = 23) completed the study. In-hospital and baseline characteristics were similar in both groups. After 12 weeks of intervention, the mean steps difference between groups was 2093 steps/day, $p = 0.018$, 95% CI 376–4012, favouring the IG. Only the IG significantly increased the number of steps/day compared to baseline (mean difference [95% CI] 2932 [1069–4795] steps; $p = 0.004$). There were no other between-group differences.

Conclusion: After hospitalization for a COPD exacerbation, a patient-tailored physical activity program based on a motivational interview and the use of pedometers, with progressive and customized targets, improved the number of steps/day.

KEYWORDS
clinical trial, COPD exacerbation, hospitalization, pedometer, physical activity, sedentary behaviour

INTRODUCTION

In recent years, the promotion of physical activity in patients with chronic obstructive pulmonary disease (COPD) has been investigated through multitude interventions[1] and is recommended in relevant COPD management guidelines[2–4] due to the impact of inactivity on disease progression and mortality.[5–7] However, current recommendations focus on the stable phase of the disease despite physical activity dramatically decreasing in patients with COPD after hospitalization for an exacerbation.[8,9] Also, severe exacerbations play a significant role in the vicious circle of dyspnoea-inactivity described in COPD and help explain the course of the disease.[10]

This study was previously presented at the 53rd Spanish SEPAR Society Congress 2020 and the 30th European Respiratory Society (ERS) Congress 2020.

Therefore, there is a need for early interventions after COPD exacerbations to reverse the detrimental effects of these events.

Indeed, there may be a window of opportunity, albeit challenging, for promoting physical activity in patients with COPD following an exacerbation.[11,12] Early post-exacerbation interventions might improve disease progression by helping patients fully recover from these events and avoiding further exacerbations. However, this path has been scarcely studied and with poor results.[13] In a recent systematic review analysing the effect of pedometer-based physical activity promotion,[14] only one study[15] recruited patients during a COPD exacerbation. Unfortunately, the trial failed to show differences in physical activity between groups, which were all still very inactive at the end of the study. Therefore, it remains unclear, whether a physical activity intervention following hospitalization for a severe COPD exacerbation might work.

We hypothesized that a 12-week, patient-tailored, pedometer-based, progressive and target-driven program could increase daily physical activity and reduce sedentary behaviour in patients with COPD following hospitalization for an exacerbation.

SUMMARY AT A GLANCE

We assessed the efficacy of a physical activity program after hospitalization for a COPD exacerbation. The participants of a 12-week patient-tailored, pedometer-based, progressive and target-driven physical activity program, increased their daily steps compared to control group after discharge.

METHODS

This was a prospective, 12-week, multicentre, two-arm parallel group, assessor-blind and randomized control trial (NCT03084874). The study was conducted according to the principles of the Declaration of Helsinki and it is reported according to the CONSORT statement.[16,17]

Study participants

Patients hospitalized due to a COPD exacerbation were asked to participate if they: (i) were adults aged 40 years or older, with COPD confirmed by forced spirometry; (ii) had smoking history of ≥10 packs/year and (iii) were willing to participate and provide signed consent. We excluded patients if: (i) were admitted to the ICU; (ii) hospitalized more than once in the previous 12 months; (iii) required newly prescribed oxygen therapy at discharge; (iv) had severe physical or psychological limitations; (v) were attending a pulmonary rehabilitation program and (vi) were unable to understand Spanish or Catalan. No changes in the eligibility criteria were made throughout the duration of the study.

Study visits

The study was organized in four visits (Figure 1). The screening visit (visit 1) was conducted during hospitalization and after obtaining informed consent. All the patients received standard medical care and supervised Monday-to-Friday physical exercise by a respiratory physiotherapist to minimize the effects of prolonged bedrest during their hospital stay (Appendix S1 in the Supporting Information).

Upon discharge, patients were given an accelerometer to measure their physical activity. The patients returned 1 week after discharge for baseline assessments and randomization (visit 2). They were randomized 1:1 to either the control group (CG) or the intervention group (IG) (Appendix S2 in the Supporting Information). Information regarding blinding of study personnel is detailed in Table S1 in the Supporting Information.

The patients underwent a standard medical visit 4 weeks later (visit 3) and the final evaluation took place 12 weeks after randomization (visit 4) (Figure 1).

Intervention

Our program aimed to increase physical activity and reduce sedentary behaviour through three components:

1. A motivational interview to explore the patient's ambivalences towards being more active and to assist them in tipping the decision balance in favour of change[18] (Appendix S3 in the Supporting Information).
2. A personalized physical activity program with a pedometer and a printed calendar to engage the subject in an individualized, 12-week, progressive and steps-targeted intervention. The program aimed to achieve a 20% monthly increment on the number of steps from the individual baseline level (i.e., Mean number of steps after discharge). The targeted step number was broken down weekly for the participants. Detailed program progression is available in Appendix S4 in the Supporting Information.
3. Weekly telephone calls with the participants to assess their progress, discuss possible barriers and set new weekly physical activity goals (Appendix S4 in the Supporting Information). Moreover, the intervention was reinforced in person during visit 3.

Patients in the CG followed the standard clinical discharge management plan. After randomization, these patients were briefly advised to meet international recommendations[18] (i.e., at least 150 min of moderate-intensity aerobic physical activity weekly) and to complete their prescribed medical treatment.

Outcomes

The primary outcomes were: (i) change in physical activity (steps per day) and (ii) change in sedentary behaviour (time

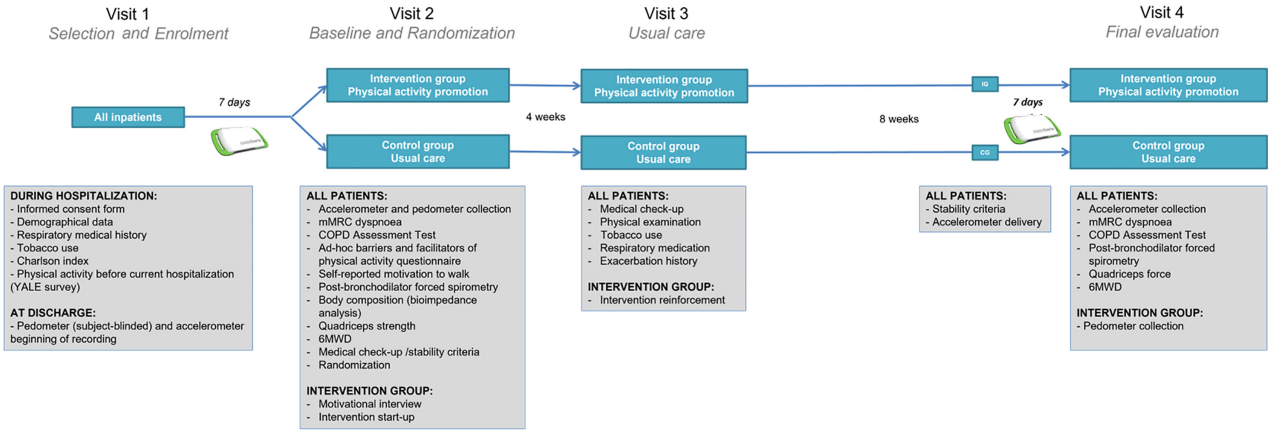

FIGURE 1 Visit schedule and study procedures. 6MWD, 6-min walking distance; CAT, COPD Assessment Test; mMRC, modified Medical Research Council

spent on sedentary activities [sitting or lying]). As complementary physical activity information, data on walking time, standing time and time spent on light and at least moderate physical activity (>3 METS) were collected.

We objectively measured physical activity with the Dynaport accelerometer (McRoberts BV, The Hague, The Netherlands) which has previously been validated in COPD.[19,20] Patients wore the device for a 7-day period during waking hours, placed on the centre of the lower back with an elastic strap. A valid measurement was defined as a minimum of 4 days with at least 8 h of recording time.[21]

As secondary outcomes we measured: (i) functional exercise capacity with the distance walked in the 6-min walk test (6MWD)[22]; (ii) quadriceps muscle force with a hand-held dynamometer[23] and (iii) health status (the COPD Assessment Test [CAT]).[24]

COPD exacerbations and other adverse events

Data regarding COPD exacerbations, related hospitalizations and other adverse events were collected throughout the study. Moderate exacerbations were defined as an acute worsening of respiratory symptoms resulting in additional therapy,[25] whereas severe exacerbations granted hospitalization. Patients were excluded only if they presented a COPD exacerbation, moderate or severe, between visit 1 and 2 (Appendix S4 in the Supporting Information).

Statistical analysis

Sample size power estimation is detailed in Appendix S5 in the Supporting Information.

Results are expressed as absolute numbers and their corresponding percentages for qualitative variables, as the mean and SD for quantitative variables with a normal distribution and as the median and 25th–75th percentiles for quantitative variables with a non-normal distribution. Between-group differences were analysed using linear mixed effect models, adjusting for group, time and group × time interaction. Goodness of fit was assessed by means of normality of residuals. Intra-group differences were analysed using the paired *t*-test. Statistical significance was set at $p < 0.05$. All statistical analyses were performed using SPSS 26 (IBM Corp, Armonk, NY) and Stata 12.1 (StataCorp, College Station, TX).

RESULTS

Between March 2017 and December 2019, we recruited 61 patients among 198 patients assessed for eligibility. After baseline assessment, 46 patients were randomized and 43 completed the study (Figure 2).

The in-hospital and baseline characteristics were similar in the two groups (Table 1). Patients were a mean (SD) of 66 (10) years old, the majority of subjects (74%) were male and spent 8 (2) days hospitalized. After discharge, they had severe airflow limitation (forced expiratory volume in 1 s [FEV_1] 46 [16] % predicted), mild breathlessness (modified Medical Research Council [mMRC] score, median [p25–75], 1[1–2]), showed preserved functional exercise capacity (6MWD of 428 [121] m) and walked 5676 (3398) steps/day.

After 12 weeks of intervention, the number of steps/day compared to baseline significantly increased only in the IG (mean difference [95% CI] 2932 [1069–4795] steps; $p = 0.004$; Table 2). In the linear mixed effect model, the difference in mean steps between groups was 2093 steps/day, $p = 0.018$, 95% CI 376–4012 (Table 2, Figure 3). Normality of residuals goodness of fit tests showed no relevant abnormality.

There was no other statistically significant between-group change in the rest of the primary and secondary outcomes (Table 2).

The overall incidence of COPD exacerbations during follow-up was similar in both groups: 7 (30%) patients in the CG and 7 (35%) patients in the IG had at least one moderate exacerbation. Only one (5%) patient (IG) was

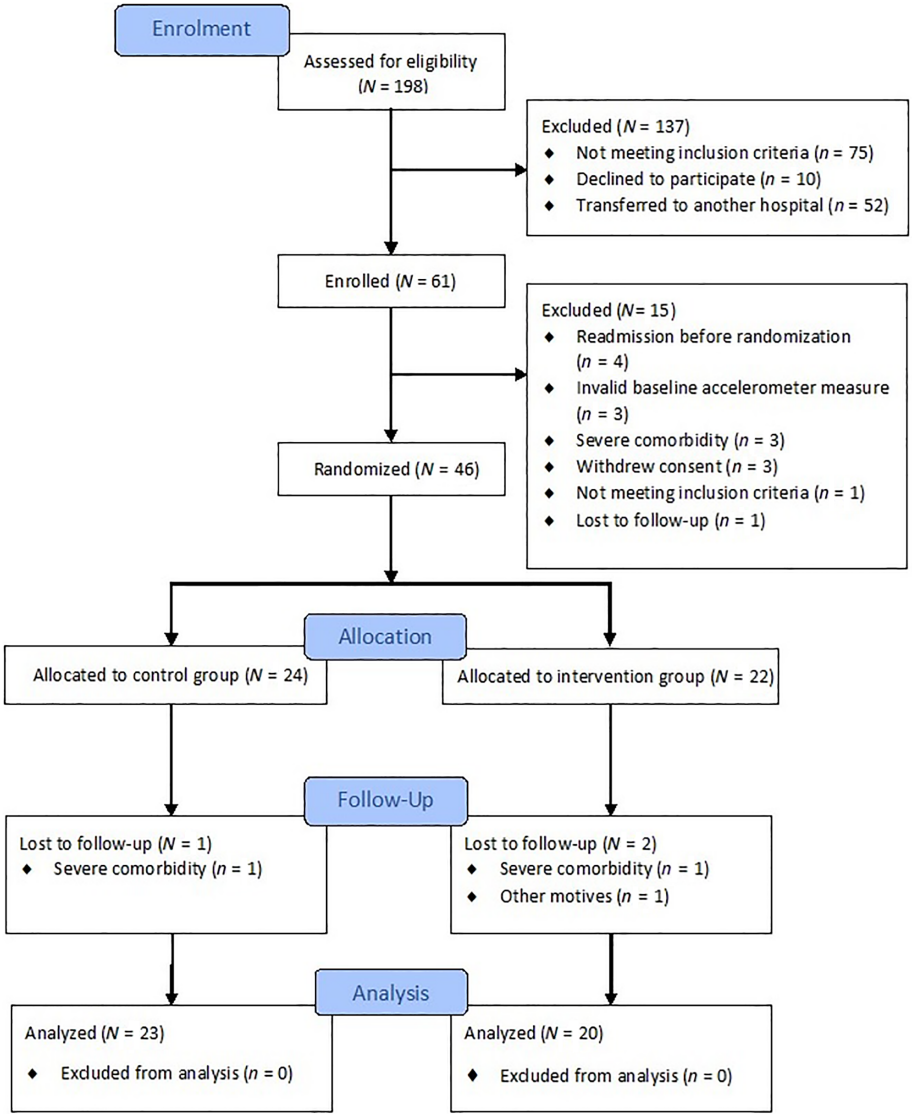

FIGURE 2 Consort flow chart of participants

hospitalized due to a severe COPD exacerbation during the study. Regarding other adverse events, one (5%) patient in the IG had an arm fracture.

DISCUSSION

This clinical trial shows that patients with COPD significantly improved the number of daily steps following a 12-week physical activity program after hospitalization. This finding supports our hypothesis that a patient-tailored, pedometer-based, progressive and target-driven program can boost daily physical activity in patients with COPD after a severe exacerbation.

To our knowledge, these are the first data demonstrating that a physical activity program following hospitalization might be effective in selected patients with COPD. Patients in the IG achieved a significant improvement in the number of daily steps, above the reported MICD,[26] while maintaining the overall sedentary behaviour. This finding may be explained by a change in the physical activity profile of the patients in the IG that increased their walking time and the physical activity intensity, while preserving their sedentary time (Table 2).

These improvements in physical activity after a COPD exacerbation differ from other studies, specifically from Hornikx et al.[15] However, several differences between the two studies could explain these discrepancies. First, we defined our study inclusion and exclusion criteria to overcome some of the reported difficulties (i.e., Hospital re-admissions), and, therefore have better fit candidates. Second, our program was of longer duration (12 vs. 4 weeks). Third, our intervention was based on an in-person motivational interview that included discussion about barriers and enablers to physical activity.[27,28] In contrast, the study by Hornikx relied on telephone contacts, which might have precluded patients to discuss further motivational aspects. Finally, it is known that hospital admissions have a significant impact on exercise

TABLE 1 Baseline characteristics of the study participants 1 week after discharge

	All ($N = 43$)	Control group ($N = 23$)	Intervention group ($N = 20$)	*p*-value
Sociodemographic characteristics				
Age, years	66 (10)	66 (10)	66 (10)	0.994
Male, *n* (%)	32 (74.4)	16 (69.6)	16 (80.0)	0.612
Smoking status				
Current, *n* (%)	24 (55.8)	12 (52.2)	12 (60.0)	0.606
PY	52 (30)	52 (27)	52 (34)	0.975
Living conditions				
Alone, *n* (%)	9 (20.9)	4 (17.4)	5 (25.0)	0.697
Education, *n* (%)				
None	11 (25.6)	4 (17.4)	7 (35.0)	
Basic or secondary	29 (67.4)	18 (78.3)	12 (55.0)	0.433[a]
University	3 (7.0)	1 (4.3)	2 (10.0)	
Charlson index	1 (1–2)	1 (1–2)	1 (1–3)	0.188
Previous physical activity (YPAS)				
Total score	38 (19)	41 (20)	35 (18)	0.251
>51, *n* (%)	10 (23.3)	6 (26.1)	4 (20.0)	0.637
Motivation to walk (0–10 point scale)	6 (3)	7 (2)	6 (3)	0.953
Ambulatory oxygen therapy, *n* (%)	4 (9.3)	3 (13.0)	1 (5.0)	0.365
Exacerbation history				
Length of, days	8 (2)	8 (3)	8 (2)	0.636
Steroid treatment current, hospitalization[b], mg	515 (247)	553 (294)	481 (197)	0.385
Other hospitalization past 12 months, yes, *n* (%)	3 (7.0)	1 (4.3)	2 (10.0)	0.480
At least one moderate exacerbation previous 12 months, yes, *n* (%)	26 (60.5)	15 (65.2)	11 (55.0)	0.488
Anthropometric characteristics				
BMI	27.3 (5.7)	27.4 (5.3)	27.2 (6.2)	0.920
Fat free mass (%)	70.6 (7.4)	66.9 (7.0)	71.3 (7.9)	0.549
Dyspnoea				
mMRC, score	1 (1–2)	1 (1–2)	1 (1–2)	0.856
Post-bronchodilator lung function				
FEV_1 (%pred)	46.0 (16.4)	45.6 (19.1)	46.5 (13.1)	0.862
FEV_1/FVC	52 (12)	51 (11)	52 (13)	0.805
Airflow limitation				
Mild, *n* (%)	2 (5)	2 (9)	0 (0)	0.450[a]
Moderate, *n* (%)	14 (33)	6 (26)	8 (40)	
Severe, *n* (%)	19 (44)	10 (44)	9 (45)	
Very severe, *n* (%)	8 (19)	5 (22)	3 (15)	

Note: Data are presented as mean (SD) or *n* (%).
Abbreviations: FEV_1, forced expiratory volume in the first second; FVC, forced vital capacity; mMRC, modified Medical Research Council; PY, packs per year; YPAS, Yale Physical Activity Survey.
[a]Among all categories.
[b]Prednisone total dose.

capacity in COPD patients.[7,8] So, we included early exercise training sessions for all patients during hospitalization to retain as much functionality as possible.

Nguyen et al.[29] also tested the efficacy of a physical activity promotion program in patients with COPD after being hospitalized for an exacerbation anytime in the previous year. While their intervention did not have any effect on the primary outcome (i.e., all-cause acute care use and death) when they analysed the patients who adhered to their Walk On program, there was a significant improvement in the time spent in any physical activity in the IG. Despite relying on subjective physical activity measurements, their results, similarly to Arbillaga et al.[30] highlight the importance of the adherence to these interventions. Although we

TABLE 2 Changes in physical activity and other outcomes after 12 weeks of intervention

	Control group, $n = 23$		Intervention group, $n = 20$		Between group differences at 12 weeks	
	Baseline	12 weeks	Baseline	12 weeks	Mean Δ (95% CI)	p-value[a]
Primary outcomes						
Steps/day	5779 (3937)	6518 (3840)	5558 (2747)	8490 (4501)[b]	2093 (376–4012)	0.018
Time spent in sedentary behaviour (h)	9.4 (2.0)	9.6 (2.4)	9.5 (1.7)	9.6 (2.0)	−0.02 (−0.92–0.87)	0.960
Secondary outcomes						
CAT (score)	12 (8)	14 (7)	12 (7)	11 (7)	−3.2 (−7.0–0.6)	0.101
6MWD (m)	432 (126)	421 (127)	423 (118)	441 (106)	18 (−49–86)	0.595
Dominant Quadriceps force (kg)	31 (9)	32 (10)	30 (7)	32 (8)	−0.2 (−3.3–2.8)	0.627
Complementary physical activity data						
Standing time (min)	155 (69)	155 (71)	150 (66)	138 (52)	−17.6 (−54.4–19.3)	0.350
Walking time (min)	65 (41)	74 (40)[b]	65 (31)	91 (44)[b]	16.7 (−0.8–34.3)	0.061
Light physical activity (min)	45 (26)	55 (35)[b]	45 (47)	39 (21)	−16.0 (−35.8–4.1)	0.120
At least moderate physical activity (min)	87 (51)	101 (54)[b]	87 (41)	115 (49)[b]	13.9 (−6.4–34.3)	0.180

Note: Data are presented as mean (SD) or median (p25–p75), between-group differences are presented as mean Δ (95% CI).
Abbreviations: CAT, COPD Assessment Test; 6MWD, 6-min walking distance.
[a]Based on linear mixed effect models, adjusting for group, time and group × time interaction.
[b]p-value < 0.05 for intra-group difference baseline versus 12 weeks. *Intervention group*: $p = 0.004$ baseline versus 12 weeks (mean difference 2932 steps, 95% CI [1069–4795]); $p = 0.006$ baseline versus 12 weeks walking time (mean difference 26 min, 95% CI [9–44]); $p = 0.008$ baseline versus 12 weeks at least moderate activity (mean difference 28 min, 95% CI [8–48]). *Control group*: $p = 0.038$ baseline versus 12 weeks walking time (mean difference 10 min, 95% CI [1–19]); $p = 0.030$ baseline versus 12 weeks light physical activity (mean difference 10 min, 95% CI [1–18]); $p = 0.017$ baseline versus 12 weeks at least moderate activity (mean difference 14 min, 95% CI [3–25]).

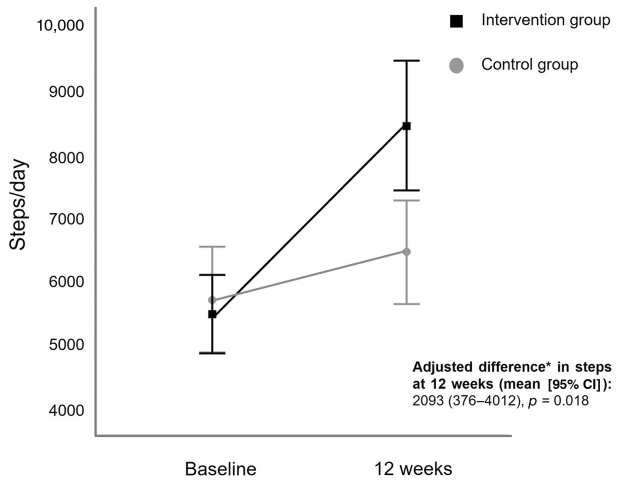

FIGURE 3 Change in steps/day after 12 weeks of intervention from baseline to 12 weeks in the control group and intervention group. Bars represent mean (SEM) for baseline and 12 weeks. *Based on linear mixed effect models, adjusted for group, time and group × time interaction

did not objectively measure the adherence, we are confident that most of our participants followed the intervention based on patients' high motivation to walk after discharge (Table 1), the successful periodic telephone contacts that ensured patient tracking, the absence of dropouts and our positive results. Also, recent research has shown that patients have some positive attitudes towards physical activity following hospitalization[28] and these might be used to enhance a more active behaviour and gain momentum to use that period as a window of opportunity for behavioural change.[12]

Our intervention did not reduce sedentary behaviour as hypothesized. We anticipated that if patients became more active, their sedentary time would decrease.[31] An explanation for our finding may be that the study intervention was primarily focused on increasing physical activity, as the target goals were set in steps per day without objectively monitoring goals on sedentary behaviour. While it has been shown that sedentary behaviour modification interventions alone might be more effective than in conjunction with physical activity goals,[32] there is still no clear evidence regarding this.[33] Given the impact of sedentary behaviour on the course of COPD,[34] more studies are needed to clarify the relationship between physical activity and sedentary behaviour in patients with COPD to design better interventions.

Spontaneous physical activity recovery after a COPD hospitalization is very limited.[8,35,36] Therefore, our results have encouraging clinical implications to improve the recovery of patients with COPD and break the vicious circle of dyspnoea-inactivity after these events.[10]

Although pulmonary rehabilitation has been found to be safe and effective after a COPD exacerbation,[37] it is scarcely accessible to patients[38] so physical activity programs might be a good alternative. We found that it is possible to increase the number of daily steps in patients with COPD after a severe exacerbation. However, it remains unclear if having a preserved exercise capacity and being already somewhat active before the hospitalization is a requirement to implement these interventions, as only 26% of our participants were classified as very sedentary before hospitalization according to the results of the Yale Physical Activity Survey. And, while high physical activity has shown to be achievable

with both low and high exercise capacity,[39] Hornikk et al. showed[15] that patients with poor exercise capacity and very low physical activity might not be good candidates. Thus, our trial design (i.e., inpatient early exercise training) and inclusion criteria (i.e., less than one hospitalization in the previous year) were set to overcome those barriers and improve the efficacy of our intervention. Indeed, our results highlight that a properly selected population might be a key element for the success of this kind of interventions.

The improvement seen in steps/day in the IG is supported by some key elements of our study. First, we objectively measured physical activity with a valid accelerometer[19,20] and patients were blind to the purpose of the device. Second, the recruitment time comprised all year round, and thus, a possible climate bias is null. Lastly, the assessor responsible for measuring all the study outcomes was blinded to patient allocation, thereby reducing the risk of detection bias.

Nonetheless, we acknowledge some limitations. The sample size was calculated to detect a significant difference in steps/day between groups, which might have limited our ability to detect further differences. For example, we observed a between-group difference of 16 min in walking time along with −3.2 points difference in the CAT questionnaire that did not reached statistical significance but it is above the MCID[40] (Table 2).

In addition, we cannot ensure that the improvement in physical activity observed with our intervention would be maintained over time, as the data presented here only describe the effect of a 12-week program. Yet, one of the main objectives of the motivational interview is to favour patients' decisions to carry out a healthier lifestyle in search of a long-lasting behaviour change.[41,42] Lastly, our results might only apply to a COPD population such as ours, that seems to be more active after hospital discharge than that observed in other studies.[8,35,36] However, Donaire-Gonzalez et al.[43] showed that COPD patients with previous hospitalizations in our geographical area walk similar number of steps and de Oliveira et al.[44] have also recently reported very similar data in Brazilian COPD patients after hospital discharge.

In conclusion, we found that a 12-week patient-tailored, pedometer-based, progressive and target-driven program increased daily physical activity, specifically steps per day, in selected patients with COPD following hospitalization for an exacerbation of their disease. Further studies are needed to confirm these results and to clarify if additional benefits can be derived from such programs.

AUTHOR CONTRIBUTION

Beatriz Valeiro: Data curation (equal); formal analysis (equal); investigation (equal); project administration (equal); writing – original draft (lead); writing – review and editing (lead). **Esther Rodríguez:** Conceptualization (lead); data curation (equal); funding acquisition (equal); investigation (equal); methodology (equal); project administration (supporting); resources (lead); supervision (supporting); writing – original draft (supporting); writing – review and editing (equal). **Paula Pérez:** Data curation (equal); investigation (supporting); project administration (supporting); resources (equal); writing – review and editing (supporting). **Alba Gómez:** Data curation (supporting); project administration (supporting); resources (supporting); writing – review and editing (supporting). **Ana Isabel Mayer:** Data curation (equal); investigation (supporting); project administration (supporting); resources (supporting); writing – review and editing (supporting). **Alejandro Pasarín:** Data curation (equal); project administration (supporting); resources (supporting); writing – review and editing (supporting). **Jordi Ibañez:** Data curation (equal); investigation (supporting); project administration (supporting); resources (equal); writing – review and editing (supporting). **Jaume Ferrer:** Conceptualization (equal); data curation (equal); investigation (equal); methodology (equal); resources (equal); supervision (equal); writing – original draft (equal); writing – review and editing (equal). **María Antonia Ramon:** Conceptualization (lead); data curation (lead); formal analysis (equal); funding acquisition (lead); investigation (lead); methodology (lead); project administration (lead); resources (equal); supervision (lead); writing – original draft (lead); writing – review and editing (lead).

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CONFLICT OF INTEREST

None declared.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

HUMAN ETHICS APPROVAL DECLARATION

This study was performed in accordance with the Declaration of Helsinki. This human study was approved by Ethics Committees of Vall d'Hebron Hospital Clinical Research Review Board and The Sisters Hospitallers of the Sacred Heart of Jesus Review Board. Approval: PR(AG)390/2015 and PR-2018-01. The study's clinical trial registration number is NCT03084874, registered with www.clinicaltrial.gov. Participant registration took place between Mar-2017 and Dec-2019. All adult participants provided written informed consent to participate in this study.

Clinical Trial Registration: NCT03084874 at www.clinicaltrial.gov

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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