Effectiveness and Safety of Supervised Home-Based Physical Training in Patients With COPD on Long-term Home Oxygen Therapy A Randomized Trial

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BACKGROUND: Patients with COPD in advanced stages who need long-term home oxygen therapy (LTHOT) have difficulty participating in outpatient pulmonary rehabilitation (PR) programs. This difficulty is due to the severity of their disease, limitations involving transportation and mobility, high costs, and issues related to patients' safety and individual needs. Unsupervised home-based physical training (PT) is frequently used.

RESEARCH QUESTION: The main objective of this study was to investigate the effectiveness of a supervised home-based PT program on exercise capacity and other outcomes in patients with COPD receiving LTHOT.

STUDY DESIGN AND METHODS: In a randomized clinical trial, patients with COPD who were on LTHOT were allocated into two groups: the supervised physical training (PT) group, consisting of patients who received home-based supervised muscle strength and endurance training in twice-weekly 60-min sessions for 12 weeks; and the unsupervised activity booklet group, consisting of patients who received a booklet advising them to perform exercise twice a week for 12 weeks. All participants were assessed prior to and following the intervention in terms of exercise capacity (6-min step-test and the 1-min sit-to-stand test); dyspnea (Medical Research Council scale); fatigue (Brazilian Portuguese version of the Fatigue Severity Scale); and health status (COPD Assessment Test).

RESULTS: A total of 44 patients were assessed (mean age, 70 ± 8 years; FEV₁, $33 \pm 14\%$ predicted) (PT group, n = 22; booklet group, n = 22). Only the PT group patients presented significant improvement in the 6-min step-test (21 ± 9 vs 14 ± 11 ; P = .001), Medical Research Council scale (3.3 ± 1.0 vs 3.9 ± 0.9 ; P = .013), Brazilian Portuguese version of the Fatigue Severity Scale (5.0 ± 1.4 vs 5.2 ± 1.3 ; P = .015), and COPD Assessment Test (21 ± 8 vs 26 ± 6 ; P = .001). No adverse effects were observed.

INTERPRETATION: Supervised home-based PT was effective and safe in improving exercise capacity, dyspnea, fatigue, and health status in patients with COPD on LTHOT.

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KEY WORDS: COPD; exercise; oxygen therapy

ABBREVIATIONS: 6MST = 6-min step test; 6MWT = 6-min walk test; GOLD = Global Initiative for Chronic Obstructive Lung Disease; LTHOT = long-term home oxygen therapy;

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PR = pulmonary rehabilitation; PT = physical training; Spo_2 = peripheral oxygen saturation; STST = 1-min sit to stand test





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COPD is characterized by the combination of respiratory and systemic symptoms that directly contribute to increased exercise intolerance and dyspnea, particularly in advanced stages of the disease.¹ Robust evidence shows that physical training (PT), the most important component of a pulmonary rehabilitation (PR) program, increases exercise capacity, reduces dyspnea and fatigue, and improves emotional function and quality of life in this population.² However, patients in advanced stages of disease who require long-term home oxygen therapy (LTHOT) often have difficulty leaving their homes, not only due to the disease severity but also due to limitations involving oxygen therapy per se (ie, heavy oxygen cylinders and refill costs)^{3,4} as well as the use of nonportable devices that limit their mobility, compromising daily life activities and resulting in considerable reduction of physical capacity and function.⁵ These difficulties, in addition to common social influences such as low income (to cover transportation costs), low levels of education,⁶ and scarcity of specialized PR centers,⁷ limit patients' participation in outpatient PR programs. In this context, home-based PT may increase access to PR for such patients.

Studies have reported the efficacy of home-based PT, which has shown comparable results to outpatient programs regarding selected outcomes such as the 6-min walk test (6MWT) in carefully selected patient populations.⁸⁻¹² However, these studies generally incorporate direct and/or indirect supervision of physical therapists via fortnightly or monthly visits or even telephone calls.

A large portion of patients with COPD on LTHOT in Brazil have low socioeconomic status,⁶ reduced selfefficacy, and other barriers to engage in unsupervised home-based PT. Therefore, the objective of the current randomized study was to verify the effects of supervised home-based exercise using endurance and strength exercises compared with unsupervised physical activity advice using a booklet, on exercise capacity, fatigue, dyspnea, and health status in patients with COPD users of LTHOT. The study hypothesis was that a supervised home-based PT program is effective and safe and can improve exercise capacity, dyspnea, fatigue, and health status in patients with COPD on LTHOT.

Patients and Methods

Study Design

This randomized trial was conducted in the homes of patients residing in Curitiba (Brazil), registered in the municipality's LTHOT program of the city of Curitiba, Brazil, from January 2016 to May 2017. The study was developed according to the Standard Protocol Items: Recommendations for Interventional Trials,¹³ approved by the Human Research Ethics Committee from the Hospital de Clínicas da

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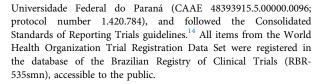
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Patients with COPD were first contacted via telephone to receive information about the study and then invited to participate. Following agreement to participate and prior to initial assessment, participants received detailed information regarding voluntary participation in the study and signed an informed consent form that had been reviewed and approved by the Human Research Ethics Committee from the Hospital de Clínicas da Universidade Federal do Paraná.

During the first home visit, demographic, anthropometric, and clinical information were collected in all patients, as well as spirometry and information regarding oxygen therapy use (type of oxygen delivery device, oxygen flow and duration of use, and interface). During the second home visit, functional tests, exercise capacity test, and questionnaires were completed. All assessments were conducted in the participant's home by the same trained physical therapist, who was blinded to group allocation. All participants continued to use oxygen therapy during the assessments and training.

Participants

The study sample comprised patients with clinical and functional diagnosis of COPD grades 2 to 4 according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria,¹ of both sexes, aged ≥ 50 years, and clinically stable (ie, no disease exacerbation for at least 1 month). Participants were not included in any rehabilitation or PT program over the previous year. Patients were recruited for the current study after taking part in a descriptive

previous study published by the same group.⁶ In the previous study, screening was done by contacting patients registered as LTHOT users in the municipality health system. Of note, among all LTHOT users registered in the municipality, 58% (n = 223) were diagnosed as having COPD. Participants were not included in any rehabilitation or PT program over the previous year and received medical clearance for the proposed intervention. They were invited to take part in this study regardless of the amount of time (hours per day) they spent on LTHOT.

Exclusion criteria were the presence of other pulmonary diseases such as asthma, pulmonary fibrosis, and pneumonia, as well as other severe nonpulmonary diseases considered to be debilitating and of difficult management, such as history of advanced cardiac diseases (eg, heart failure, severe valve disease, coronary disease with left ventricular systolic dysfunction [ejection fraction < 50%], uncontrolled arrhythmias), and acute or chronic orthopedic or neurologic diseases that could hinder completion of assessments; cognitive impairment, according to Mini-Mental Status Examination scores (< 13 for illiterate individuals; < 18 for people with 1-7 years of education; and < 26 for those with ≥ 8 years of education)¹⁵; and use of noninvasive mechanical ventilation during the trial.

Lung function was assessed according to the American Thoracic Society/European Respiratory Society recommendations¹⁶ using reference values for the Brazilian population.¹⁷ Severity of airway obstruction was classified according to GOLD criteria.¹ Information on oxygen use (type of oxygen delivery device, oxygen flow and duration of use, and interface), as well as patient history, were recorded in an assessment form created by the researchers.

Oxygen Therapy

All participants received oxygen therapy during assessments and training, with dose sufficient to maintain a peripheral oxygen saturation $(\text{Spo}_2) \ge 88\%$.¹⁸ The oxygen supply came from an electric oxygen concentrator (EverFlo 5 LPM; Philips HealthCare), and all participants used a nasal cannula as the interface. The flow rate (liters per min) and daily usage of oxygen therapy (hours) were determined according to each participant's medical prescription. All equipment and interfaces used were supplied by the municipal LTHOT program.

Primary Outcomes

Exercise capacity was assessed by using the 6-min step test (6MST) and the 1-min sit-to-stand test (STST). The 6MST was conducted following

TABLE 1 Stages of the Physical Training Program

the American Thoracic Society recommendations,¹⁹ using an antislip step that was 20 cm high, and with a nonslip floor.²⁰ Participants were instructed to go up and down the step at their own pace for 6 min¹⁹; the patient was allowed to slow down or stop if necessary, and the number of steps was counted at the end of the test.²⁰ This test was chosen because it is easy to apply in every environment, including the patient's home, which is frequently not the case for the 6MWT and the shuttle walk test. In addition, the 6MST can objectively assess exercise capacity, is a valid test for patients with COPD, and correlates well with the 6MWT.^{21,22}

The STST was conducted by using an armless chair with a set height of 46 cm. Participants were instructed to keep their arms crossed against their chest and hands resting on their shoulders, and to sit down and stand up as many times as possible over the 1-min period following the initial command to start. Time was measured by using a digital timer, and the number of repetitions in 1 min was recorded by the evaluator, from the initial command to the completion of 1 min.²³

Secondary Outcomes

Details on the assessment of secondary outcomes (dyspnea, fatigue, and health status) are described in e-Appendix 1.

Groups

Randomization and allocation procedures were conducted by an independent physical therapist not involved with recruitment, assessment, or interventions. The initial and final assessments for each outcome were conducted by the same assessor, who was blinded to the study interventions. More information on randomization, allocation concealment, and blinding are provided in e-Appendix 1. Following randomization, participants were allocated to one of two groups: the supervised PT group or the unsupervised activity booklet group. Participants' vital signs (heart rate, respiratory rate, BP, and Spo₂) were monitored at the start, during, and at the end of each session by using a heart rate monitor (ONrhythm 50; Geonaute), aneroid sphygmomanometer (P. A. Med), and oximeter (Oxy Control; Geratherm). Perceived effort was assessed by using the Borg CR-10 scale.²⁴ All participants were familiarized with the Borg CR-10 scale, as well as with the exercises, 1 week prior to the start of the interventions.

Participants were instructed to maintain their usual activities of daily living and to not participate in any other structured PT program while participating in this study. To foster adherence to treatment, participants were allowed to miss up to two training sessions, with replacement sessions at a previously scheduled day and time.

Stage	Frequency	Intensity	Duration	Modality	Method	Progression
Warm-up	Twice a week	10-20 rpm and Borg CR-10 scale score < 4	5-10 min	Portable lower limb cycle ergometer	Continuous	Not applicable
Endurance training	Twice a week	Moderate (50%- 70% of HRR and Borg CR-10 scale score 4-6)	20 min	Portable lower limb cycle ergometer	Continuous or interval	10% monthly increment
Muscle strength exercises	Twice a week	Moderate (60%- 80% of 1 RM and Borg CR-10 scale score 4-6)	15 min	Dumbells and ankle weights	3 sets of 8 repetitions; 2- min interval between sets	10% monthly increment
Cool down	Twice a week	Not applicable	10 min	Active-assisted	1 set of 30 s	Not applicable

1 RM = one repetition maximum; HRR = heart rate reserve; rpm = revolutions per minute.



For the safety of the participants, exercises were immediately interrupted if any adverse events occurred such as heart rate > 130 beats/min or < 40 beats/min, Spo₂ < 88%, BP > 180/100 mm Hg, or important perceived fatigue and dyspnea (> 6 on the BORG CR-10 scale),²⁴ and resumed after the participant's condition was normalized.

Supervised PT Group

Each participant allocated to the PT group was offered 24 individual sessions of endurance and strength training, supervised by a physical therapist who provided immediate assistance when needed during training. The 60-min sessions were conducted twice weekly for 12 weeks. Exercise prescription was based on the American College of Sports Medicine recommendations,^{25,26} and all training sessions included four sequential stages: (1) warm-up; (2) endurance training; (3) muscle strength exercises; and (4) cooling down. Patients were instructed to perform pursed-lips breathing during the exercises. A description of the four stages, including exercise type and intensity, is shown in Table 1. Additional details are found in e-Appendix 1. The equipment used for training in the study was provided to the patients in their homes for the study period and was returned to the physical therapist at the end of the study.

Unsupervised Booklet Group

Participants allocated to the booklet group did not receive any supervised PT; they received a booklet containing a description of two physical exercises they should perform at home at least twice a week, for 12 weeks (24 days of exercise), on days chosen by the participants themselves. The exercises were: sit and stand from a chair (sitting, forward lean and prepare for the hips to leave the sit,

Results

Of the 223 patients with COPD on LTHOT who were initially contacted, 92 were potentially eligible according to the study criteria. Of those 92 subjects, 60 were enrolled and randomized to therapy (Fig 1). Sixteen patients (eight from each group) dropped out, mostly for severe exacerbations or personal reasons; the remaining 44 patients (PT group, n =22; booklet group, n = 22) performed 24 exercise sessions and were analyzed at the end of the study (71% were female, and the majority had severe or very severe airway obstruction). There were no between-group differences in baseline characteristics (Table 2).

Primary Outcomes

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Table 3 shows that, following 12 weeks of training, individuals in the PT group had a significant increase in the 6MST and STST, which was not found with the booklet group. Furthermore, the PT group had a significantly greater improvement in the 6MST compared with the booklet group (P = .001).

There was no between-group difference in the number of STST repetitions (Table 3); however, the increase in trunk and hips start to extend until full standing position, then sit back down again; repeat the movement) and flexion and extension of the elbow with the upper limbs supported by a wall in a standing position. Participants were instructed to perform one set of 10 repetitions for each exercise. All participants were instructed to stop the exercises if they experienced any discomfort and to record the reason for stopping in the booklet. They were also instructed to indicate whether the exercise was performed and on what day of the week in a calendar within the booklet.

Statistical Analysis

Statistical analysis was performed by using SPSS version 22 for Windows (IBM SPSS Statistics, IBM Corporation). Normal distribution and homogeneity were assessed by using the Shapiro-Wilk and Levene tests, respectively. Results are presented as mean, SD, median, interquartile range, and frequency. Sample size calculation resulted in a sample of 60 patients (30 in each group), and the calculation is described in full in e-Appendix 1.

Comparison of baseline characteristics was performed by using the unpaired Student *t* test and standardized mean differences (effect size, Cohen's d). Within-group comparisons (pretraining and posttraining) were performed by using paired Student *t* tests or Wilcoxon test for continuous variables, and a χ^2 test was used for categorical variables. To compare the change between groups, the pretraining to posttraining difference was calculated ($\Delta = \text{post} - \text{pre}$) for each group and an independent Student *t* test or Mann-Whitney test was used to compare groups. Statistical significance was set at P < .05.

the number of repetitions in the PT group was 34.9% in contrast to only 6.3% in the booklet group.

Secondary Outcomes

Only participants allocated to the PT group exhibited a significant improvement in dyspnea, fatigue, and health status following the intervention (Table 3). Similarly, between-group comparisons revealed that the improvement in these three outcomes was significantly higher in the PT group. Conversely, the booklet group presented a significant worsening of health status.

Adverse Events

During the 12-week intervention phase of the study, 10 adverse events occurred. Four participants in each group were admitted to hospitals due to COPD exacerbation. One patient in the booklet group died, and one patient in the PT group developed herpes zoster. No adverse effects during the training sessions were registered and/ or reported.

Discussion

Studies on home-based rehabilitation are usually performed with no direct supervision, with telephone supervision or telemonitoring,^{12,27} and do not involve patients with COPD on LTHOT. This gap in the current

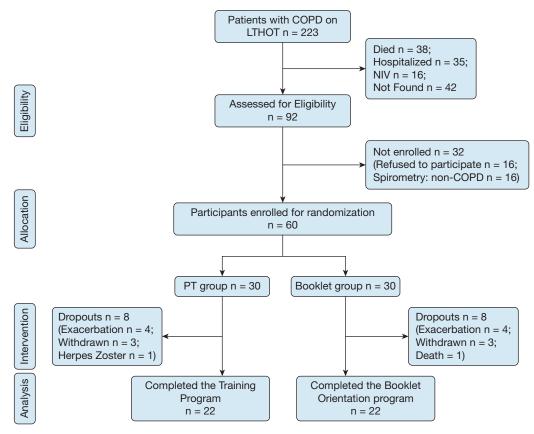


Figure 1 – Study flow chart according to Consolidated Standards of Reporting Trials recommendations. LTHOT = long-term home oxygen therapy; NIV = noninvasive ventilation; PT = physical training.

literature motivated this study. The current study showed that a 12-week (24 sessions) home-based PT program with direct supervision was effective and safe for patients with COPD on LTHOT, resulting in marked improvements in exercise capacity, dyspnea, fatigue, and health status. Coquart et al,²⁸ in a similar study, showed

Variable	PT Group (n $= 22$)	Booklet Group (n $=$ 22)	Pa	Cohen's d
Age, y	70 ± 8	70 ± 7	.96	0
Sex, male/female, No.	7/15	6/16	.17	
BMI, kg/m ²	26 ± 6	26 ± 7	.83	0
Smoking (pack-years)	41 (25-59)	51 (29-96)	.27	-0.60
Oxygen, h/d	19 ± 6	19 ± 6	.74	0
Oxygen, L	$\textbf{2.2}\pm\textbf{0.64}$	$\textbf{2.4} \pm \textbf{0.62}$.43	-0.31
FEV ₁ (% predicted)	31 ± 13	34 ± 14	.57	-0.22
FEV ₁ /FVC	46 ± 13	47 ± 10	.31	-0.08
GOLD I/I /III/IV, No.	0/3/8/11	0/3/9/10		
Cognitive impairment (MMSE)	23 ± 4	23 ± 3	.80	0
Medications, No. (%)				
Bronchodilator	18 (81)	17 (77)	.71	
Inhaled corticosteroids	13 (59)	12 (55)	.76	

TABLE 2] Demographic, Anthropometric, and Clinical Characteristics in the PT Group and the Booklet Group

Data are presented as mean \pm SD, median (interquartile range), or and frequency (%). GOLD = Global Obstructive Lung Disease; MMSE = Mini-Mental Status Examination; PT = physical training.

^a*P* value refers to Student *t* test, Mann-Whitney test, and χ^2 test.

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	PT Group (n $= 22$)			Booklet Group (n $= 22$)		Average
Variable	Pre	Post	Average % Change	Pre	Post	% Change
6MST (steps)	14 ± 6	$21\pm9^{a,b}$	47.8	15 ± 8	14 ± 11	-11.8
STST (repetitions)	12 ± 4	16 ± 5^{a}	34.9	12 ± 6	12 ± 7	6.3
MRC (1-5 points)	$\textbf{3.9}\pm\textbf{0.9}$	$3.3\pm1.0^{\text{a,b}}$	-18	$\textbf{3.9} \pm \textbf{1.2}$	3.9 ±0.9	14
FSS-BR (1-63 points)	$\textbf{5.7} \pm \textbf{1.2}$	$5.0\pm1.4^{\text{a,b}}$	-9.7	$\textbf{5.2} \pm \textbf{1.5}$	5.2 ± 1.3	2.3
CAT (0-40 points)	25 ± 7	$\textbf{21}\pm\textbf{8^{a,b}}$	-12.8	$\textbf{23}\pm\textbf{7}$	26 ±6 ^a	11.4

TABLE 3] Functional and Clinical Outcomes Preintervention (Pre) and Postintervention (Post)

Data are presented as mean \pm SD. 6MST = 6-min step test; CAT = COPD Assessment Test; FSS-BR = Brazilian Portuguese version of the Fatigue Severity Scale; MRC = Medical Research Council scale; STST = 1-min sit to stand test. See Table 2 legend for expansion of other abbreviation. ^aP < .05 in within-group analysis.

 ${}^{\mathrm{b}}\mathit{P}<$.05 in between-group analysis (Δ PT group $>\Delta$ booklet group).

that an 8-week home-based rehabilitation program with direct supervision once a week was feasible and safe, and significantly improved the number of steps in the 6MST in 27%, anxiety and depression in 10.3% and 17.3%, respectively (according to the Hospital Anxiety and Depression scale), and quality of life in 10% (according to a COPD-specific health-related quality of life questionnaire). However, PT was not the only intervention performed in that study. In addition to exercises, they provided broader PR support such as noninvasive mechanical ventilation and/or long-term oxygen therapy (according to each participant's needs), psychosocial support, therapeutic education, and motivational communication to encourage health behavior changes and self-management during the weekly supervised visits. The current study therefore achieved larger or at least similar benefits compared with the study by Coquart et al,²⁸ however, using considerably fewer PR resources.

Sahin et al²⁹ compared the effectiveness of a conventional outpatient center-based PR program between patients with COPD on LTHOT and those not on LTHOT, and they concluded that patients on LTHOT achieved significantly better results regarding exercise capacity and dyspnea. This more pronounced improvement among patients on LTHOT was hypothesized to be due to the fact that they were more sedentary at baseline. These findings are in line with the study by Mazzarin et al⁵ in a sample of patients with COPD on LTHOT, which showed that the daily duration of LTHOT was a determinant of physical inactivity in these patients. These findings reinforce the novelty of our results, given that this was the first study, to the best of the authors' knowledge, to investigate supervised twice-weekly home-based PT exclusively in patients with COPD on LTHOT. Furthermore, in terms

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of the exercise capacity assessment (the primary outcome in the current study), this study was the first to use the 6MST and the STST, as previous studies generally used the 6MWT. Given the difficulty in finding a 30-m corridor suitable for the 6MWT in a participant's home, both tests used in the current study were shown to be useful by being easily performed in a home environment.

Participants allocated to the PT group achieved a considerable increase in the number of steps in the 6MST (47.8%) posttraining compared with the booklet group. Of note, the baseline number of steps reported in the current study was considerably below the cut-off proposed by Pessoa et al²¹ (78 steps), indicating that these participants had markedly reduced exercise tolerance. In another study,²² the difference between the number of steps compared with those of the current study is very large (461 \pm 154 steps vs 14 \pm 6 steps). However, the involved samples have contrasting characteristics, such as marked differences in the disease severity (FEV₁, 55 \pm 19% vs 31 \pm 13% predicted; patients in GOLD stage III to IV, 34% vs 86%), and number of LTHOT users included (4% vs 100%), in addition to the fact that subjects in the study by Grosbois et al²² did not receive exercise training at home but at a rehabilitation center. These factors possibly explain the contrasting results.

There was no significant difference between groups in the STST, although a considerably larger improvement was observed in the PT group compared with the booklet group. In addition, the difference in the number of repetitions between groups was 3.5. This finding supports the study by Vaidya et al,³⁰ which indicated an increase of at least three repetitions to be consistent with physical benefits at the end of treatment. Regarding secondary outcomes, only the PT group achieved significant improvements in dyspnea and fatigue. The PT group also had a considerable improvement in health status, as it reached a four-point average on the COPD Assessment Test following the intervention, above the two-point minimal clinically important difference proposed by Kon et al.³¹

This study has some limitations. First, the fact that participants received only supervised PT or exercise instructions may be seen as a limitation, as the exercises proposed for each group were different, not to mention that a broader PR program, including health education, psychological and nutritional support, and pharmacologic optimization, could result in greater benefits than those achieved by administration of PT alone. However, this study aimed to investigate the effects of a more easily applicable intervention without other components, which may reflect the possible scenario for patients with COPD receiving LTHOT in different contexts. Second, the lack of specific cut-off points and minimal clinically important differences to critically assess the improvement in certain outcomes in the target population of this study is another limitation: the profile of the sample is very specific and included patients with severe or very severe airway obstruction who were hypoxemic and dependent on oxygen therapy. Third, the feasibility of this supervised home PT program was not assessed in terms of costs. However, the authors believe that the considerable costs to the patient and/or to health-care systems related to transportation to/from a rehabilitation center and oxygen

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therapy, among others, may lead home-based rehabilitation programs to present a favorable cost/benefit relationship. Furthermore, the implementation of supervised programs, although possible in Brazil, may be difficult to generalize to other settings where that practice is not possible. However, the home-based approach may be the only option for certain patients with severe or very severe disease with marked clinical and locomotion limitations, generating positive results. Finally, patient acceptability and perception of treatment were not evaluated. However, due to the very good adherence to the training sessions, the authors believe that patients had a positive perception regarding the program. Furthermore, patients with more comorbidities may benefit more from the treatment strategy presented here due to the convenience of receiving care in a familiar environment and at lower risk of falls and other complications, although the relatively small sample did not allow investigation of this topic in-depth in the current study.

Conclusions

A supervised PT program using simple equipment is safe and effective to improve exercise capacity, dyspnea, fatigue, and health status in selected patients with advanced COPD on oxygen therapy for approximately 18 to 20 hours per day. These patients are extremely limited physically and have difficulties leaving their homes, and this program provides a valuable opportunity to improve their function.



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Author contributions: D. K. was responsible for the literature search, data collection, study design, analysis of data, manuscript preparation, and manuscript review; A. R. S. G. and F. P. were responsible for the literature search and manuscript review; C. M. and S. K. B. were responsible for data collection, analysis of data, and manuscript review; and S. V. was responsible for study design, analysis of data, and manuscript review.

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Additional information: The e-Appendix can be found in the Supplemental Materials section of the online article.

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