Efficacy Of Unsupervised Home-Based Pulmonary Rehabilitation For Patients With Chronic Obstructive Pulmonary Disease

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Keywords: Chronic obstructive lung disease, Chronic obstructive lung disease assessment test, Home-based pulmonary rehabilitation, modified Medical Research Council, Pulmonary rehabilitation.

DOI: https://doi.org/10.21203/rs.3.rs-35242/v1

Abstract

Background: Pulmonary rehabilitation (PR) is a well-established treatment for chronic obstructive pulmonary disease (COPD). The standard protocol for PR requires frequent hospital visits, which can be difficult for patients. We performed this study to assess whether unsupervised home-based PR (HBPR) is effective for patients with COPD.

Methods: This investigation was a prospective cohort study. After assessing the outcome data, including the results of a COPD assessment test (CAT); the body mass index, airflow obstruction, dyspnea, and exercise capacity (BODE) index; a pulmonary function test; the modified Medical Research Council (mMRC) dyspnea scale; and the 6-min walking test (6MWT), specialists imparted education to patients about unsupervised HBPR. Patients who exercised more than three times per week were classified as the compliant group, and the others were categorized as the noncompliant group. Changes in the outcomes were compared between the compliant and noncompliant groups.

Results: 41 patients were enrolled in this study. After 8 weeks of unsupervised HBPR, there were significant improvements in CAT scores, BODE index, and forced expiratory volume in 1 s among patients in the compliant group compared with those in the noncompliant group. Moreover, their CAT and mMRC scores improved significantly after 8 weeks compared with those at baseline. On the other hand, patients in the noncompliant group showed no significant improvement in any of the outcomes.

Conclusions: Unsupervised HBPR can be effective for compliant patients with COPD. We recommend unsupervised HBPR for patients with COPD even when regular hospital visits for PR are not possible.

Trial registration: NCT03754881

Background

Chronic obstructive pulmonary disease (COPD) is the fourth leading cause of death worldwide, with a global prevalence of 11.7%.[1] Currently, inhaled bronchodilators are the mainstay of treatment for COPD. Although bronchodilators can improve lung function as well as alleviate symptoms and reduce acute exacerbation in patients with COPD,[2-4] evidence regarding their effect on these patients' performance and exercise capacity remains relatively insufficient. Because of this limitation associated with COPD pharmacotherapy, there is a need for a combination of nonpharmacologic therapies, which include smoking cessation, vaccination, and long-term oxygen supply. Among these therapies, pulmonary rehabilitation (PR) has been considered as one of the most well-established treatments for COPD.[5]

PR constitutes a multidisciplinary intervention that includes exercise training, physical therapy, and education of patients.[6] Although PR can be applied to several chronic respiratory diseases, patients with COPD are known to benefit most from PR. Studies have shown that PR can improve exercise capacity, dyspnea, and quality of life and reduce acute exacerbations, hospital admission, and depression in patients with COPD.[5, 7-12] In addition, landmark studies on PR have included programs with hospital

visits 2 or 3 days per week for a period 8–12 weeks,[13, 14] with each session consisting of 1–4 h of PR training under supervision. Although this standard protocol is reasonable, it is not easy to perform in practice due to the frequent visits required.[15] Hence, to overcome this issue, several evidence-based studies have suggested home-based PR (HBPR).[16-21] Nevertheless, the majority of these studies were performed with relatively frequent periodic supervision of specialists, which is not always feasible in communities with limited medical resources. Because of these limitations, compliance to PR remains inadequate among patients.

To apply PR to patients with COPD and enable them to understand its concept, PR may be performed intermittently at patients' clinic visits every 2–3 months. However, there is a lack of firm evidence supporting this practice. Therefore, in the present study, we educated patients with COPD at baseline about HBPR and trained them to perform it without supervision. After 8 weeks, we compared the compliant group with the noncompliant group in terms of the improvement in the quality of life, dyspnea, pulmonary function test (PFT) and 6-min walking test (6MWT) results, and other prognostic factors. Our aim was to determine the feasibility and the preliminary efficacy of an unsupervised HBPR in patients with COPD.

Methods

Patients and study design

We conducted a prospective cohort study at the Asan Medical Center in South Korea. Eligible patients with COPD were screened, considering the following inclusion criteria: patients (1) with forced expiratory volume in 1 s (FEV_1)/forced vital capacity (FVC) <0.7; (2) aged >40 years; (3) with no history of acute exacerbations within the past 4 weeks; (4) with no history of PR within the past 6 months; (5) with no change in the COPD maintenance regimen within the past 3 months; and (6) with modified Medical Research Council (mMRC) dyspnea scale score >1. Our exclusion criteria were (1) patients with the presence of a comorbidity that made PR difficult, including cardiac disease, orthopedic disease, neurologic disease, visual disturbance, or uncontrolled hypertension and (2) those under long-term oxygen therapy.

After the assessment of PFT and 6MWT results, COPD assessment test (CAT) scores, and dyspnea[22] at baseline, patients underwent HBPR that included supervised exercise, education, and physical therapy for 1 h. They were provided with a booklet describing the prescribed exercise protocol and a diary to record information about their exercise habits (Supplementary Figure 1). For a period 8 weeks, we made weekly calls to examine patients whether they were performing HBPR and maintaining an exercise diary. After 8 weeks of HBPR, patients again underwent PFT, 6MWT, and CAT. We then reviewed their diaries and categorized the patients into two groups. Those who exercised more than three times per week were classified as the compliant group, and the others were categorized as the noncompliant group (Figure 1).

This study was approved by the Asan Medical Center's Institutional Review Board (No. 2018-0964) and registered at ClinicalTrials.gov (NCT03754881) in November 2018. Written informed consent was obtained from all study participants, and the study was conducted in accordance with the amended Declaration of Helsinki.

PR program

The PR program included the following sessions: education about the methods for effective breathing and inhaler use, stretching aerobic exercise, and muscle training for lower and upper extremities. Clinicians and specialists evaluated the intensity of exercise that each patient should endure according to his or her 6MWT results and endurance during the education sessions.[23, 24] Aerobic exercise consisted of walking or indoor cycling. Velocity and time were used to prescribe the intensity for aerobic exercise. Rubber bands and various other exercise methods were used for muscle exercise.

Data collection and measurement and statistical analysis

All patient data were collected from electronic medical records and examined for baseline characteristics, medical history regarding COPD, past medical history, patient questionnaire results, and laboratory test results. The primary outcome was change in the CAT score at 8 weeks. CAT consisted of questions about respiratory symptoms and quality of life.[22] The secondary outcome was change in the mMRC score; the body mass index, airflow obstruction, dyspnea, and exercise capacity index (BODE index); FEV_1; and 6MWT results at 8 weeks. The BODE index consisted of the following variables: FEV_1, 6MWT, mMRC score, and body mass index.[25]

We assumed that the probability of improvement in CAT with HBPR was approximately 70% and noncompliance might not present improvement in CAT. In our hospital, compliance with HBPR in outpatients was approximately 20%. Our calculation demonstrated that more than eight patients would be required in each group to detect a significant difference at the 0.05 level with a power of 0.8. We enrolled a total of 50 patients considering loss to follow-up.

Categorical variables are expressed as numbers and percentages of the participants. The χ^2 or Fisher's exact test was used to analyze between-group differences. Continuous variables are presented as mean values with standard deviations. The Kolmogorov–Smirnov test was used to confirm the normality of distribution. Differences in continuous variables were analyzed using the Student's *t*-test, except mMRC. Because the variables did not satisfy normality, the Mann–Whitney test was used to analyze the differences in mMRC. All tests of significance were analyzed using two-sided tests; *P* values <0.05 were considered to be statistically significant. All analyses were performed using the SPSS software (version 24.0; Chicago, IL, USA).

Results

Patient enrollment and baseline characteristics

During the study period, 50 patients with COPD were screened, of whom 9 were excluded, including 6 due to loss to follow-up loss, 2 who had not undergone examination at 8 weeks, and 1 due to acute exacerbations during the study period (Fig. 2). Table 1 shows the baseline characteristics of the remaining 41 participants according to the study group. There were no significant between-group differences in baseline characteristics of these patients.

Table 1
Baseline characteristics

	Total (N = 41)	Compliant group (N = 26)	Noncompliant group (N = 15)	P value
Male, n (%)*	37 (90.2)	25 (96.2)	12 (80.0)	0.130
Age (years)	68.73 ± 8.31	68.69 ± 9.34	68.80 ± 6.46	0.969
BMI (kg/m^2)	22.87 ± 3.07	22.96 ± 3.26	22.72 ± 2.83	0.809
Smoking, n (%)	8 (19.5)	5 (19.2)	3 (20.0)	0.089
Current	28 (68.3)	20 (76.9)	8 (53.3)	0.104
Ex-smoker	5 (12.2)	1 (3.8)	4 (26.7)	
Never smoker	45.16 ± 28.92	50.75 ± 29.35	35.47 ± 26.32	
Smoking (pack*years)				
Comorbidity, n (%)	4 (9.8)	3 (11.5)	1 (6.7)	> 0.999
DM*	9 (22.0)	3 (11.5)	6 (40.0)	0.053
HTN*	5 (12.2)	2 (7.7)	3 (20.0)	0.336
Cardiovascular*	8 (19.5)	5 (19.2)	3 (20.0)	> 0.999
Malignancy*				
History of acute exacerbation, n (%)	37 (90.2)	23 (88.5)	14 (93.3)	0.735
0	3 (7.3)	2 (7.7)	1 (6.7)	
1	1 (2.4)	1 (3.8)	0 (0.0)	
2				
Drug compliance*	37 (90.2)	24 (92.3)	13 (86.7)	0.615

Abbreviations: 6MWT: 6-min walking test; BMI: body mass index; BODE index: the body mass index, airflow obstruction, dyspnea, and exercise capacity index; DM: diabetes mellitus; HTN: hypertension; CAT: chronic obstructive pulmonary disease assessment test; mMRC: modified Medical Research Council; PFT: pulmonary function test; FEV_1: forced expiratory volume in 1 s; FVC: forced vital capacity

Between-group differences were analyzed using chi-square test, Fisher's exact test, or independent two-sample *t*-test. * Variables analyzed using Fisher's exact test

	Total (N = 41)	Compliant group (N = 26)	Noncompliant group (N = 15)	P value
Pre CAT	16.49 ± 7.56	16.46 ± 7.80	16.53 ± 7.38	0.977
Pre mMRC, n (%)	28 (68.3)	16 (61.5)	12 (80.0)	0.367
2	7 (17.1)	6 (23.1)	1 (6.7)	0.129
3	6 (14.6)	4 (15.4)	2 (13.3)	
4	3.68 ± 1.97	4.04 ± 1.93	3.07 ± 1.94	
Pre BODE index				
Pre PFT	1.35 ± 0.51	1.32 ± 0.47	1.41 ± 0.58	0.595
FEV_1 (L)	3.29 ± 0.82	3.38 ± 0.75	3.14 ± 0.94	0.361
FVC (L)	41.61 ± 13.00	38.89 ± 9.80	46.32 ± 16.54	0.128
FEV_1/FVC (%)				
Pre 6MWT (m)	413.63 ± 89.71	400.35 ± 97.31	436.67 ± 72.03	0.216

Abbreviations: 6MWT: 6-min walking test; BMI: body mass index; BODE index: the body mass index, airflow obstruction, dyspnea, and exercise capacity index; DM: diabetes mellitus; HTN: hypertension; CAT: chronic obstructive pulmonary disease assessment test; mMRC: modified Medical Research Council; PFT: pulmonary function test; FEV_1: forced expiratory volume in 1 s; FVC: forced vital capacity

Between-group differences were analyzed using chi-square test, Fisher's exact test, or independent two-sample *t*-test. * Variables analyzed using Fisher's exact test

Comparison of study outcomes at 8 weeks between the compliant and noncompliant groups

Table 2 presents the changes after 8 weeks from baseline in the two study groups. Clinical outcomes were significantly improved in the compliant group compared to those in the noncompliant group in terms of the CAT score (− 4.62 ± 4.61 vs. 2.40 ± 6.73; $P = 0.002$), BODE index (− 1.00 ± 1.06 vs. −0.20 ± 0.56; $P = 0.01$), and FEV_1 (0.05 ± 0.19 vs. −0.09 ± 0.16; $P = 0.02$). The mMRC score (− 0.73 ± 0.83 vs. −0.27 ± 0.88; $P = 0.183$) and 6MWT results (18.23 ± 43.96 vs. 4.87 ± 46.25; $P = 0.36$) were also improved in the compliant group, but the difference was not significant.

The changes in the two groups after 8 weeks are presented in Figs. 3 and 4. There were significant improvements in the CAT (16.46 ± 7.80 vs. 11.85 ± 7.23; $P = 0.03$) and mMRC (2.54 ± 0.76 vs. 1.81 ± 0.63; $P = 0.001$) scores in the compliant group. However, the BODE index (4.04 ± 1.93 vs. 3.04 ± 1.97; $P = 0.07$), FEV_1 (1.32 ± 0.47 vs. 1.37 ± 0.46; $P = 0.71$), and 6MWT results (400.35 ± 97.31 vs. 418.58 ± 88.07; $P = 0.48$) presented no significant changes. In the noncompliant group, there were improvements in the

mMRC score, BODE index, and 6MWT results and the CAT score and FEV_1 were also increased after 8 weeks; however, none of these changes exhibited a significant difference.

Discussion

This study demonstrated that unsupervised HBPR in outpatient clinics can improve clinical outcomes in patients with COPD, thereby suggesting that PR can be recommended even when regular hospital visits are difficult. After 8 weeks of unsupervised HBPR, patients in the compliant group showed favorable outcomes; the CAT score, BODE index, and FEV_1 were improved significantly. To our knowledge, this is the first study to suggest the benefits of unsupervised HBPR in compliant patients.

The CAT and mMRC scores were improved significantly compared with those at baseline in the compliant group. Considering that a score of ≥ 2 in CAT was regarded as a significant change,[26] the change of −4.61 in the present study indicated clinically meaningful improvement.[27] The BODE index, one of the secondary outcomes in this study, is a well-known prognostic index for patients with COPD.[25, 28] The compliant group showed a marginal significant improvement in the BODE index (from 4.04 to 3.04; $P = 0.07$), which suggests that this type of unsupervised HBPR improves prognosis, although further study with more patients is necessary.

PR is considered as one of the highly effective treatment interventions for patients with COPD, with reports stating that PR alleviates dyspnea and fatigue and improves physical and emotional functions.[12] In particular, improved physical function is directly associated with improved prognosis in patients with COPD.[29] However, in real-world practice, PR is underperformed among these patients.[30, 31] The standard PR protocol requires multiple visits, high medical costs, and specialists from various fields. In addition, adherence to prescribed PR remains relatively low.[15] Therefore, a large proportion of patients with COPD do not sufficiently benefit from an adequate prescription for PR. To overcome this issue, HBPR may be applied, which is considered as an alternative for standard PR. Nevertheless, the majority of studies on HBPR have included specialist supervision for PR,[16–20] which may be another hurdle as it increases medical costs and the requirement of resources.[20] In those studies, specialists periodically visited patients and reeducated them about inhaler use and training methods, supervised the exercise sessions, and encouraged the patients using HBPR. Low socioeconomic status and transport-related inconveniences have been reported to be other reasons for the low adherence to PR.[32–34] From this perspective, the present study was meaningful as it demonstrated that unsupervised HBPR with one session can still have beneficial effects in patients with COPD. This study will be the basis for a better treatment strategy for patients with COPD who have difficulty in frequent hospital visits.

Horton et al.[21] compared the effects of unsupervised HBPR with those of center-based PR. They found that HBPR failed to show noninferiority in most of the outcomes because several participants in the HBPR group did not complete the PR programs. Therefore, we hypothesized that compliance is the key factor in the success of HBPR. In the present study, the compliant patients were compared with the noncompliant patients. The results clearly demonstrated that the benefit of PR was noted only in the

compliant group and that even one-time intervention could benefit the patients if they followed the training provided to them. Therefore, compliance, motivation, and appropriate education may be more important than where or how frequently these patients receive PR. Furthermore, the majority of participants preferred HBPR.[21, 35] In this context, the critical measure is educating patients about performing PR outside of hospital.

There are several limitations in this study. First, few outcomes showed no significant differences between the two groups and between pre- and post-HBPR in the compliant group, although all outcomes demonstrated trends of improvement. This could be due to the inclusion of a relatively small number of patients in this study, which might have been insufficient to show significance. Therefore, studies with larger sample sizes will be needed to confirm this aspect. Second, the efficacy of education on unsupervised HBPR at 8-week intervals was compared with noncompliance. We did not compare the education at 8-week intervals with standard PR. In addition, we observed the participants for only 8 weeks. Therefore, further study would be required to validate the noninferiority and the long-term effects of patient education at 8-week intervals for unsupervised HBPR.

Despite these limitations, this study has indicated the importance of clinicians' efforts to promote PR in patients with COPD. These efforts can lead to improved symptoms and quality of life in compliant patients. Education about unsupervised HBPR can be performed even when there is a lack of medical resources. Although a randomized controlled study with a large number of patients would be ideal, the present study demonstrates unsupervised HBPR as a possibility when it is not easy to prescribe standard PR for patients with COPD. Because only approximately 60% of patients adhered to unsupervised HBPR, further study on the strategy to increase compliance is necessary to benefit more patients with COPD.

Conclusions

Unsupervised HBPR performed for 8 weeks improved the symptoms and quality of life in patients with COPD. These results suggest that compliant patients with COPD can benefit from PR even when they cannot regularly visit hospital and when medical resources are lacking. Therefore, clinicians should actively recommend HBPR and try to increase patient compliance.

List Of Abbreviations

6MWT: the 6-min walking test;

BODE index: the body mass index, airflow obstruction, dyspnea, and exercise capacity index;

CAT: chronic obstructive pulmonary disease assessment test;

COPD: chronic obstructive pulmonary disease;

FEV1: forced expiratory volume in 1 s;

FVC: forced vital capacity;

HBPR: home-based pulmonary rehabilitation;

mMRC dyspnea scale: modified Medical Research Council dyspnea scale;

PFT: pulmonary function test;

PR: pulmonary rehabilitation

Declarations

Ethics approval and consent to participate: This study was approved by the Asan Medical Center's Institutional Review Board (No. 2018-0964). Written informed consent was obtained from all study participants.

Consent for publication: Not applicable

Availability of data and materials: Not applicable

Competing interests: The authors declare that they have no competing interests

Financial/nonfinancial disclosure: This study was supported by grants (2018-0964) from the Asan Institute for Life Sciences, Asan Medical Center, Seoul, Korea.

Author's contributions: S. W. L. is guarantors of the study. S. W. L, J. H. L., J. S. L, Y. M. O. and S. D. L. contributed substantially to the study design and data analysis. H. Y. L. and Y. J. performed the clinical study with the supervision of S. W. L and J. H. L. S. W. L. and J. H. L interpreted data and wrote manuscript.

Acknowledgements: This manuscript has been edited for English language, grammar, punctuation, and spelling by Enago, an editing brand of Crimson Interactive Pvt. Ltd.

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Figures

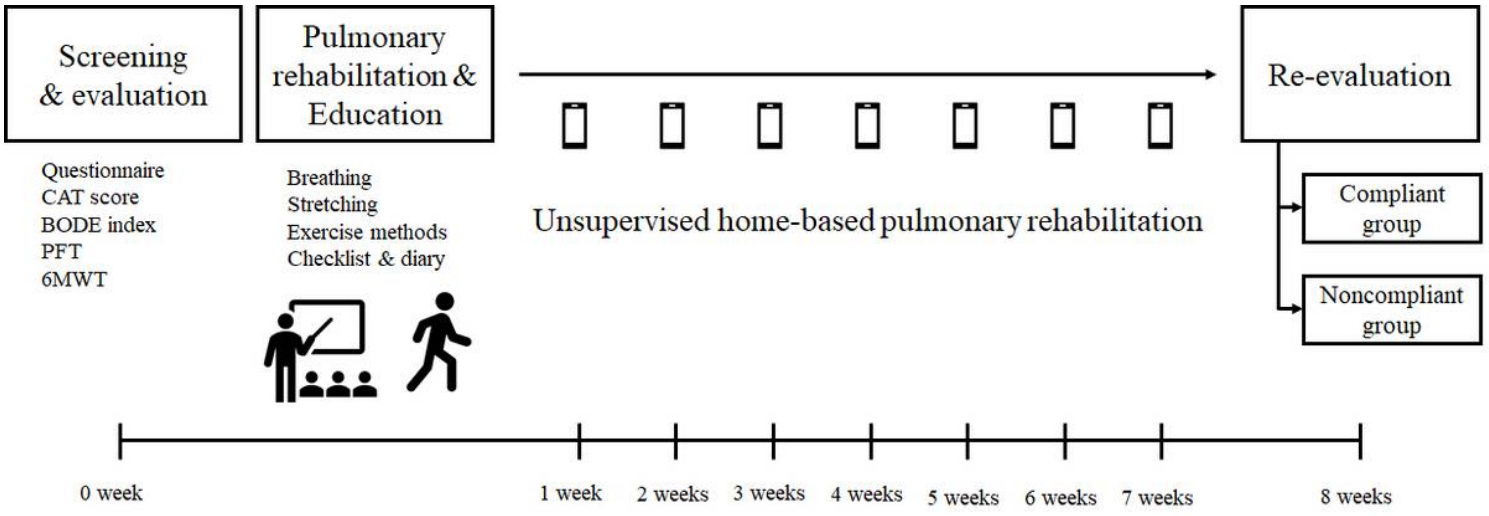

Figure 1

Study design Baseline measurements were obtained after enrolling eligible patients. The patients performed unsupervised home-based pulmonary rehabilitation after receiving education on it at baseline. The patients were called weekly and encouraged to perform home-based pulmonary rehabilitation and maintain a diary. After 8 weeks, patients were categorized as either the compliant or noncompliant group, and measurements were repeated for outcomes.

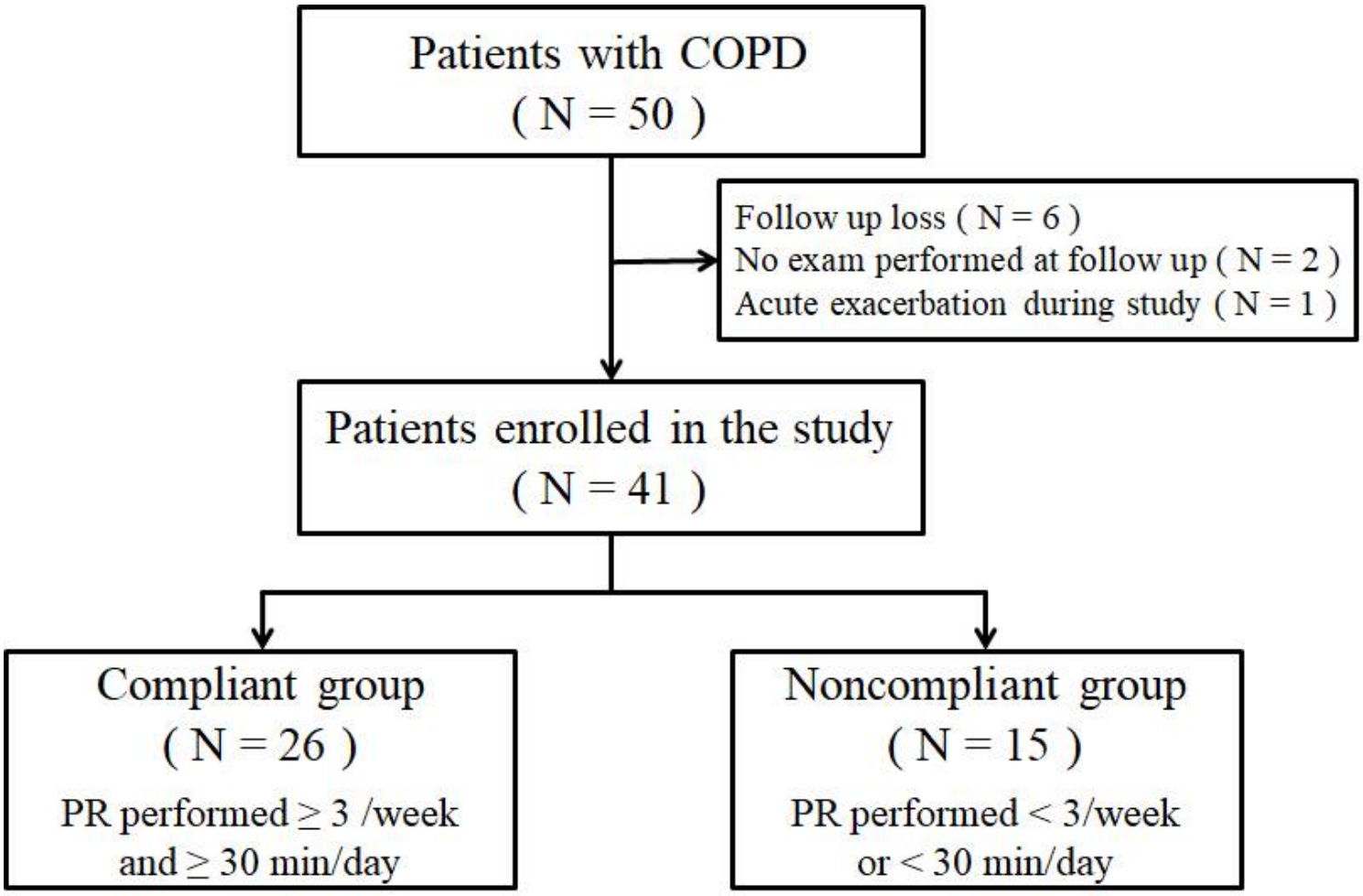

Figure 2

Study flow Fifty patients were screened for the study; of them, 9 patients were excluded. Among 41 patients, 26 patients were enrolled in the compliant group and 15 patients were included in the noncompliant group.

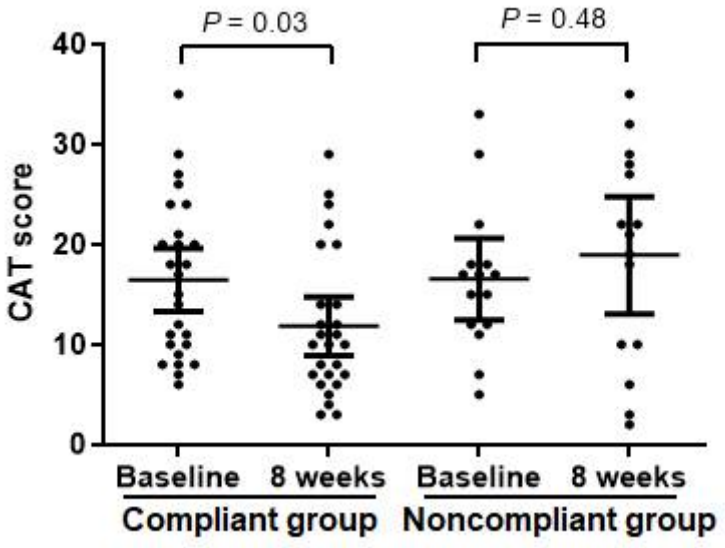

Figure 3

Primary outcome and CAT changes after 8 weeks of home-based pulmonary rehabilitation A scatter plot graph presents chronic obstructive pulmonary disease assessment test (CAT) results at baseline and at 8 weeks. The plot is presented as mean with 95% confidence interval. Differences between baseline values and values obtained after 8 weeks were analyzed using an independent two-sample t-test. In the compliant group, CAT scores significantly improved (16.46 ± 7.80 vs. 11.85 ± 7.23; P = 0.03), whereas in the noncompliant group, there was no significant change in CAT scores (16.53 ± 7.38 vs. 18.93 ± 10.59; P = 0.48).

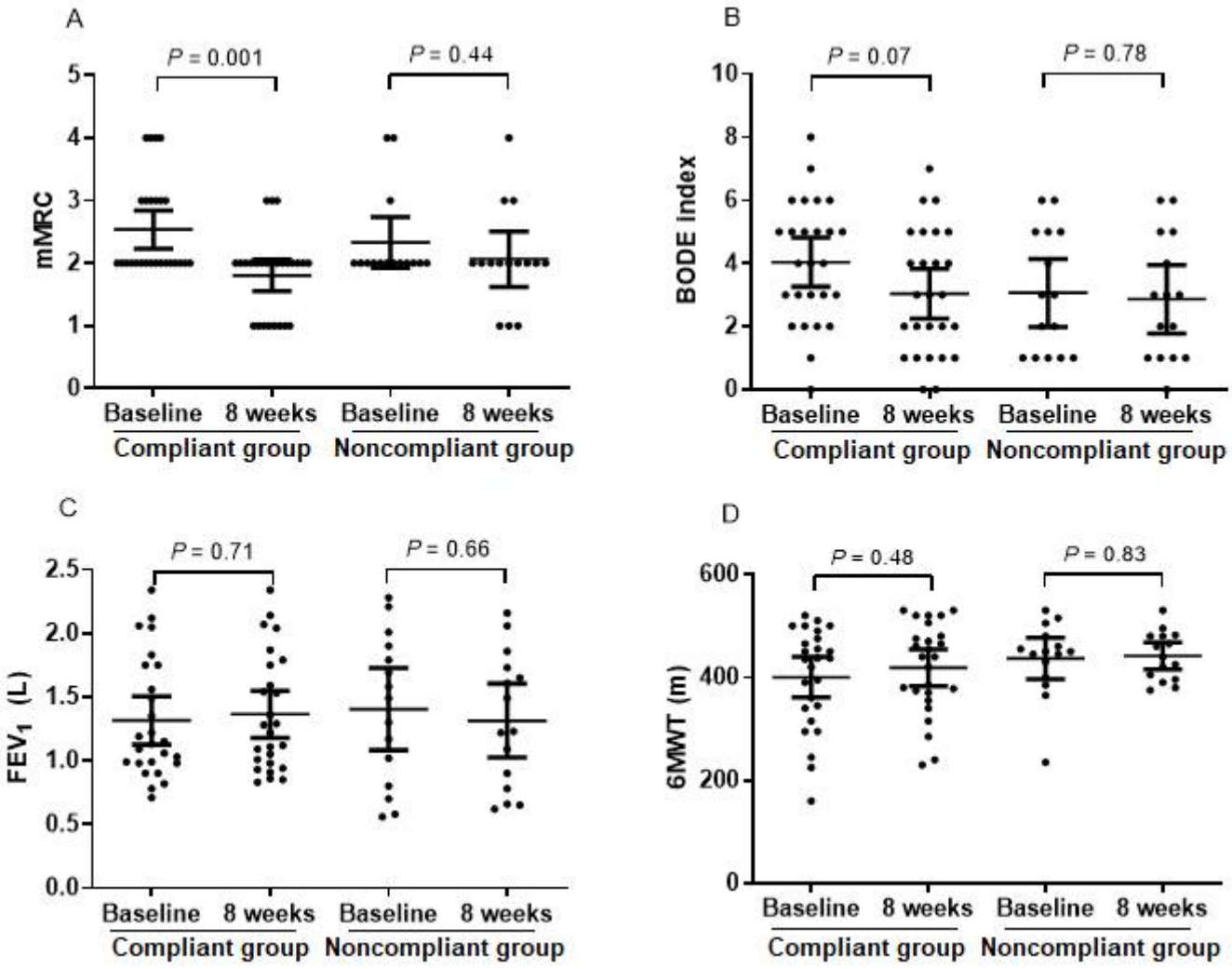

Figure 4

Secondary outcomes: mMRC, BODE index, FEV1, and 6MWT after 8 weeks of home-based pulmonary rehabilitation A scatter plot graph presents secondary outcomes at baseline and after 8 weeks. The plots are presented as mean with 95% confidence interval. Difference between baseline values and values obtained after 8 weeks were analyzed using an independent two-sample t-test. In the compliant group, mMRC scores (2.54 ± 0.76 vs. 1.81 ± 0.63; P = 0.001) significantly improved after 8 weeks. However, the BODE index (4.04 ± 1.93 vs. 3.04 ± 1.97; P = 0.07), FEV1 (1.32 ± 0.47 vs. 1.37 ± 0.46; P = 0.71), and 6MWT results (400.35 ± 97.31 vs. 418.58 ± 88.07; P = 0.48) did not show significant changes. In the noncompliant group, mMRC scores (2.33 ± 0.72 vs. 2.07 ± 0.80; P = 0.44), BODE index (3.07 ± 1.94 vs. 2.87 ± 1.96; P = 0.78), 6MWT results (436.67 ± 72.03 vs. 441.53 ± 47.20; P = 0.83), and FEV1 (1.41 ± 0.58 vs. 1.31 ± 0.52; P = 0.66) were not significantly different. Abbreviations: 6MWT: 6-min walking test; BODE index: the body mass index, airflow obstruction, dyspnea, and exercise capacity index; FEV1: forced expiratory volume in 1 s; mMRC: modified Medical Research Council

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- protocolsubmittedAMKRCK1613.pptx

Table 2
Changes in clinical, pulmonary function test, and 6-min walking test outcomes from baseline to 8 weeks in both groups

	Compliant group (N = 26)	**Noncompliant group (N = 15)**	**P value**
CAT	−4.62 ± 4.61	2.40 ± 6.73	0.002
mMRC	−0.73 ± 0.83	−0.27 ± 0.88	0.183
BODE index	−1.00 ± 1.06	−0.20 ± 0.56	0.010
FEV_1	0.05 ± 0.19	−0.09 ± 0.16	0.019
6MWT	18.23 ± 43.96	4.87 ± 46.25	0.363
Abbreviations: 6MWT: 6-min walking test; BODE index: the body mass index, airflow obstruction, dyspnea, and exercise capacity index; CAT: chronic obstructive pulmonary disease assessment test; mMRC: modified Medical Research Council; FEV_1: forced expiratory volume in 1 s			
Between-group differences were analyzed using the independent two-sample *t*-test.			