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Impact of self-management interventions initiated during hospitalization on inhaler adherence and functional outcomes in patients with acute exacerbation of chronic obstructive pulmonary disease: a randomized controlled trial

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Ethics approval and consent to participate: the institutional Ethics Committee (JIP/D(R)/IECIS-5/O724/102) for the Interventional Studies and Research Monitoring Committee (JIP/CON/NRMC/M.Sc./2023/MSN/5) approved the study. The procedures followed were in accordance with the institution's ethical standards. The trial was prospectively registered with the Clinical Trials Registry of India (CTRI/2024/09/073).

Informed consent: written informed consent was obtained from all participants prior to enrollment.

Patient consent for publication: all participants provided written informed consent for the publication of anonymized data generated from this study.

Availability of data and materials: the datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request.

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Abstract

Chronic obstructive pulmonary disease (COPD) remains a leading global health burden, with acute exacerbations accelerating functional decline and impairing quality of life. Reduced inhaler adherence is a well-recognized contributor to exacerbations and poorer outcomes in COPD. While self-management interventions are well established in stable COPD, their initiation during acute exacerbations has been inadequately explored. This randomized controlled trial, conducted in a South Indian tertiary hospital between July 2024 and May 2025, evaluated the effectiveness of a structured self-management program initiated during hospitalization for acute exacerbation of COPD. The intervention included individualized counseling, family engagement, structured telephonic follow-ups (weekly for 3 months, then monthly for 3 months), and scheduled outpatient reviews, while controls received standard care.

Primary outcomes were inhaler adherence assessed by the Test of Adherence to Inhalers, health-related quality of life (HRQoL) measured with the St. George's Respiratory Questionnaire (SGRQ), and functional capacity assessed by the six-minute walk test. At six months, good inhaler adherence was observed in 66.7% of the intervention group compared to 10% of controls ($p<0.001$). The mean between-group difference in six-minute walk distance at six months was 92.8 meters [95% confidence interval (CI): 58.1 to 127.6; $p<0.001$], favoring the intervention group. HRQoL also improved significantly, with a mean between-group difference in SGRQ score of -38.2 (95% CI: -46.7 to -29.8; $p<0.001$).

These findings indicate that initiating structured self-management during hospitalization for acute exacerbation of COPD results in significant improvements in inhaler adherence, functional capacity, and quality of life. Integrating self-management into acute care pathways may therefore optimize patient-centered outcomes in this high-risk population.

Key words: chronic obstructive pulmonary disease, COPD, self-management, quality of life, inhalers, 6-minute walk test.

Introduction

Non-communicable diseases remain the predominant cause of global mortality, and chronic respiratory conditions such as chronic obstructive pulmonary disease (COPD) represent a major contributor. Recent estimates indicate that COPD has emerged as the third leading cause of death worldwide, with millions of lives lost annually In India [1], its prevalence is rising due to smoking, biomass fuel exposure, and air pollution, resulting in frequent hospitalizations and poor quality of life [2]. Acute exacerbations of COPD (AECOPD) accelerate decline and increase healthcare costs, emphasizing the need for effective management beyond drug therapy [3]. Self-management programs (SMPs) have emerged as a promising approach for managing various chronic diseases, including COPD. The rationale behind SMPs is to empower patients with the knowledge and skills needed to proactively manage their condition, adhere to treatment regimens, and recognize and respond appropriately to worsening symptoms [4-6]. Evidence suggests that enhanced self-management skills can potentially reduce the severity and frequency of exacerbations and improve overall health-related quality of life [7-10]. While proven in stable COPD, its role after exacerbations is less explored, particularly in low- and middle-income countries [11]. This study evaluates a structured self-management program in patients recovering from acute exacerbation of COPD (AECOPD), focusing on inhaler adherence and functional outcomes. Functional outcomes were defined as a composite of health-related quality of life, assessed using the St. George's Respiratory Questionnaire, and functional capacity, measured by the six-minute walk test. This composite approach was chosen to capture complementary aspects of patient status, integrating subjective perceptions of well-being with objective measures of physical performance. The novelty lies in delivering a multi-component, family-supported intervention during the post-exacerbation phase in the Indian context. By combining education, symptom recognition, inhaler training, and exercise support, the program highlights the potential of self-management to improve patient-centered outcomes and reduce the burden of COPD.

Materials and Methods

Design and setting

A prospective, randomized controlled trial with two study arms was implemented at a tertiary care center in South India. Adult patients experiencing acute exacerbation of chronic obstructive pulmonary disease (AECOPD), admitted to the Pulmonary Medicine ward, were recruited and subsequently followed up through the Pulmonary Medicine outpatient services. The enrollment period spanned from July 2024 to May 2025.

Sample size and sampling

Participants were enrolled through convenience sampling and randomly assigned to the experimental or control group. The sample size was calculated based on a comparison of two independent means, using the 6-minute walk distance (6MWD) as the primary outcome. A minimum detectable difference of 50 meters with a standard deviation of 65 meters was assumed between the groups [12]. With a significance level of 5% (one-sided) and 80% power, the required sample size was estimated to be 23 participants per arm. To account for an anticipated attrition rate of 23.3%, the final target was set at 30 participants per group, yielding a total of 60 participants. Eligible participants were adults aged 18 years or older who were hospitalized with an acute exacerbation of COPD. Exclusion criteria included the presence of sensory or cognitive impairment, other coexisting pulmonary diseases (such as lung cancer, pulmonary tuberculosis, or interstitial lung disease), congestive left heart failure, and hemodynamic instability requiring mechanical ventilation or vasopressor support.

Allocation concealment mechanism

Block randomization with permuted blocks of varying sizes was used to achieve balanced allocation across study groups. The random sequence was prepared by a faculty expert and implemented through sequentially numbered, sealed envelopes. Participant enrollment and group assignment were carried out by the principal investigator, independent of sequence generation.

Ethical considerations

The study protocol received approval from the Institutional Ethics Committee – Interventional Studies (IEC-IS) (Approval No. JIP/D(R)/IECIS-5/0724/102; dated July 5, 2024). Written informed consent was obtained from all participants before enrolment. The trial was prospectively registered with the Clinical Trials Registry of India (CTRI/2024/09/073).

Intervention and data collection procedure

After the baseline evaluation, participants assigned to the intervention arm received a structured self-management education program consisting of two individualized counselling sessions supported by audiovisual materials. The content was adapted from Living Well with COPD and the Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2023 recommendations [13].

The first counselling session was delivered once the patient was clinically stable. Regardless of severity classification, all patients were included after their clinical stabilization. It focused on broad aspects of COPD self-management. Topics included the nature and long-term impact of the disease, treatment principles, the importance of medication adherence, dietary

considerations, strategies to manage stress, avoidance of triggers, early identification of exacerbations, and the benefits of maintaining regular physical activity. The second session, conducted at the time of hospital discharge, reinforced earlier teaching and emphasized hands-on practice. Demonstrations included proper use of inhalation devices and respiratory exercises, such as controlled coughing, pursed-lip breathing, and deep-breathing techniques. Using the "teach-back" approach, patients were asked to repeat the skills to confirm their understanding. Each session lasted approximately 30–45 minutes, with participation of family members encouraged. To facilitate ongoing practice, participants were issued an educational pamphlet and an activity logbook to record adherence to inhalers, prescribed medications, and physical activity.

A structured follow-up plan included weekly telephone calls for the first three months, followed by monthly calls for the next three months. Clinical reviews were scheduled monthly in the pulmonary medicine outpatient department, and outcome assessment was performed after 6 months of follow-up (Figure 1).

All counselling sessions were conducted by the principal investigator, who had received institutional training in patient counselling prior to the study. Delivering the intervention by a single trained investigator ensured uniformity and minimized variability in implementation.

Control group: Participants in the control arm received usual care, which included pharmacological management in accordance with established COPD treatment guidelines, along with standard written discharge instructions on medication use and inhaler technique. They did not receive structured educational sessions, scheduled telephonic follow-up, or supervised reinforcement of self-management skills.

Outcome measurement

At the end of the six-month follow-up, participants in both study arms completed the final evaluation. Functional performance was measured using the Six-Minute Walk Test, quality of life was assessed with the St. George's Respiratory Questionnaire, and medication adherence was determined using the Test of Adherence to Inhalers. To limit observer bias, inhaler technique and adherence were independently assessed by two junior resident medical officers from the Department of Pulmonary Medicine who were not involved in administering the intervention.

Inhaler adherence was evaluated using the 12-item Test of Adherence to Inhalers (TAI). The first 10 items are patient-reported and generate a total score ranging from 10 to 50. Based on this score, adherence is classified as good (score = 50), intermediate (46–49), or poor (≤45).The remaining two items are completed by a healthcare professional to assess inhaler technique and understanding of the prescribed regimen. In addition to quantifying adherence, the TAI identifies patterns of non-adherence. Items 1–5 explore unintentional

(Sporadic/erratic) non-adherence related to forgetfulness or inconsistency, with scores below 25 indicating this pattern. Items 6–10 assess intentional (deliberate) dose omission or modification, with scores below 25 suggesting deliberate non-adherence. Items 11–12 assess unwitting/ Unconscious non-adherence due to inadequate technique or lack of knowledge; a combined score below 4 indicates this subtype [14,15].

The Test of Adherence to Inhalers (TAI) is a psychometrically validated tool designed to evaluate adherence to inhaled medications in individuals with asthma and COPD. The 10-item patient-reported section has demonstrated good internal consistency (Cronbach's α = 0.86) and satisfactory test–retest reliability (intraclass correlation coefficient = 0.87).

Health-related quality of life was assessed using the St. George's Respiratory Questionnaire (SGRQ), a disease-specific instrument developed for patients with chronic airflow limitation. The questionnaire comprises 50 items grouped into three domains: Symptoms, Activity, and Impacts. Responses are weighted and aggregated using standardized scoring algorithms to generate domain-specific and total scores on a 0–100 scale, with higher scores indicating worse health status [16].

The St. George's Respiratory Questionnaire (SGRQ) has demonstrated strong psychometric properties in patients with chronic respiratory diseases, including COPD. The instrument shows high internal consistency across domains, with reported Cronbach's alpha coefficients generally exceeding 0.70. Test–retest reliability has also been found satisfactory, indicating score stability in patients who are clinically stable [17,18].

After data collection was completed, the self-management intervention was also offered to the control group during their outpatient visits to ensure equitable access to the program's benefits.

Statistical analysis

Categorical variables were summarized as frequencies and percentages, and group comparisons were performed using the Chi-square test. Continuous variables were presented as mean ± standard deviation or as median with interquartile range, depending on the distribution assessed by the Kolmogorov–Smirnov test and kurtosis. Between-group differences were analysed using either the independent Student's t-test or the Mann–Whitney U test, as appropriate. Paired t-tests were applied to assess changes from baseline to 6 months in exercise tolerance (six-minute walk test), and quality of life (St. George's Respiratory Questionnaire), with Analysis of Covariance (ANCOVA) used to adjust for baseline values. Both Intention-To-Treat (ITT) and per-protocol analyses were conducted, and as the results were consistent, the ITT analysis was used for final interpretation. All statistical analyses were performed using SPSS version 27.

Results

Table 1 illustrates the baseline characteristics of the intervention and control groups (N = 60). No significant differences were observed in inhaler adherence, types of non-compliance, functional capacity, or quality of life, confirming group homogeneity. Poor inhaler adherence was prevalent in both groups (96.7% vs. 93.3%; $P = 1.00$), and sporadic non-compliance was universal (100%). Although the intervention group showed a higher mean six-minute walk distance (159.30 ± 88.61 m vs. 124.17 ± 91.02 m), the difference was not statistically significant ($P = 0.135$). Baseline St. George's Respiratory Questionnaire (SGRQ) scores were also comparable across all domains ($P > 0.05$).

Figure 2 shows the adherence levels (good, intermediate, poor) across different groups. The intervention group showed a significant increase in adherence, with 66.7% demonstrating good adherence, compared with only 10% in the control group. On the other hand, poor adherence was much higher in the control group (90%) than in the intervention group (16.7%). Both groups had minimal intermediate adherence. These results emphasize the strong positive effect of the intervention on adherence.

Table 2 demonstrates the types of non-compliance, showing significantly lower rates of sporadic, deliberate, and unconscious non-compliance in the intervention group. Only 16.7% of intervention participants reported sporadic or deliberate non-compliance, compared with 96.7% in the control group ($p < 0.001$ for both comparisons). Unconscious non-compliance was also markedly reduced in the intervention group (30%) versus the control group (93.3%; $P < 0.001$).

Table 3 illustrates the six-month changes in St. George's Respiratory Questionnaire (SGRQ) scores. The intervention group demonstrated a clinically meaningful improvement, with a reduction of 30.39 points (95% CI: −38.09 to −22.69; $P < 0.001$), whereas the control group showed only a slight improvement of 7.99 points (95% CI: 2.30–13.69; $P = 0.008$). After adjusting for baseline values, the between-group difference remained highly significant (adjusted mean difference: −38.22; 95% CI: −46.66 to −29.79; $P < 0.001$). Domain-specific analyses confirmed consistent improvements in the intervention group: symptoms (−30.82; 95% CI: −43.67 to −17.98; $P < 0.001$), activity limitation (−29.49; 95% CI: −36.21 to −22.78; $P < 0.001$), and impact (−45.41; 95% CI: −55.42 to −35.39; $P < 0.001$).

Table 4 illustrates changes in six-minute walk distance (6MWD) from baseline to six months. The intervention group improved significantly from 159.30 ± 88.61 m to 207.78 ± 110.72 m (mean change: +48.48 m; 95% CI: 25.88–71.08; $P < 0.001$), whereas the control group declined from 124.17 ± 91.02 m to 88.77 ± 72.31 m (mean change: −35.39 m; 95% CI: −64.12 to −6.67; $P = 0.017$). The unadjusted between-group difference at six months was 119.00 m (95% CI: 70.67–167.33; $P < 0.001$). After adjustment for baseline values using

ANCOVA, the intervention effect remained robust (adjusted mean difference: 92.83 m; 95% CI: 58.09–127.56; $P < 0.001$).

Discussion

This study found that the structured intervention produced significant improvements in inhaler adherence, patterns of non-compliance, quality of life (QoL), and functional capacity over six months compared with usual care. The absence of significant baseline differences between groups supports the comparability of participants and strengthens confidence that the observed changes were intervention-related.

Poor adherence was highly prevalent at baseline in both groups, reflecting the well-documented challenge of long-term inhaler adherence in chronic respiratory diseases, where sustained adherence to inhaled therapy is often compromised by behavioural, cognitive, and system-related factors, including "treatment fatigue" from prolonged use, incorrect inhaler technique, and poor disease-related knowledge. Non-adherence commonly coexists with these factors, leading patients to underestimate the importance of regular use. Inadequate follow-up support may further contribute to sporadic or unconscious non-compliance. Following the intervention, a substantial proportion of participants achieved good adherence, while poor adherence markedly declined compared with the control group. Improved adherence to inhalers supports the intervention that targeted behavioural, educational, and organizational strategies to improve long-term outcomes [19,20].

In the present study, participants who received the self-management intervention showed a marked improvement in adherence. Good adherence was observed in 66.7% of the intervention group, whereas only 10% of participants in the control group achieved similar adherence, indicating substantially higher non-adherence in the control group.

The intervention effectively addressed all categories of non-compliance—intentional, sporadic, and unconscious. Notably, unconscious non-adherence, often linked to inadequate understanding of inhaler technique or suboptimal patient–provider communication, decreased dramatically in the intervention group, from 96.7% at baseline to 30% after the program. It is consistent with the findings in previous studies that underscore structured self-management approaches are useful in strengthening treatment consistency and minimizing both deliberate and unintentional deviations from prescribed therapy as reported in previous [21-23].

Reduced physical activity is closely associated with diminished quality of life, increased risk of hospital readmission, and higher mortality in individuals with chronic conditions. Therefore, assessing functional endurance is essential when evaluating the impact of self-management strategies [10]. In this study, the Six-Minute Walk Test (6MWT) was utilized as a measure of physical activity and a significant improvement in walking distance was

observed among participants in the self-management group, increasing from 159.30 metres to 207.78 metres, compared to a decline in the usual care group, from 124.17 metres to 88.77 metres. These findings align with those of Ninot et al., and others who reported enhanced walking performance in stable COPD patients following a supervised exercise program [6,12,24,25]. However, it is important to note that their study was conducted in a stable COPD population, whereas the present study focused on patients recovering from acute exacerbations. This distinction is critical, as exacerbated patients often present with greater variability and reduced baseline exercise tolerance, making the observed improvement in the intervention group particularly noteworthy. However, these findings contrast with those reported by Frei et al., who evaluated the long-term impact of a home-based strength training program and found no significant difference in 6MWT distance between groups after 12 months. This divergence may be attributed to the extended 12-month duration, coupled with minimal supervision may have reduced the consistency and intensity of engagement, thereby attenuating measurable gains in exercise tolerance [26].

Health-related quality of life (HRQoL), which is significantly impaired in patients with COPD following exacerbations, was assessed using the St. George's Respiratory Questionnaire (SGRQ). Post-intervention, the self-management group demonstrated a notable improvement, with a substantial reduction in total SGRQ scores (−30.39), compared to a modest change in the control group (mean difference of 7.99). Even after adjusting for baseline HRQoL, the between-group difference remained statistically significant. These outcomes are consistent with findings from the Cochrane review by Schrijver et al.,and others which reported that self-management interventions are associated with improvements in health-related quality of life among individuals following COPD exacerbation [27-29]. These findings contrast with those reported by Aboumatar et al., who found no statistically significant improvement in SGRQ scores [6]. At six months post-discharge, the mean change in total SGRQ score was 2.81 in the intervention group and −2.69 in the usual care group, yielding a non-significant difference. Even after adjustment for hospital unit and baseline SGRQ. This divergence may be attributable to a higher attrition rate in the comparator study, particularly among participants aged over 60, which could affect the reliability and generalizability of its findings [30]. This study is subject to certain limitations. The single-center design with a small sample size restricts the extent to which the findings can be generalized. In addition, the relatively short follow-up period limits conclusions regarding long-term outcomes. Another limitation is the absence of spirometric confirmation of COPD, which may have affected diagnostic precision. Finally, the lack of blinding could have introduced assessment bias.

Conclusions

The self-management program led to improved inhaler adherence, better quality of life, and enhanced exercise tolerance among patients with acute exacerbation of COPD. These findings support the incorporation of structured education, inhaler technique reinforcement, and regular follow-up into routine care. Such interventions can empower patients, reduce symptom burden, and improve functional outcomes in daily life.

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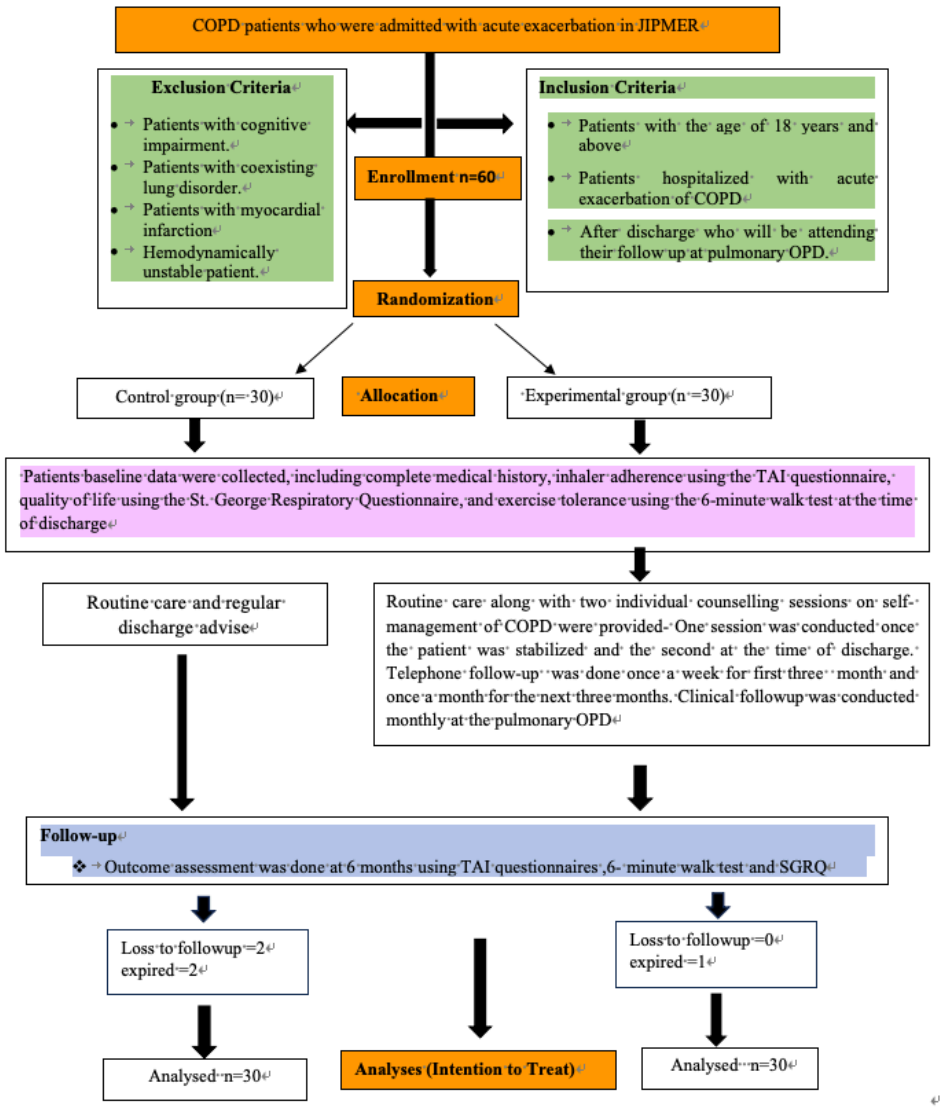

Figure 1. Consort diagram.

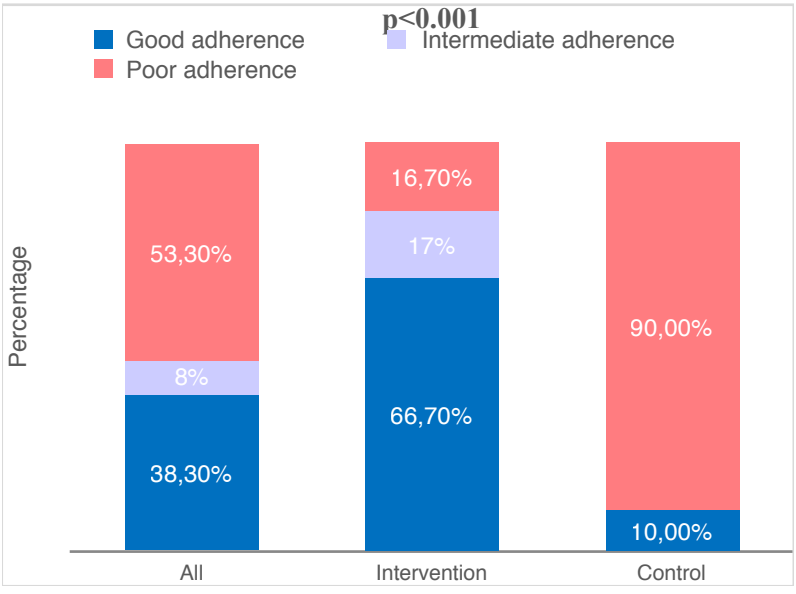

Figure 2. Distribution of inhaler adherence categories (Test of Adherence to Inhalers – TAI) between the study groups following the intervention.

Table 1. Baseline Comparison of inhaler adherence, functional capacity, and quality of life (n=60).

Clinical characteristics	All	Intervention (n=30)	Control (n=30)	p-value
Level of inhaler adherence[1]				
Good adherence	0	0	0	
Intermediate adherence	3 (5)	1 (3.3)	2 (6.7)	1.000
Poor adherence	57 (95)	29 (96.7)	28 (93.3)	
Types of non-compliance[1]				
Sporadic non-compliance	60 (100)	30 (100)	30 (100)	
Deliberate non-compliance	59 (98.3)	30 (100)	29 (96.7)	1.000
Unconscious non-compliance	58 (96.6)	29 (96.7)	29 (96.7)	1.000
Six- minute walk test (metre)[2]	141.73±90.80	159.30±88.61	124.17±91.02	0.135
Quality of life (SGRQ)[2]				
Total score	77.24±12.40	77.36±10.92	77.11±13.92	0.940
Symptoms score	76.01±15.42	75.94±14.35	76.08±16.67	0.970
Activity score	85.79±13.35	85.57±13.27	86.01±13.66	0.900
Impact score	72.74±15.93	73.12±13.67	72.36±18.14	0.860

[1]Frequency(percentage) and Chi-square test; [2]mean ± standard deviation and independent student t-test; $p<0.05$.

Table 2. Comparison of Test of Adherence to Inhalers (TAI) scores (type of non-compliance) between the intervention and control groups following the intervention (n=60).

Types of non-compliance[1]	All, n (%)	Intervention	Control	p-value*
Sporadic non-compliance	34 (56.7)	5 (16.7)	29 (96.7)	<0.001
Deliberate non-compliance	34 (56.7)	5 (16.7)	29 (96.7)	<0.001
Unconscious non-compliance	37 (61.7)	9 (30)	28 (93.3)	<0.001

*Frequency(percentage) and Chi-square, $p<0.05$.

Table 3. Comparative analysis of within-group changes and between-group differences (unadjusted and adjusted) in quality of life following an intervention.

	Intervention Mean ±SD		Control Mean ±SD		Between-group difference			
					Unadjusted[1]		Adjusted[2]	
					Mean difference (95%CI)	p	Mean difference (95%CI)	p
Total SGRQ score								
Baseline	77.36±10.92		77.11±13.92					
At 6 months	46.97±19.88		85.11±12.83		-38.14 (-46.79,-29.49)	<0.001	-38.22 (-46.66,-29.79)	**<0.001**
Within-group difference[3]	**Mean difference**	**p**	**Mean difference**	**P**				
	-30.39 (-38.09,-22.69)	<0.001	7.99 (2.30,13.69)	**0.008**				
Symptoms score								
Baseline	75.94±14.35		76.08±16.67					
At 6 months	55.32±18.69		86.67±15.69		-31.34 (-40.26,-22.42)	<0.001	-30.82 (-43.67,-17.98)	**<0.001**
Within-group difference[3]	**Mean difference**	**P**	**Mean difference**	**p**				
	-20.61 (-29.18,12.04)	<0.001	10.59 (3.04,18.15)	**0.008**				
Activity score								
Baseline	85.57±13.27		86.01±13.66					
At 6 months	65.40±15.08		94.96±10.56		-29.56 (-36.29,-22.42)	<0.001	-29.49 (-36.21,-22.78)	**<0.001**
Within-group difference[3]	**Mean difference**	**p-value**	**Mean difference**	**p-value**				
	-20.17 (-27.04,13.29)	<0.001	8.96 (2.96,14.95)	**0.005**				
Impact score								
Baseline	73.12±13.67		72.36±18.14					
At 6 months	33.83±23.95		78.99±14.74		-45.16 (-55.44,-34.88)	<0.001	-45.41 (-55.42,-35.39)	**<0.001**
Within-group difference[3]	**Mean difference**	**p**	**Mean difference**	**p**				
	-39.29 (-48.66,-29.91)	<0.001	6.63 (-0.26,13.59)	**0.059**				

[1] Independent student t-test, [2]Analysis of Covariance,[3] Paired t-test, p<0.

Table 4. Comparative analysis of within-group changes and between-group differences (unadjusted and adjusted) six-minute walk distance between intervention and control group

	Intervention Mean ±SD		Control Mean ±SD		Between-group difference			
					Unadjusted[1]		Adjusted[2]	
					Mean difference (95%CI)	p	Mean difference (95%CI)	p
Six minute walk distance								
Baseline	159.30±88.61		124.17±91.02					
At 6 months	207.78±110.72		88.77±72.311		119.00 (70.67,167.33)	<0.001	92.83 (58.09,127.56)	**<0.001**
Within-group difference[3]	**Mean difference**	**p**	**Mean difference**	**p**				
	48.48 (25.88,71.08)	<0.001	-35.39 (-64.12,-6.67)	0.017				

[1]Independent student T test, [2]Analysis of Covariance, [3]Paired t test, p<0.05.