

Addressing inhaler technique challenges in cognitively impaired chronic obstructive pulmonary disease patients: the impact of customized training programs

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Abstract

Individuals with chronic obstructive pulmonary disease (COPD) and cognitive impairment (CI) often face difficulties accurately administering inhalers, which are essential for managing their respiratory condition. Many elderly individuals make major errors that prevent proper medication administration. Maintaining proper inhaler use skills is critical in controlling COPD. Our goal was to examine and evaluate the inhaler use skills of CI patients with COPD during both the initial evaluation and subsequent appointments. The Respiratory Department of KLEs Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi, Karnataka, India, was the site of this prospective interventional study. Based on the Montreal Cognitive Assessment Scale (MoCA), a subset of patients with COPD exhibited mild CI. Patients exhibiting improper inhaler-using skills were detected, corrected, and trained. Inhaler techniques were reassessed immediately and at follow-up visits. The modified Medical Research Council scale score (mMRC), COPD Assessment Test (CAT) score, St. George Respiratory Questionnaire (SGRQ), and pulmonary function tests were reassessed. A total of 56 COPD and CI patients who had made at least one significant mistake when using an inhaler device were added to the study. The mean age was 66.89±9.85 years. When evaluated with MoCA, the mean score was 17.02±3.91. At baseline, the mean number of mistakes was 1.38±0.93, which decreased to 0.54±0.57 after face-to-face demonstration of correct inhaler techniques. Correlational analysis revealed MoCA scores were negatively associated with the number of mistakes ($r=-0.344$). At follow-up, the CAT score (25±5.61 vs. 18.48±5.24 $p=0.001$), SGRQ score (53.82±20.59 vs. 37.61±22.17 $p=0.001$), mMRC score (3.21±0.76 vs. 3.20±0.75 $p=0.001$), and forced expiratory volume in 1 second/forced vital capacity score (66.86±9.35 vs. 70.08±9.07 $p=0.001$) had significantly improved in patients demonstrating the correct technique.

Pharmacist-led interventions demonstrated improvements in health-associated quality of life and therapeutic outcomes for individuals with COPD and CI. The study highlighted the importance of cognitive evaluation in routine COPD therapy, identifying potential impediments to effective therapy, and offering face-to-face presentations of inhaler techniques. The best inhalers and methods for COPD patients experiencing CI should be further investigated, according to the study.

Key words: COPD, cognitive impairment, mMRC, CAT, SGRQ, Montreal cognitive assessment scale.

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Introduction

Chronic obstructive pulmonary disease (COPD) is a pressing global health challenge characterized by an increasing mortality rate, ranking as the third leading cause of death worldwide and accounting for more than 5% of all fatalities [1].

In 2019, COPD was projected to be the sixth leading cause of death globally. According to the 2017 Global Burden of Disease research, COPD accounted for 50% of all chronic respiratory illnesses and 69% of years spent with impairments. Developing countries account for more than 90% of COPD-related hospitalizations. In addition to posing a considerable financial burden, COPD diminishes productivity, causes impairment, increases hospital admissions, and increases the chance of premature death [2].

Effective COPD care often involves the use of inhaled medications delivered through devices like metered-dose inhalers (MDIs) and dry powder inhalers (DPIs).

Types of inhalers available in the market are MDIs, DPIs, and soft mist inhalers. MDIs provide a specific dosage of medication, often used with a spacer device, and require careful coordination between breathing and inhaler activation due to the suspension of the medication. Whereas DPIs deliver medicine in the form of a fine powder and are activated by the user's inhalation, no propellant is required. It needs to be inhaled more forcefully and quickly than MDIs. Compared to MDIs, less coordination is required. Turbuhaler is an example of DPIs. Soft mist inhalers represent recent technology that creates a thin medicine mist, making inhalation easier and reducing the need



for propellants. This allows more medication to enter the lungs effectively.

Management of COPD also involves bronchodilators, corticosteroids, pulmonary rehabilitation programs, oxygen therapy, and smoking cessation support. Inhaled treatment is preferred over oral administration due to its precise transfer of active molecules and quick onset of action, reducing the adverse effects of the drug [2].

Patients with COPD, particularly patients with cognitive decline or motor/sensory impairments, have difficulty managing inhaler devices, which are the primary method of treating pulmonary blockage.

This highlights the need for interventions that can improve inhaler technique and potentially mitigate the negative impact of COPD on cognitive function and health-related quality of life (HRQoL).

Certainly, research conducted by Dal Negro *et al.* depicted that chronic lung diseases increase cognitive impairment (CI), potentially due to decreased oxygen delivery, deteriorating brain neurons, and delayed recall and attention [3]. A meta-analysis by Yohannes *et al.* found that 1 in 4 chronic lung patients have mild CI, while 32% experience moderate CI [4].

Chronic lung disease, especially when combined with improper inhaler skills, can also contribute to cognitive dysfunction. Extrapulmonary manifestations, such as reduced oxygenation, persistent pulmonary obstructive disorder, and cardiovascular diseases, can also lead to CI. Age and smoking are risk factors for cognitive decline [1,4].

Inhaler device handling can be challenging for patients with persistent lung disease, especially those with cognitive decline. Montreal Cognitive Assessment Scale (MoCA) and inhalational techniques assessment are used to reduce errors [3].

The study by Arora *et al.* on 188 bronchial asthma patients found that only 17.7% showed correct inhalation technique, with 94.3% using MDI and 82.3% using DPI. This highlights the prevalence of critical inhalation errors, causing increased hospitalization and poor disease control [5].

Hongyu Qian *et al.*'s study found that patients with stable COPD scored less on the MoCA test, with severe COPD patients showing lower scores (MoCA score <10). Age and partial pressure of carbon dioxide negatively correlated with cognitive dysfunction [6].

Chronic pulmonary diseases with cognitive dysfunction combined with improper inhaler skills lead to higher mortality and decreased treatment adherence, necessitating a comprehensive examination of psychological, physical, and social aspects to enhance patient quality of life.

The COPD Assessment Test (CAT) serves as a crucial marker for monitoring daily symptoms in COPD patients. Changes in CAT scores can provide valuable insights into their health status and potentially identify impending COPD exacerbations. Hospitalizations are often linked to a substantial rise in CAT scores. The Respiratory Questionnaire from St. George's University of London (SGRQ) is a well-known and often used tool for assessing HRQoL in respiratory patients [7]. Ahmed *et al.*'s study revealed that 124 COPD patients experienced reduced quality of life, with the symptom domain being most negatively affected. Severe COPD stages lead to a lower quality of life [8].

The present study aimed to assess inhaler skills of COPD patients having MCI immediately after training and at a follow-up visit. To investigate the potential benefits of improved inhaler technique, this study evaluated the impact of a clinical pharmacist-led inhaler use training program on patients with COPD and

mild CI. Furthermore, this study explored the broader impact of this intervention by examining its effect on HRQoL in this patient population.

Materials and Methods

Study design

A prospective interventional study was conducted at KLEs Dr. Prabhakar Kore Hospital in Belagavi, Karnataka, India, from September 2023 to May 2024. We recruited participants aged 45 years and older with COPD having CI, with a mean age of 66.89 ± 9.85 years [standard deviation (SD)]. All participants were on regular maintenance inhaler therapy, using either one or more pressurized MDI or DPI devices.

Only participants who exhibited at least one incorrect maneuver in their inhaler technique were eligible to participate. Patients with a history of head injury or brain tumor, epilepsy, or substantial kidney or liver disease were excluded.

The KLE COP Ethics Committee in Belagavi approved the study protocol (reference number-KLECOPBGM/EC/D005-2023). Each subject provided written informed consent prior to enrolment. The study comprised i) a MoCA scale to test cognition levels in COPD patients; ii) standardized evaluations of inhaler handling to be conducted for COPD patients with CI; iii) CAT questionnaire to assess symptom burden to be completed by the patient; iv) HRQoL was assessed using the SGRQ, while pulmonary function tests were conducted to measure [forced expiratory volume in 1 second (FEV1)] and forced vital capacity (FVC)]. These parameters were re-assessed at the follow-up. Participants underwent a validated MoCA, with scores below 26, indicating mild CI, as administered by a trained professional. COPD patients with a MoCA score below 26 underwent an inhaler technique assessment compared to National Heart, Lung, and Blood Institute guidelines, identifying critical errors and providing face-to-face instruction using dummy inhalers. To accurately assess the number of errors made by COPD patients with CI, 10 phases of the inhaling procedure were outlined for each inhaler and graded as correct or incorrect. Participants were evaluated to determine the acuteness of breathlessness or dyspnea in individuals with COPD and mild CI using the modified Medical Research Council (mMRC) dyspnea scale. Each statement is associated with a rating, ranging from 0 to 4, with a higher rating indicating more breathing distress. The CAT quantified symptoms and their impact on daily functioning, ranging from 0 to 40, assessing severity and monitoring effects over time. To assess quality of life in respiratory patients, SGRQ was used, consisting of three domains: symptoms (severity and frequency of symptoms), activity (limitations on physical activities), and impacts (emotional and social effects). A total score represents a projection of respiratory health. Each component is scored on a scale of 0-100, with a greater number indicating poor health. The impact of face-to-face demonstration and correction of critical errors with the help of dummy inhalers was assessed through a re-evaluation of inhaler techniques during follow-up at the Outpatient Department. The process also involved reassessing improvement in patient HRQoL using the SGRQ and mMRC. Additionally, a comparison of the baseline values of pulmonary function tests (PFT) and CAT, SGRQ scores, number of mistakes, and mMRC was done at the time of follow-up. This comparison provides valuable insights into any changes or improvements in lung function that may have occurred as a result of intervention.



Outcomes

The mitigation of CI through proactive measures involves testing with the Montreal Cognitive Assessment Scale, stalling or deferring the disease's underlying processes, and addressing any functional deficits that might interfere with COPD therapy. Following inhaler technique tutorials in person and the correction of handling errors, patients with mild CI showed improvements in their inhaler usage. The SGRQ revealed a significant increase in HRQoL among COPD patients following pharmacist intervention.

Statistics analysis

Statistical analysis was performed using IBM SPSS 27 (Armonk, NY, USA). Continuous variables were summarized as mean \pm SD, and categorical variables as frequencies and percentages.

Descriptive statistics of the interested variables were computed. To compare mean of different groups, the analysis of variance test was implemented. Comparison of continuous variables with pre-post outcomes was done by pair t-test. To check the linear relationship between two continuous variables, Pearsons Correlation test was used.

Results

The study enrolled 56 individuals, comprised of 39 men and 17 women. Table 1 depicts the demographic details of the study. Participants in this study had a mean age of 66.89 \pm 9.85 years (SD). According to mMRC, one patient was classified as GRADE I, eight as GRADE II, 26 as GRADE III, and 23 as GRADE IV. Amongst the study population, 25 used MDI and 31 used DPI. In comorbidities, most of the patients had hypertension, 28.6% (n=16), the least prevalent were ischemic heart disease [3.6% (n=2)] and post-tuber-

culosis obstructive airway disease [3.6% (n=2)]. The mean MoCA score among COPD patients assessed with the MoCA was 17.02 \pm 3.91. Patients among the study population identified with moderate CI (MoCA score 11-17) were 50% (n=28), and the least prevalent patients with severe CI (MoCA score \leq 10) were 7.1% (n=4). The average number of errors decreased significantly from 1.38 \pm 0.93 at baseline to 0.54 \pm 0.57 after the intervention. The number of mistakes performed by both males and females in the pre-test was 1.41 \pm 0.97 and 1.29 \pm 0.85, respectively. After successful demonstration of correct inhaler techniques, the number of mistakes decreased significantly in both males and females, 0.51 \pm 0.56 and 0.59 \pm 0.62, respectively (Figure 1). A negative association between MoCA scores and the number of mistakes at baseline ($r=-0.344$, $p=0.009$) is observed. The average number of mistakes made by par-

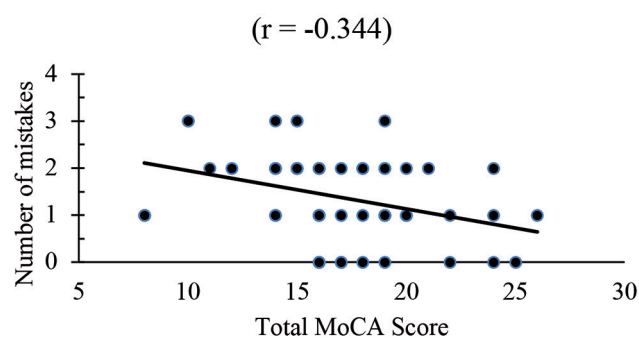


Figure 1. Correlation between Montreal Cognitive Assessment (MOCA) score and number of mistakes.

Table 1. Frequency distribution of the study variables.

Variable	Characteristics	n	%
Gender	Male	39	69.6
	Female	17	30.4
Age group (in years)	45-54	6	10.7
	55-64	13	23.2
	65-74	26	46.4
	75-84	9	16.1
	85-94	2	3.6
Comorbidities	No	19	33.9
	BA	2	3.6
	HTN	16	28.6
	IHD	2	3.6
	T2DM	6	10.7
	Post-TB	2	3.6
	HTN+T2DM	9	16.1
Duration of COPD code (in years)	1	8	14.3
	2	11	19.6
	3	9	16.1
	4	10	17.9
	5	6	10.7
	>6	12	21.4
Type of inhalation	MDI	28	50
	PMDI	28	50

BA, bronchial asthma; HTN, hypertension; IHD, ischemic heart disease; T2DM, type 2 diabetes mellitus; TB, tuberculosis; COPD, chronic obstructive pulmonary disease; MDI, metered-dose inhaler; PMDI, pressurized metered-dose inhaler.



Participants with severe CI (n=4) was 2.00 (SD=1.15), whereas the average number of mistakes for participants with moderate impairment (n=28) and mild impairment (n=24) was 1.46 (SD=0.96) and 1.17 (SD=0.82), respectively. Figure 2 depicts that upon entry into the study, the median CAT score was 25 (minimum-maximum: 21-29), and the post-intervention score was 18 (minimum-maximum: 16-22). Median difference in CAT score pre- and post-intervention was 6.5 (p<0.05). FEV1/FVC values during pre-test were 67 (minimum-maximum: 52-82), and post-test were 69.5 (minimum-maximum: 55-84). Hence, the above figure describes those median values of FEV1/FVC after intervention was found to be significant by 2.5 (p<0.05). In particular, the average MoCA score for those who made no mistakes was 18.73±3.38, while the mean score for those who made one mistake was 17.63±4.56. Comparably, the average score for those who committed two errors was 16.45±3.12, and the average score for those who committed three errors was 13.83±3.43. The mean total MoCA scores were decreased, indicating cognitive decline as the number of mistakes was increased from 18.73 for 0 mistakes to 13.83 for 3 mistakes (Figure 3). The comparison of

before and post-test errors shows considerable improvement following intervention (p<0.05), with the median range of errors decreasing from 1 to 0.5. Figure 4 presents median SGRQ scores post-test was 36 (minimum-maximum: 19-59), whereas in the pre-test it was 57 (minimum-maximum: 38-76). The median score for the SGRQ's symptom domain was 38 in the post-test, with a range of 5 to 8. After intervention, the symptom domain score decreased significantly (p<0.05) by a median of 10.0. Median activity domain score of SGRQ at the time of pre-test was 75 (minimum-maximum: 21-100). At the time of post-test, the median activity domain score of SGRQ was 39.5 (minimum-maximum: 7.5-100). Decrease in median activity domain score of SGRQ after intervention was 35.5 (p<0.05). Median impact domain score of SGRQ at pre-test was 42.5 (minimum-maximum: 2.5-82) and at the post-test was 22, with a range of 5 to 78. After the intervention, the impact domain score of SGRQ decreased significantly (p<0.05) by a median of 20.5. Figure 5 shows the correlation between MoCA scores and SGRQ scores is -0.120. This indicates a negative correlation. Correlation analysis between SGRQ scores and the average number of errors was done.

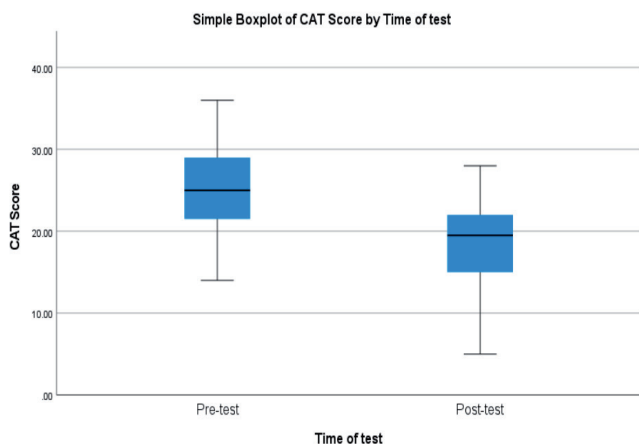


Figure 2. Distribution of chronic obstructive pulmonary disease assessment test (CAT) scores by pre-test and post-test performance.

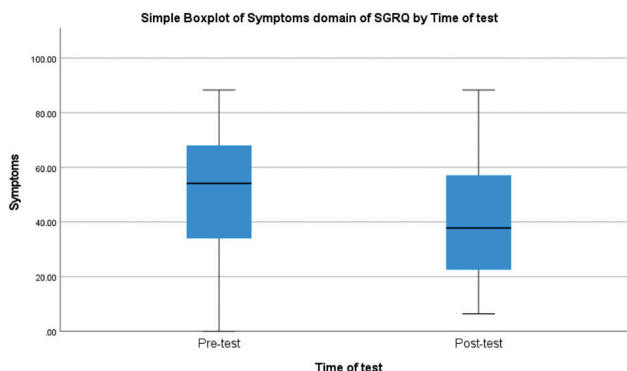


Figure 4. Distribution of symptom domain scores by pre-test and post-test performance. SGRQ, St. George Respiratory Questionnaire

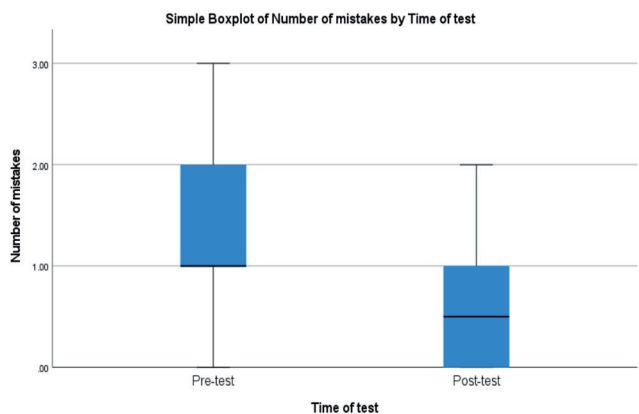


Figure 3. Variability in number of mistakes across pre-test and post-test groups.

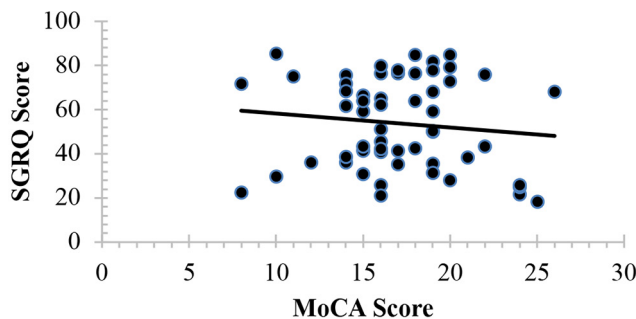


Figure 5. Correlation between Montreal Cognitive Assessment (MOCA) and St George Respiratory Questionnaire (SGRQ) scores.



At baseline mean SGRQ score was 53.82 (SD=20.59), whereas at post-test was 37.61 (SD=22.17). When correlating PFTs with the number of inhaler mistakes, the mean FEV1/FVC ratio increased significantly from 66.86 (SD=9.35) in the pre-test group to 70.08 (SD=9.07) in the post-test group. The study revealed a significant correlation between CAT scores and the number of inhaler mistakes, with an average CAT score of 25.04 (SD=5.61) and a mean of 1.38 errors at baseline.

Post-intervention CAT score was 18.48 (SD=5.24), and the mean number of mistakes was 0.54.

Discussion

The efficiency of inhaler therapy in COPD patients with CI is hampered by several errors. By identifying and addressing crucial mistakes, individuals using various inhaler devices had a significant fall in errors, as seen by a median reduction from 1 to 0.53 ($p<0.05$). As indicated by the differences in CAT, SGRQ, and PFT scores, this corresponded with an improvement in the severity of symptoms. These findings align with previous research, confirming the effectiveness of in-person training for enhancing inhalation performance [3,5,9].

Assessment of inhaler techniques at baseline revealed that patients with CI were more prone to making mistakes. These findings underscore the need for ongoing assessment, repeated training, and tailored device selection to optimize inhaler use in this vulnerable patient population.

In previous research, Luley *et al.* and Kon identified a two-point decrease in the CAT score, which was defined as the minimum clinically important difference. Therefore, the current study's lowering of the median CAT score by 6.5 points is classified as clinically significant [4,9].

FEV1/FVC also increased by 2.5 points. Despite a significant reduction in SGRQ scores, indicating fewer respiratory symptoms post-intervention, the mMRC score did not show substantial improvement, highlighting the non-reversible nature of COPD as a lung disease. These findings align with the research by Farag *et al.* Additionally, the number of inhaler technique errors decreased, indicating improved inhaler proficiency.

The intervention effectively improved both respiratory health and inhaler technique, leading to better HRQoL. The study

revealed that COPD patients with moderate CI are most affected, with 50% of the population ($n=28$) making more mistakes in inhaler technique compared to those with mild impairment, highlighting the impact of CI on inhaler technique. Simplified inhaler devices, personalized training, memory aids, caregiver support, cognitive stimulation, and comprehensive care are essential for patients with respiratory and cognitive health issues. Potential interventions for this age group include a comprehensive approach to inhaler care, including tailored education programs, technology-assisted reminders, caregiver training, multi-sensory training, regular follow-ups, cognitive rehabilitation, simplified medication regimens, environmental modifications, peer support groups, and interdisciplinary care teams, all designed to support proper inhaler use. The current study found that cognitive function had a detrimental impact on inhaler use, with lower MoCA scores suggesting poorer cognitive ability and being associated with a higher risk of inhaler errors [10]. The MoCA domains that exhibited the most significant decline in our study were delayed recall, abstraction, and language. These findings were consistent with the results reported by Iamthanaporn *et al.* and Luley *et al.*

The current research sought to investigate the influence of clinical pharmacist intervention on inhaler usage skills, health-related well-being, CAT score, mMRC, FEV1/FVC values, and SGRQ. Similar to the findings of other studies [1-3,11-16], the current study shows that CI is connected with inappropriate inhalational procedures in older COPD patients. The current research indicates that dyspnea symptoms, as measured by the mMRC score, did not significantly improve following the intervention. Nonetheless, CAT scores, SGRQ scores, and PFT values showed considerable improvement from baseline to post-intervention in patients with COPD and CI, aligning with the findings of Iamthanaporn *et al.*, Luley *et al.*, and Gil *et al.* [4,17,18].

Supporting the conclusions of Gil *et al.* and Farag *et al.* [17,18], significant improvement was observed in CAT scores (25.04±5.61 vs. 18.66±5.6, $p=0.001$), SGRQ scores (53.82±20.59 vs. 37.61±22.17, $p=0.001$), and FEV1/FVC (66.86±9.35 vs. 70.08±9.07, $p=0.001$) when compared with baseline values of the study participants (Table 2).

Similar to the findings of Siraj *et al.* and Henkle *et al.* [1,3], there was no noticeable improvement observed in the mMRC score. Dyspnea score (mMRC scale score) did not improve significantly (3.21±0.76 vs. 3.20±0.75).

Table 2. Impact of intervention by comparing various parameters (before intervention), such as inhalational techniques, chronic obstructive pulmonary disease assessment test, St George Questionnaire respiratory, health-related quality of life, pulmonary function tests (forced expiratory volume in 1 second/forced vital capacity), and modified Medical Research Council Scale, and dyspnea score with those at the time of follow-up.

Variable	Pre-test		Post-test		p
	Mean	SD	Mean	SD	
COPD Assessment Test	25.04	5.61	18.48	5.24	0.001*
St George Questionnaire	53.82	20.59	37.61	22.17	0.001*
Symptoms domain	51.75	20.47	41.23	21.7	0.001*
Activity domain	69.34	21.21	47.32	27.72	0.001*
Impact domain	45.82	23.97	30.34	23.06	0.001*
Modified Medical Research Council Scale	3.21	0.76	3.2	0.75	0.568
FEV1/FVC	66.86	9.35	70.08	9.07	0.001*
Number of mistakes	1.38	0.93	0.54	0.57	0.001*

COPD, chronic obstructive pulmonary disease; FEV1, forced expiratory volume in 1 second; FVC, forced vital capacity; SD, standard deviation; *



Previous studies investigating the effects of inhaler training on dyspnea, health, and quality of life have varied in duration, but their findings generally align with those of earlier research [3,19,20].

This study has several limitations; in particular greater sample size would have allowed for more data to be compared within the domains, making the study more successful. Additionally, a longer time period may be required to conduct the study to establish maximum efficacy. The study's 56 participants limit its statistical power and depth of analysis. The study's limitations include a small sample size, which limits statistical power and subgroup analyses. The short duration of the study restricts our understanding of long-term effects, sustainability, and impact on health outcomes. Additionally, the lack of assessment of training effect duration prevents us from understanding how long skills are retained, optimal reinforcement schedules, individual differences, and cost-effectiveness considerations.

Conclusions

Examining inhaler management proficiency in COPD patients with neurocognitive decline, alongside investigating the impact of a pharmacist-led intervention, resulted in improved HRQoL, therapy outcomes, and enhanced COPD management strategies. Research suggests that individuals with COPD are at increased risk of CI (MoCA<26), which may lead to the incorrect use of inhalers.

When severe errors in inhaler handling are rectified in COPD patients with CI, their health-associated quality of life improves.

This study optimizes patient outcomes through recognizing potential impediments to effective therapy and additionally offering face-to-face presentations of inhaler techniques.

The study emphasizes the value of including cognitive evaluation in routine COPD therapy to improve treatment results and quality of care in COPD patients with CI.

Assessment of cognitive function, appraisal of correct inhaler techniques, identification of errors while using inhalers, and face-to-face demonstration of right inhaler techniques all help to enhance COPD management. This strategy provided significant benefits to patients with CI.

Further research is imperative to discover the best inhalers and procedures for COPD patients with cognitive decline, as well as how long patients with CI can continue proper inhaler techniques. Long-term studies that use years of data for long-term follow-up would be useful in assessing how long-lasting changes in inhaler technique and quality of life are maintained after an intervention, as well as for establishing the best frequency for reinforcement training. Technology-assisted training will help investigate how well tech-based therapies (such as virtual reality and smartphone apps) can help patients with cognitively impaired COPD improve their inhaler technique. Cost-effectiveness analysis would evaluate the financial benefits of inhaler technique training programs for individuals with cognitively impaired COPD, focusing on reducing hospital stays and improving outcomes.

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Conflict of interest: the authors declare that they have no competing interest, and all authors confirm accuracy.

Ethics approval and consent to participate: the study protocol was approved by the KLE COP Ethics Committee Belagavi (reference number KLECOP-BGMEC/D005-2023).

Informed consent: written informed consent was obtained from each participant before enrolment.

Patient consent for publication: obtained.

Availability of data and materials: raw data were generated at KLEs Dr Prabhakar Kore Hospital and MRC Belagavi, Karnataka. Derived data supporting the findings of this study are available from the corresponding author. Data was collected anonymously.

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