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

Vaishnavi V Gaonkar, Vinay V Shanbhag, Shreya S Kajave,
Mahek R Mattikop, Mandati Santhosh Reddy

Department of Pharmacy Practice, KLE College of Pharmacy, Belagavi, KLE Academy of Higher Education and Research, Karnataka, India

Correspondence: Mandati Santhosh Reddy, Department of Pharmacy Practice, KLE College of Pharmacy, KLE Academy of Higher Education and Research, Belagavi, Karnataka, India.
Tel.: 7349022785. E-mail: mandatisanthoshreddy954@gmail.com

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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 medicine 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, 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.

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 (GBD) 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 hospitalisations. 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).

Type of inhalers available in the market are Metered-dose inhalers (MDIs), Dry powder inhalers (DPIs), 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 is activated by the user's inhalation, no propellant is required. 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 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 HRQoL.

Certainly, research conducted by Dal Negro et al depicted chronic lung diseases increase cognitive impairment, 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 cognitive impairment, while 32% experience moderate cognitive impairment [4].

Chronic lung disease, especially when combined with improper inhaler skills, can also contribute to cognitive dysfunction. Extra pulmonary manifestations, such as reduced oxygenation, persistent pulmonary obstructive disorder, and cardiovascular diseases, can also lead to cognitive impairment. 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. MoCA and inhalational techniques assessment are used to reduce errors [3].

The study by Arora P 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 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 PaCO2 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 life quality.

The 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. Respiratory Questionnaire from St. George's University of London 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 symptom domain being most negatively affected. Severe COPD stages lead to lower QoL [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 cognitive impairment. 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 Chronic Obstructive Respiratory Disease having CI, with a mean age

of 66.89 ± 9.85 years (SD). All participants were on regular maintenance inhaler therapy, using either one or more pressurized Metered-Dose Inhalers or Dry Powder Inhaler devices.

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

The KLE COP Ethics Committee in Belagavi granted approval for the study protocol (reference number-KLECOPBGMEC/D005-2023). Each subject provided written informed permission prior to enrolment. The study comprised of a) a MoCA scale to test cognition levels in COPD patients and b) Standardized evaluations of inhaler handling to be conducted for COPD patients with cognitive impairment. c) CAT questionnaire to assess symptom burden to be completed by the patient d) Health-related quality of life [HRQoL] was assessed using the St.GRQ, while pulmonary function tests were conducted to measure (FEV1) and (FVC).These parameters were re-assessed at the follow-up. Participants underwent a validated MoCA, with scores below 26, indicating mild cognitive impairment, 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 (NHLBI) 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 dyspnoea in individuals with COPD & mild cognitive impairment using the mMRC-Dyspnoea scale. Each statement is associated with a rating, ranging from 0 to 4, higher rating indicating more breathing distress. The COPD Assessment Test (CAT) quantified symptoms and their impact on daily functioning, ranging from 0 to 40, assessing severity and monitoring effects over time. To assesses 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 Out Patient Department (OPD). The process also involved reassessing improvement in patient HR-QoL using the SGR-Questionnaire and mMRC. Additionally, a comparison of the baseline values of pulmonary function tests (PFT) and CAT, SGRQ scores, Number of Mistakes, 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 cognitive impairment through proactive measures, which 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 cognitive impairment showed improvements in their inhaler usage. The St. George's Questionnaire revealed a significant increase in HRQoL among COPD patients following pharmacist intervention.

Statistics analysis

Statistical analysis was performed using IBM SPSS 27. Continuous variables were summarized as mean ± standard deviation, and categorical variables as frequencies and percentages.
Descriptive statistics of the interested variables were computed. To compare mean of different groups, ANOVA test was implemented. Comparison of continuous variables with pre-post outcomes were 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 ± 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 having Hypertension 28.6% (n=16), least prevalent were IHD (Ischemic Heart Disease) 3.6% (n=2) and Post TB OAD (Post Tuberculosis Obstructive Airway Disease) 3.6% (n=2). The mean MoCA score among COPD patients assessed with Montreal Cognitive Assessment Scale was 17.02±3.91. Patients amongst the study population identified with moderate cognitive impairment (MoCA score 11-17) were 50% (n=28), and least prevalent patients with severe cognitive impairment (MoCA score <=10) were 7.1% (n=4). The average number of errors decreased significantly from 1.38 ± 0.93 at baseline to 0.54 ± 0.57 after the intervention. No. of mistakes performed by both males and females in pre-test was 1.41±0.97 and 1.29±0.85, after successful demonstration of correct inhaler techniques the number of mistakes decreased significantly in both males and females, 0.51±0.56 and 0.59±0.62 respectively (Figure 1). Shows a negative association between MoCA scores and number of mistakes at baseline (r=-0.344, p=0.009).The average number of mistakes made by participants with severe cognitive impairment (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, median CAT score was 25 (minimum-maximum: 21-29) and 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 was 67(minimum-maximum: 52-82) and post-test was 69.5(minimum-maximum: 55-84). Hence the above figure describes those median values of FeV1/FVC after intervention was found out 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 mean score for those who made one mistake was 17.63 ± 4.56. Comparably, 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 were 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), where in pre-test it was higher 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, median activity domain score of SGRQ was 39.5 (min – max: 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 average number of errors was done. 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 mean number of mistakes was 0.54.

Discussion

The efficiency of inhaler therapy in COPD patients with cognitive impairment 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 cognitive impairment were more prone to conducting 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 M et al and Kon SS identified a two-point decrease in CAT score, which was defined as the Minimum Clinically Important Difference (MCID). Therefore, the current study's lowering of median CAT score by 6.5 points classifies 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 cognitive impairment 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 cognitive impairment on inhaler technique. Simplified inhaler devices, personalized training, memory aids, caregiver support, cognitive stimulation, and comprehensive care is essential for patients with respiratory and cognitive health issues. Potential interventions for this age group include 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 Chonnipha 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 St

George Questionnaire. Similar to the findings of other studies [1-3,11-16], the current study shows that cognitive impairment 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 shown considerable improvement from baseline to post-intervention in patients with COPD and CI, aligning with the findings of Chonnipha Iamthanaporn et al, Luley et al. and Gil HI 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), 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. Dyspnoea score (mMRC scale score) did not improve significantly [3.21±0.76 vs 3.20±0.75].

Previous studies investigating the effects of inhaler training on dyspnoea, 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 cognitive impairment (MoCA <26), which may lead to the incorrect use of inhalers.

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

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

The study emphasises the value of including cognitive evaluation into routine COPD therapy to improve treatment results and quality of care in COPD patients with cognitive impairment. Assessment of cognitive function, appraisal of correct inhaler techniques, identification of errors while using inhalers, and face-to-face demonstration of right inhaling techniques all help to enhance COPD management. This strategy provided significant benefits to patients with cognitive impairment.

Further research is imperative to discover the best inhalers and procedures for COPD patients with Cognitive Decline, as well as how long the patient with cognitive impairment 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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Table 1. Frequency distribution of the study variables.

Variable		n	%
Gender	**Male**	39	69.6
	Female	17	30.4
Age group	**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	**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

Table 2. Impact of intervention by comparing various parameters (before intervention), such as inhalational techniques, COPD Assessment test, St George Questionnaire respiratory, health related quality of life, pulmonary function tests (FEV1/FVC) and modified Medical Research Council Scale, and dyspnoea score with those at the time of follow up.

Variable	Pre test		Post test		p value
	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*

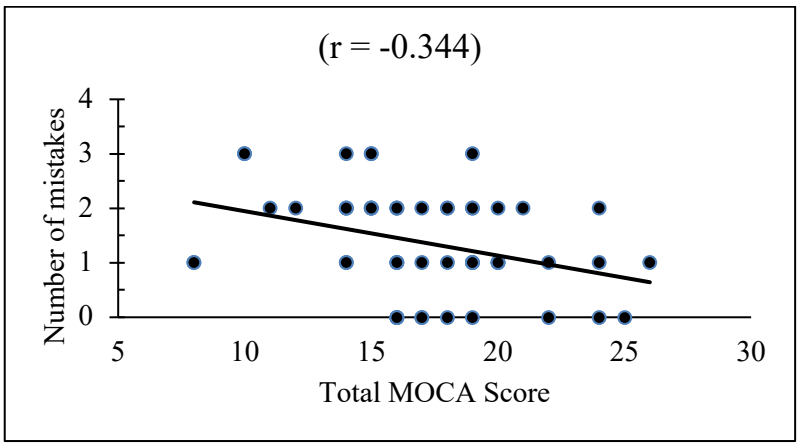

Figure 1. Correlation between Montreal Cognitive Assessment score and number of mistakes.

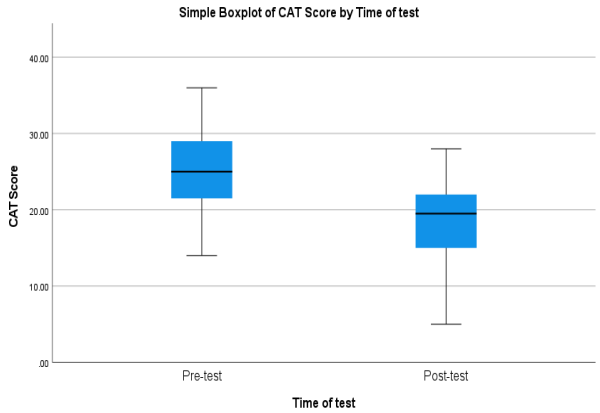

Figure 2. Distribution of chronic obstructive pulmonary disease assessment test scores by pre-test and post-test performance.

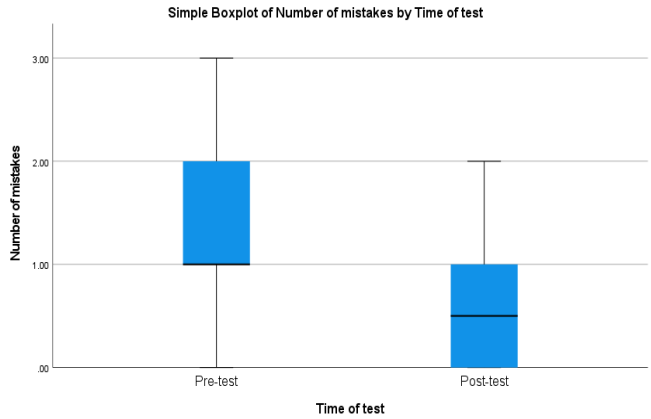

Figure 3. Variability in number of mistakes across pre-test and post-test groups

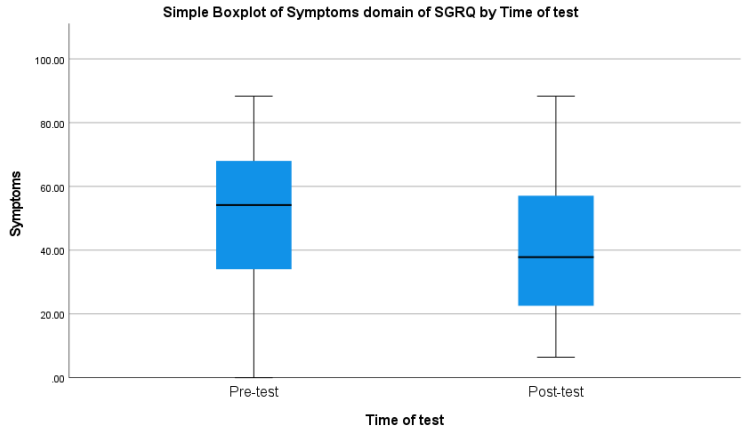

Figure 4. Distribution of symptom domain scores by pre-test and post-test performance.

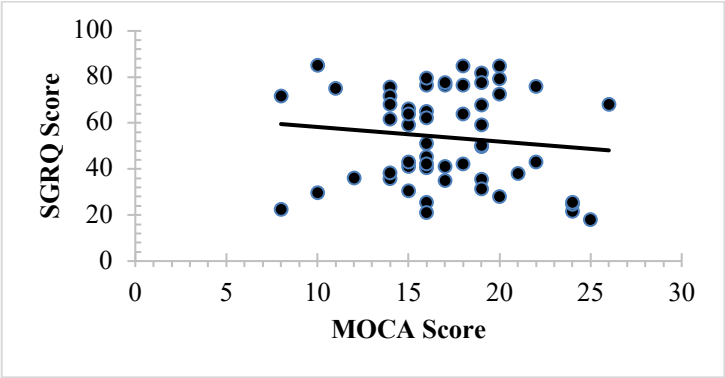

Figure 5. Correlation between Montreal Cognitive Assessment and St George Respiratory Questionnaire scores.