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ORIGINAL ARTICLE – OPEN ACCESS

Effect of Inhaler Training on Self-Care Agency and Self-Efficacy of COPD Patients: A Randomized Controlled Trial

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ABSTRACT

Objective: The aim of this randomized controlled trial was to investigate the effect of inhaler technique training on the self-care agency and self-efficacy level of patients with chronic obstructive pulmonary disease (COPD).

Materials and Methods: Sixty-seven patients were randomized and recruited. Thirty-four patients were allocated to an intervention group and 33 to a control group. The study data were collected using a questionnaire form, the COPD Self-Efficacy Scale (CSES), the Exercise of Self-Care Agency Scale (ESCAS), the Medical Research Council Dyspnea Scale, and the modified Borg Dyspnea Scale. Interim and final follow-up was conducted with both groups 1 month and 3 months after the initial visit.

Results: In the final follow-up, it was observed that the majority of the patients (91.2%) in the intervention group used their inhaler drugs correctly. The intervention group dyspnea scores were better than those of the control group ($p<0.05$). In addition, the mean score of all subdimensions of the CSES and the total ESCAS score showed increased in the intervention group ($p<0.05$).

Conclusion: The findings indicated that inhaler training reduced the incorrect use of inhaler medication and the dyspnea experienced patients with COPD, and also improved self-care agency and self-efficacy.

Keywords: Chronic obstructive pulmonary disease, inhaler training, self-care agency, self-efficacy, randomized controlled trial

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INTRODUCTION

The primary symptom of chronic obstructive pulmonary disease (COPD) is dyspnea, which can lead to insufficient ability to practice adequate self-care (1). As self-care agency decreases, the level of self-efficacy typically also decreases (2) as well as quality of life (3). The respiratory difficulties associated with COPD can contribute to a lack confidence in the ability to perform certain activities, and low self-efficacy impedes productivity (4, 5). Diminished self-efficacy can significantly hinder even patients who are physically capable, reducing their ability to perform activities of daily living. The breathing difficulties that COPD patients experience can be a significant factor in the development of low self-efficacy, reduced quality of life, and capacity for self-management (2, 6, 7). Patients with high self-efficacy demonstrate greater treatment adherence and life satisfaction (8). Adequate symptom management can increase the self-care agency and self-efficacy of individuals with COPD, and represents an important treatment consideration.

The medication in short-acting bronchodilator inhalers can significantly reduce COPD symptoms and is typically the first choice of treatment, due to the effectiveness of small doses, given that the medication is delivered directly to the airway, and the limited systemic side effects (9). However, proper use technique is important, since incorrect use of inhalers can fail to control the symptoms (1). Improper use is an acknowledged problem. Incorrect adherence or inhaler use technique reduces the treatment benefits and can contribute to additional consequences. Studies have shown that inhalers were used incorrectly and irregularly at a rate of 21% to 91% (10, 11).

Nurses often have a significant role in COPD management services (12). Some programs have demonstrated success with individualized training and guidance about how to control symptoms, reduce or prevent complications, and promote self-efficacy (2, 13, 14). Previous studies have indicated that 10% to 25% of patients using inhaler medications did not receive any training from healthcare personnel (15). Research has suggested that following education on proper use, errors in inhaler use were reduced, the medications began to show the desired effect, disease symptoms decreased, and treatment compliance increased (1). Patient self-care and self-efficacy could be expected to improve due to the alleviation of symptoms, particularly reduced dyspnea. The aim of this study was to evaluate the effect of inhaler use training on self-care and self-efficacy levels in patients diagnosed with COPD.

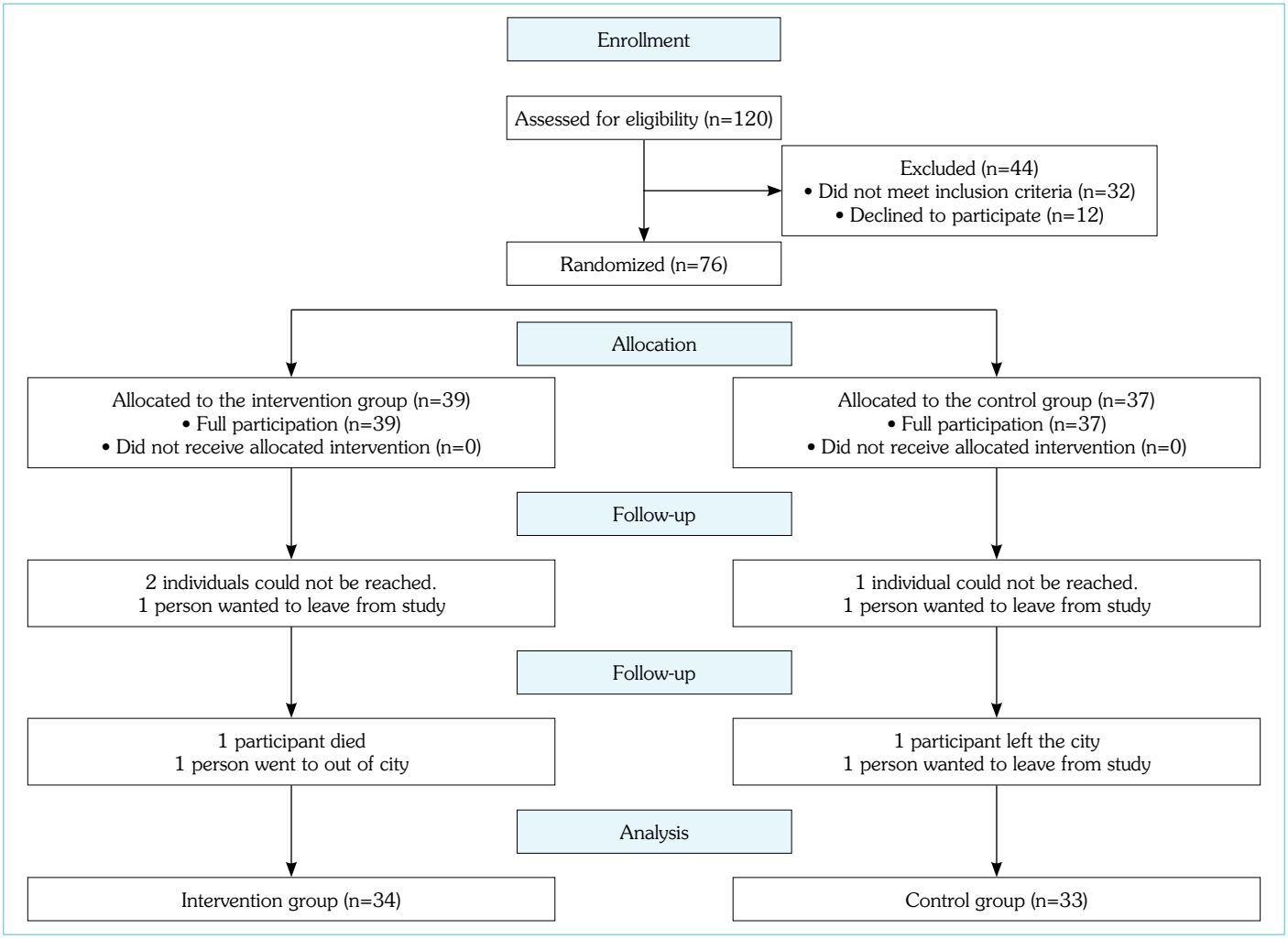

Figure 1. The CONSORT flowchart of the study

Research Hypotheses

$H0_1$: Inhaler training given to COPD patients does not improve self-care agency.

$H1_1$: Inhaler training given to COPD patients improves self-care agency.

$H0_2$: Inhaler training given to COPD patients does not improve the level of self-efficacy.

$H1_2$: Inhaler training given to COPD patients improves the level of self-efficacy.

MATERIALS and METHODS

Ethical Dimensions of the Study

The study was approved by the Nevşehir Hacı Bektaş Veli University Ethics Committee (no: 2017.08.06) and the Turkish Ministry of Health also reviewed and approved the study protocol. Written consent was obtained from the participants.

Study Design

This research was designed as a randomized clinical trial according to the CONSORT (Consolidated Standards of Reporting Trials) guidelines (16) and the study was registered with the US National Library of Medicine database of clinical trials (ClinicalTrials.gov identifier: NCT04052906). Since no other studies of the same design were found, data from similar studies were used to determine a need for a minimum of 60 patients, with 30 in the study group and 30 in the control group (17). The final study group comprised a total of 67 subjects: 34 in the study group and 33 in the control group. The power of the study was calculated using G*Power 3 software (Faul, F., Erdfelder, E., Lang, A.-G., & Buchner, A.) (18). The effect size was calculated to be 2.262, α=0.05, and the post power of the study was 99.9%. The research was conducted at Ömer Halisdemir University Training and Research Hospital in Niğde, Turkey between November 1, 2017 and May 1, 2018 (Fig. 1).

Inclusion Criteria

Literate

Diagnosis of COPD at least 6 months prior and use of an inhaler for at least 3 months

Moderate or severe COPD, according to Global Initiative for Obstructive Lung Disease (GOLD) criteria

Incorrect use of inhaler according to inhaler technique checklist

No mental confusion, psychiatric problem, or communication problems

Exclusion Criteria

Cognitive dysfunction

Severe pulmonary, cardiological, or malignant illness

Current period of exacerbation

Correctly performed all steps of inhaler use technique according to checklist

Withdrawal Criteria

Participant request to leave the study

Incomplete follow-up

Moved out of the province during the study period

Passed away during the study period

Randomization Procedure

Eligible COPD patients were distributed to 2 groups, intervention or control, using the simple random sampling technique and drawing of lots by a nurse in the chest disease service. The patients' discharge plans were used to prevent interaction of the groups.

Outcome Measures

Questionnaire Form

The questionnaire form consisted of 25 questions based on a review of the literature (17). The first part of the form comprised 7 questions about the sociodemographic characteristics of the patients (age, gender, education, etc.), and the second part consisted of 18 questions about characteristics of the disease (time since diagnosis, duration of inhaler usage, type of inhaler, etc.).

COPD Self-Efficacy Scale

The COPD Self-Efficacy Scale (CSES), originally developed by Wigal et al. (7), consists of 34 items and 5 subscales. Kara and Mirici (2) conducted a validity and reliability study of a Turkish version. The scale consists of 5 dimensions: negative effect, emotional arousal, physical exertion, weather/environment, and behavioral risk factors. Test-retest reliability of the scale results yielded an r=0.89 and an internal consistency of 0.94. The overall score of the scale is obtained by summing the scores of the subdimensions. A higher score indicates greater confidence in the ability to manage respiratory distress (2).

Exercise of Self-Care Agency Scale

The 43-item Exercise of Self-Care Agency Scale (ESCAS) was developed by Kearney and Fleischer (19) and uses a 5-point Likert-type scale. A preliminary validity and reliability study of a Turkish version was conducted by Nahcivan (15). A score of <82 is considered low, a score of 82–120 is considered average or medium, and a score >120 is considered to reflect high self-care agency (15).

Medical Research Council Dyspnea Scale

The Medical Research Council Dyspnea Scale (MRC) was adapted from the instrument introduced by Fletcher in 1952. This scale measures various physical activities that can produce dyspnea. A high MRC score indicates greater shortness of breath (20, 21). Studies have demonstrated the validity and reliability of a Turkish version of the scale (1, 17). Since it is a one-dimensional scale, a Cronbach's alpha value was not calculated.

Modified Borg Dyspnea Scale

The Borg Dyspnea Scale was developed in 1982 by Gunnar Borg to describe breathing difficulty. The American College of Sports Medicine modification of the scale in 1986 uses a score range of 0–10. The Modified Borg Dyspnea Scale is now generally used to define the severity of dyspnea during exercise and to assess the severity of resting dyspnea (22). Previous studies conducted in Turkey have noted that the scale can be used reliably (17). Since it is a one-dimensional scale, a Cronbach's alpha value was not calculated.

Inhaler Use Skill Checklist

A chart to examine inhaler use technique was prepared by the primary researcher based on a review of the literature for several types of inhalers (Diskus, Aerolizer, Handihaler, Turbuhaler, metered-dose inhaler) (17, 23). Each step of the correct procedure was identified and the list of steps were evaluated and approved by experts. Performance of all of the steps for proper use of the inhaler was considered correct; if ≥1 of the steps was performed inadequately, the technique was assessed as incorrect.

Inhaler Use Guide for COPD Patients

There is substantial literature that has provided guidance on training materials, including specific step-by-step instructions, for several types of inhaler (17, 23, 24). The researcher collected information and images of how to use various types of inhalers for distribution to the patients.

Data Collection

Intervention Group

The questionnaire form, the Modified Borg Dyspnea Scale, the MRC dyspnea scale, the ESCAS, the CSES, and the inhaler medication use checklist were administered to the intervention group at the first visit and the scores were recorded. The researcher subsequently demonstrated and provided an explanation of how to correctly use the inhaler in a one-to-one oral presentation.

After the patients were advised of proper technique for each type of inhaler, healthcare staff followed up with regular communication.

When the patients were asked to demonstrate inhaler use, they were encouraged to use their own inhaler if it was an appropriate time to administer medication or provided with a placebo inhaler to prevent excess intake. Inhaler use was monitored individually by the researcher, and additional training was given until the steps were performed correctly. The training was conducted on a one-to-one basis in a private room. The mean duration of training for each patient was 45 minutes. After the instruction, each patient was given a reference guide, the Inhaler Use Guide for COPD Patients, prepared by the researcher based on a review of the literature, and the patients were informed that they could use the guide as a reminder of the steps applicable for the type of inhaler they used, as needed. The patients were also provided with a telephone number that they could call at any time. In the interim follow-up performed 1 month after the initial visit, the Modified Borg Dyspnea Scale, MRC dyspnea scale, ESCAS, CSES, and inhaler checklist were readministered. Instruction on inhaler use was provided again as necessary. The same tests were administered once again in the 3-month follow-up. All of the forms were completed in face-to-face interviews with the researcher.

Table 1. Comparison of the characteristics of the intervention and control groups

Characteristics	Intervention group (n=34)		Control group (n=33)		Statistical analysis
	n	%	n	%	
Gender					
Female	7	20.6	7	21.2	χ^2=0.004
Male	27	79.4	26	78.8	p=0.950
Mean age (Mean±SD, years)	66.24±10.41		63.26±10.70		t=0.723
					p=0.473
Education status					
Literate	8	23.5	10	30.3	χ^2=0.417
Primary school	23	67.6	20	60.6	p=0.863
High school or more	3	8.8	3	9.1	
Marital status					
Married	26	76.5	29	87.9	χ^2=1.482
Single	8	23.5	4	12.1	p=0.223
Time since diagnosis (Mean±SD, years)	8.47±6.14		7.39±6.05		t=0.723
					p=0.473
Duration of inhaler usage (Mean±SD, years)	7.94±5.91		6.90±5.90		t=-0.714
					p=0.478
Type of inhaler (Mean±SD)	2.82±0.79		2.93±0.86		t=-0.571
					p=0.570
Inhaler training					
Yes	17	50.0	19	57.6	χ^2=0.534
No	17	50.0	14	42.4	p=0.387
Training provider					
Doctor	11	64.7	11	57.9	χ^2=0.223
Nurse	1	5.9	1	5.3	p=0.861
Pharmacist	5	29.4	7	36.8	

t: t-test; χ^2: Chi-squared test; SD: Standard deviation

Control Group Procedures

In the first meeting with the control group, the questionnaire form, the Modified Borg Dyspnea Scale, MRC dyspnea scale, ESCAS, CSES, and inhaler medication use skills checklist were administered to record baseline data.

The control group was not given any training. The patients were asked to come for follow-up in 1 month and again at 3 months. All of the scales and the questionnaire were readministered to the patients in face-to-face interviews by the researcher. After the data collection process was completed, the patients were given the Inhaler Use Guide for COPD Patients.

Statistical Analysis

Statistical analysis was performed using the IBM SPSS Statistics for Windows, Version 23.0 software (IBM Corp., Armonk, NY, USA). The distribution of variables was assessed using the Shapiro-Wilk normality test and the homogeneity of the variances was evaluated with the Levene test. An independent samples t-test and the Mann-Whitney U test were used in the comparison of 2 groups, a paired samples t-test was used to evaluate 2 consecutive and nonparametric measurements, and repeated measures analysis of variance and the Friedman test were used to assess >2 measurements. A chi-squared analysis and Fisher's exact test were used to compare categorical variables. A value of $p<0.05$ was considered statistically significant.

RESULTS

In the intervention group, 79.4% of the participants were male, the mean age was 66.24±10.41 years, 67.6% were primary school graduates, 76.5% were married, the mean length of time since diagnosis was 8.47±6.14 years, the mean length of inhaler use was 7.94±5.91 years, 50.0% had received inhaler use education, and 64.7% had received inhaler training from a doctor. In the control group, 78.8% were male, the mean age was 63.26±10.70 years, 60.6% were primary school graduates, 87.9% were married, the mean length of time since diagnosis was 8.47±6.14 years, the mean length of inhaler use was 7.39±6.05 years, 57.6% had received in-

Table 2. Inhaler use status of intervention and control group at interim and final follow-up

Follow-up	Control group		Intervention group		Statistical analysis
	n	%	n	%	
Interim (1 month)					
Correct use	0	0.0	27	79.4	χ^2:43.89
Incorrect use	33	100.0	7	20.6	p<**0.001**
Final follow-up (3 months)					
Correct use	0	0.0	31	91.2	χ^2:55.99
Incorrect use	33	100.0	3	8.8	p<**0.001**

χ^2: Chi-squared test (Fisher exact test)

haler use education, and 57.9% had received inhaler training from a doctor. There was no statistically significant difference between the intervention and control groups in sociodemographic and disease characteristics (Table 1).

The correct use of an inhaler was statistically significantly higher in the intervention group compared with the control group in both follow-up sessions (p<0.001) (Table 2).

The mean subdimension and total CSES and ESCAS scores in the intervention group were higher at the 1-month and 3-month follow-up compared with the initial scores. The difference was statistically significant (p<0.05). Comparison tests showed statistically significant differences between the follow-up results (p<0.001). In the control group, the mean subdimension and total scores of the CSES and ESCAS scales declined in the follow-up sessions, with the exception of the negative effect and behavioral risk factor subdimensions. This decrease was also statistically significant (p<0.05). All of the subdimension and the total scores of the CSES and ESCAS scores at the interim and final follow-up in the experimental group were higher than those of the control group. The difference was statistically significant. The MRC dyspnea scale scores at 1 month and 3 months in the intervention group decreased significantly compared with the initial visit (p<001). Multiple comparison tests indicated that there was a statistically significant difference between the initial and the final results. The interim and final follow-up scores of control group patients had increased over time, and this increase was statistically significant (p<0.05). The MRC dyspnea scale scores of the experimental group were lower than those of the control group, with statistically significance, at the final follow-up (p<0.001).

The Modified Borg Dyspnea Scale scores of the intervention group were significantly lower at the interim and final follow-up compared with the initial score (p<001). The results of multiple comparison tests revealed statistically significant differences between all follow-up findings (p<0.001). The interim scores of the control group did not change significantly compared with the initial findings, however, there was a statistically significant increase recorded at the final follow-up (p<0.05). The Modified Borg Dyspnea Scale scores of the experimental group were lower than those of the control group and the decrease was statistically significant at the final follow-up (p<0.001) (Table 3).

DISCUSSION

Maximizing the effect of inhaler medication for COPD depends on correct use of the device. Training for patients can ensure correct use technique and minimize errors in the application of medication. Previous studies have reported that written and visual inhaler use training for COPD patients improved their technique and reduced errors (10, 17). The results of this study were consistent: at the final follow-up, 91.2% of the study group patients used their inhaler correctly, whereas the control group patients demonstrated incorrect use. The follow-up of the patients for 3 months and correction of technique appears to have contributed to correct use of an inhaler. Training sessions and long-term follow-up of patients to ensure correct usage is advisable. Moriyama et al. (25) also found that a 6-month, nurse-led, self-management program led to improved medication use and a significant decrease in dyspnea scores. Other reports have similarly noted positive effects of inhaler drug training on dyspnea scores (1, 17).

The results of our study also demonstrated that inhaler training was effective and reduced dyspnea scores in COPD patients. The dyspnea scores of the control group had increased at the final follow-up. Other studies have noted similar findings: dyspnea severity increased over time in the patients who were not given inhaler training (1, 17). These results show that the correct use of the right inhaler is important in reducing the symptoms of dyspnea. It was also observed in this study that there was an increase in the self-care and self-efficacy levels of the patients in parallel with a decrease in dyspnea complaints. The individuals in the control group displayed a decrease in the level of self-efficacy and self-care. Increased dyspnea in COPD patients frequently leads to a decrease in self-confidence, which, in turn, may reduce self-efficacy, as patients lose belief in their capability to carry out activities. In a study that examined the self-efficacy level of patients with various chronic diseases, those with COPD had the lowest mean score (26). It has been noted that training on how to cope with dyspnea increased the self-efficacy scale scores of COPD patients (27). Kara and Asti (28) also examined the effect of a structured training program for COPD patients, and found that their total self-efficacy scores and subdimension scores increased. Şimşekli (29) also reported improvement in the self-efficacy levels of individuals after inhaler drug training. Furthermore, Poureslami et al. (30) examined the use of visual and auditory training on self-management in COPD, it was determined that the patients in the intervention group improved their inhaler use technique after training.

Table 3. Distribution of the mean scale score scores according to follow-up visits of the intervention and control groups

COPD Self-Efficacy Scale	Intervention group (n=34) (Mean±SD)	Control group (n=33) (Mean±SD)	p**
Negative effect			
Initial visit	1.90±0.54[a]	1.92±0.51	0.848
Interim follow-up	2.48±0.46[b]	1.93±0.46	**<0.001**
Final follow-up	2.94±0.69[c]	1.95±0.39	**<0.001**
p*	**<0.001**	0.833	
Emotional arousal			
Initial visit	1.86±0.61[a]	1.95±0.53[a]	0.557
Interim follow-up	2.49±0.75[b]	1.87±0.54[a]	**<0.001**
Final follow-up	2.90±0.81[c]	1.70±0.46[b]	**<0.001**
p*	**<0.001**	**<0.001**	
Physical exertion			
Initial visit	1.17±0.32[a]	1.27±0.44[ab]	0.310
Interim follow-up	1.48±0.53[b]	1.22±0.42[b]	**0.029**
Final follow-up	3.01±1.31[c]	1.19±0.36[b]	**<0.001**
p*	**<0.001**	**0.011**	
Weather/environment			
Initial visit	1.46±0.58[a]	1.48±0.54[a]	0.862
Interim follow-up	1.73±0.68[b]	1.31±0.46[bc]	**0.005**
Final follow-up	3.06±1.31[c]	1.26±0.42[bc]	**<0.001**
p*	**<0.001**	**<0.001**	
Behavioral risk factors			
Initial visit	1.55±0.57[a]	1.68±0.58	0.370
Interim follow-up	1.98±0.57[b]	1.56±0.59	**0.005**
Final follow-up	3.11±1.04[c]	1.53±0.60	**<0.001**
p*	**<0.001**	0.081	
Total score			
Initial visit	1.67±0.47[a]	1.73±0.45	0.612
Interim follow-up	2.16±0.47[b]	1.67±0.43	**<0.001**
Final follow-up	2.98±0.77[c]	1.62±0.36	**<0.001**
p*	**<0.001**	**0.018**	
Self-Care Agency Scale			
Initial visit	101.44±17.19[a]	104.57±17.03	0.456
Interim follow-up	116.94±13.58[b]	105.09±17.92	**0.003**
Final follow-up	120.47±14.55[c]	102.51±20.43	**<0.001**
p*	**<0.001**	0.131	
	Intervention group Avg (25% p–75% p)	**Control group Avg (25% p–75% p)**	
MRC Dyspnea Scale			
Initial visit	3.5 (3.0–4.0)	3.0 (3.0–4.0)	0.270¥
Interim follow-up	3.0 (2.0–4.0)	4.0 (3.0–4.0)	0.067¥
Final follow-up	3.0 (2.0–3.0)	4.0 (3.0–4.0)	**<0.001**¥
p***	**<0.001**	**0.001**	
Modified Borg Dyspnea Scale			
Initial visit	5.5 (4.0–7.0)	5.0 (4.0–7.0)	0.344¥
Interim follow-up	4.0 (3.0–5.0)	5.0 (4.0–7.0)	**0.001**¥
Final follow-up	3.0 (2.0–5.0)	5.0 (4.5–7.0)	**<0.001**¥
p***	**<0.001**	**0.003**	

SD: Standard deviation; *: Variance analysis was conducted for repeated measurement; **: Two-sample t-test was conducted in independent groups; ***: Friedman test; ¥: Mann-Whitney U test; a, b, c: Significant difference according to multiple comparison test (post hoc test: Bonferroni, Dunn) results

To the best of our knowledge, no study has yet examined the effects of inhaler education on self-efficacy and self-care. In our study, the patients were required to perform each step of the inhaler use technique one by one, any shortcomings were identified and addressed, the steps were repeated until they were performed correctly, there was a suitable environment for asking questions, and there was follow-up communication by phone.

Limitations

The knowledge level of the patients was measured for only 3 months. The results of our study may be limited in generalizability. Finally, the lack of an objective measurement of dyspnea is a limitation to the interpretation of the findings.

CONCLUSION

The study results indicated that inhaler use training given to patients with COPD increased correct usage as well as the level of self-care agency and self-efficacy.

In line with these results, the following recommendations are suggested:

Step-by-step instruction of proper inhaler use should be provided and evaluated until the patient demonstrates the correct technique.

Evidence-based guidelines should be used when providing inhaler training,

Follow-up should be performed at appropriate intervals after the initial training, and inappropriate practices should be corrected.

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Ethics Committee Approval: The Nevşehir Hacı Bektaş Veli University Clinical Research Ethics Committee granted approval for this study (date: 24.08.2018, number: 2017.08.06).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – ÇE, GM, HÖ; Design – ÇE, GM, HÖ; Supervision – GM, HÖ; Resource – GM, HÖ; Data Collection and/or Processing – ÇE; Analysis and/or Interpretation – ÇE, GM; Literature Search – ÇE; Writing – ÇE, GM, HÖ; Critical Reviews – HÖ, GM.

Conflict of Interest: The authors have no conflict of interest to declare.

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