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Original Article

Effects of a structured, nurse-led follow-up program on clinical outcomes in chronic obstructive pulmonary disease patients: A randomized controlled trial

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ABSTRACT

Background & Aim: Post-discharge follow-up is essential to prevent exacerbation in patients with COPD. This study examined the impact of a 3-month nurse-led follow-up program on early symptom worsening and severe post-discharge outcomes.

Methods & Materials: A single-center, parallel-group randomized clinical trial was conducted among 88 hospitalized COPD patients in Gonabad, Iran, in 2022. The intervention group received a structured nurse-led follow-up program for three months, including planned education, telephone-based symptom monitoring, and zone-based triage with referral when needed. The control group received usual post-discharge care without scheduled follow-up. Primary outcomes were the Modified Borg Dyspnea Scale and the COPD Assessment Test at baseline and three months. Secondary outcomes included unplanned emergency department visits, readmissions, and post-discharge physical complications. Data analysis was performed in SPSS 21.0 using the Chi-square test, Fisher's exact test, ANCOVA, and paired t-test.

Results: Modified Borg Dyspnea Scale and COPD Assessment Test scores decreased in the intervention group from 3.31 (SD=2.32) to 2.71 (SD=2.84) and 14.91 (SD=10.91) to 12.65 (SD=11.04), respectively, while they increased in control group from 4.08 (SD=2.56) to 4.43 (SD=2.72) and 16.27 (SD=11.22) to 18.36 (SD=11.70) (adjusted p=0.002 for both outcomes. Clinically meaningful improvement was more frequent in the intervention group for both Modified Borg Dyspnea Scale (p=0.013) and CAT (p=0.007). Physical complications were lower in the intervention group (25.6% vs 48.9%; p=0.024), but emergency department visits and readmissions did not differ significantly.

Conclusion: A structured nurse-led follow-up program improved symptoms and reduced complications among patients with COPD. Its integration into transitional care is recommended to enhance recovery after hospitalization.

Introduction

Chronic obstructive pulmonary disease (COPD) is a chronic, heterogeneous lung disease characterized by persistent airflow limitation and an exaggerated inflammatory response to harmful particles or gases. As the third leading cause of death worldwide, it remains a major public health challenge (1). Globally, COPD prevalence is estimated at 10.3% using Global Initiative for Chronic Obstructive Lung Disease criteria and 7.6% using lower limit of normal criteria. A systematic review of 162 studies across 65 countries reported regional prevalence ranging from 11.7% in the Western Pacific to 6.8% in the Americas (2). In Iran, prevalence estimates range from 2.8% to 13.9%, indicating a substantial disease burden and marked regional variation (3).

COPD imposes a substantial healthcare and economic burden worldwide. Annual per-patient costs range from $1,721 to $30,826 and include hospitalizations, outpatient and emergency department (ED) visits, medications, home oxygen therapy, and productivity loss (4). Frequent exacerbations further increase this burden by

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raising hospitalization and readmission rates, mortality, and healthcare utilization (5). The early post-discharge period is particularly vulnerable because of clinical instability, suboptimal treatment adherence, and unresolved needs related to inhaler technique, comorbidities, and pulmonary rehabilitation, making effective follow-up essential (6). Accordingly, various nurse-led follow-up and transitional care interventions have been developed to improve continuity of care. Systematic reviews and meta-analyses indicate that these interventions may improve exacerbation prevention, well-being, physical activity, exercise capacity, self-efficacy, emotional health, anxiety, depression, and pulmonary and physical functioning (7–9). However, evidence regarding quality of life, dyspnea, and hospitalization remains inconsistent. Considerable heterogeneity in patient populations, healthcare settings, intervention components, outcome measures, and follow-up duration, together with limited evidence from low- and middle-income countries, restricts the generalizability of existing findings (10–13). These limitations highlight the need for context-specific evidence.

In Iran, the Ministry of Health and Medical Education developed a national follow-up nurse protocol for patients with chronic diseases to strengthen continuity of care after hospital discharge (14). Consistent with international principles of transitional care and nurse-led chronic disease management, the protocol incorporates standardized patient education, early telephone follow-up within 3–7 days after discharge, and a zone-based triage system (Green, Yellow, and Red) with predefined referral pathways. Although the protocol has gradually been introduced in hospitals nationwide, its implementation does not itself establish effectiveness. To our knowledge, no published randomized controlled trial has specifically evaluated this national protocol among patients with COPD. Therefore, in the present study, the national nurse-led follow-up protocol was implemented within a randomized controlled trial to evaluate its effectiveness.

This randomized controlled trial evaluated the effects of the national nurse-led follow-up program on clinically relevant indicators of COPD exacerbation, including dyspnea severity and COPD-related health status, as well as objective outcomes, including unplanned hospital readmissions, ED visits, and post-discharge physical complications.

Methods

Study design, setting, and participants

This study was a single-center, parallel-group, controlled, randomized clinical trial with 1:1 balanced randomization, conducted from May to November 2022, involving 88 patients with COPD admitted to Bohlol Hospital in Gonabad, Iran. The trial was registered in the Iranian Registry of Clinical Trials (IRCT20191223045868N2; registration date: 27 May 2022), and was reported in accordance with the CONSORT 2010 guidelines.

Eligibility criteria

The inclusion criteria were as follows: A definitive diagnosis of COPD by a specialist; discharge from the hospital and referral to the hospital's self-care and follow-up unit; consciousness; age of 18 years or higher, informed consent to participate in the study; access to a landline or cell phone; being able to communicate and having no speech, hearing, or vision impairment; residency in Gonabad County; and no acute psychiatric disorders that could interfere with participation (e.g., active psychosis, uncontrolled bipolar disorder with a current manic episode, acute suicidal ideation, or moderate-to-severe substance use disorder), based on medical records and reports from the patient or their accompanying relatives**.** No restrictions were applied regarding COPD severity stage or GOLD classification, and patients from all severity categories were eligible for enrollment. There were no

additional exclusion criteria beyond failure to meet the inclusion criteria**.** Participants who withdrew from the study or died during the study period were considered study discontinuations and reported according to CONSORT guidelines**.**

Sample size and sampling

The sample size was calculated to detect differences in the proportions of patients experiencing disease exacerbations between groups. Using the formula for comparing two proportions and based on a similar study with $p_1 = 0.376$ and $p_2 = 0.672$ (15), with a 95% confidence level ($\alpha = 0.05$, two-tailed) and 80% statistical power, the minimum required sample size was 44 participants per group. Accounting for a 10% attrition rate, the sample size was increased to 49 participants per group, resulting in a total of 98 patients. Patients were selected using a convenience sampling method.

Randomization & Blinding

Randomization was performed by the data analyst using a computer-generated sequence with random permuted blocks of sizes 2 and 4 via the web-based Sealed Envelope service (https://www.sealedenvelope.com). To ensure allocation concealment, assignments were kept in sequentially numbered, opaque, sealed envelopes stored in a secure location, accessible only to an individual independent of the trial team and the enrolment process. After a participant was deemed eligible and provided informed consent, their details were relayed to this independent individual, who then selected the corresponding envelope strictly based on the order of enrolment, wrote the participant's name on it, and opened it to reveal the allocation. Due to the nature of the intervention, blinding of participants was not feasible. In this single-centre study, resource constraints necessitated that the same individual served as both the intervention provider and the outcome assessor; therefore, neither the provider nor the assessor was blinded to group allocation. To minimize bias, the data analyst remained blinded, with groups coded as A and B throughout the analysis.

Interventions

According to the protocol, the study nurse held at least a bachelor's degree in nursing, a valid professional license, and a minimum of two years of clinical experience. The nurse had completed training in patient and family education, communication, home and palliative care, and management of non-communicable diseases. Prior to the study, the nurse received additional training on the standardized intervention manual developed by the Iranian Ministry of Health, which guided patient education, telephone follow-up, and zone-based decision-making in accordance with GOLD 2022 guidelines (14) and the national structured post-discharge follow-up program. To ensure consistency in outcome assessment, all patient-reported outcomes were collected by the same study nurse, who was trained to administer standardized, scripted questionnaires verbatim.

Referral to the follow-up unit (for both groups)

After discharge, all patients (intervention and control) were referred to the hospital follow-up unit. In accordance with hospital protocol, all patients underwent an initial assessment of their medical history and clinical status, after which the nurse provided the hospital's standardized discharge education to patients and caregivers on medication management, correct inhaler use, alarm symptoms, breathing exercises, physical activity, smoking cessation, nutrition, and mental health support. Therefore, initial assessment and discharge education were identical in both groups and part of routine hospital care.

Intervention group (structured nurse-led post-discharge follow-up)

Within 3–7 days after discharge, the nurse conducted the first structured telephone follow-up. Patients were classified into Green, Yellow, or Red zones according to the

national structured post-discharge follow-up program of the Iranian Ministry of Health, which determined follow-up intensity and required actions (Table 1), supplemented by physician orders when necessary. Each call assessed treatment adherence, self-care practices, and home care needs. Zone-based education and counseling were provided, and the nurse coordinated referrals to home care, long-term care, or outpatient services when required.

Throughout the intervention:

- Education for patients and caregivers was mandatory
- Follow-up frequency could be increased based on clinical judgment
- Physician orders overruled zoning decisions

Follow-up frequency was determined by zone classification:

- Green zone: every two weeks
- Yellow zone: weekly follow-up until improvement and transition to green
- Red zone: immediate hospital referral if ≥2 critical symptoms were present; for patients living alone, EMS transfer was coordinated; twice-weekly monitoring continued until stabilization

Table 1. Patient Classification and Follow-Up Protocol in the structured nurse-driven follow-up program for patients with COPD

Severity Zone	Clinical Criteria (Patient must have ≥2)	Nursing Interventions and Follow-up Frequency
Green Zone	Patient has **two or more** of the following signs and symptoms: 1) Stable vital signs including: • Temperature < 37.5°C • Heart rate 60–100 bpm • Respiratory rate < 20/min 2) SpO_2 > 90% 3) No severe hypoxia or airway compromise 4) No evidence of latent hypoxia (metabolic acidosis or elevated lactate) 5) Adherence to prescribed pharmacological and non-pharmacological therapies as advised by specialists 6) No history of hospitalization due to known psychiatric disorders in the patient or caregivers 7) Adequate response to oxygen therapy or non-invasive ventilation based on specialist judgment	**Follow-up Frequency: Every two weeks** • Conduct telephone follow-up to assess patient status and provide necessary education. • Reinforce COPD self-management education, medication adherence, correct inhaler technique, and recognition of alarm symptoms. • Provide counseling on healthy diet, physical activity, smoking cessation, and mental health support. • Encourage daily monitoring of weight and fluid/sodium intake.
Yellow Zone	Patient has **two or more** of the following signs and symptoms: 1) Temperature 37.5–38°C (low-grade fever) 2) SpO_2 85–90% despite oxygen therapy 3) Respiratory rate > 20/min 4) Mildly impaired consciousness 5) At least three reports of non-adherence to treatment (especially to critical medications such as antihypertensives, antibiotics, etc.)	**Follow-up Frequency: Weekly until transition to Green Zone** • Perform all Green Zone interventions with increased emphasis and frequency. • Closely monitor for any warning signs or clinical deterioration. • Coordinate with the attending physician regarding treatment adjustments if needed.
Red Zone	Patient has **two or more** of the following signs and symptoms: 1) Altered level of consciousness 2) Severe comorbid condition (e.g., heart failure, renal failure, etc.) 3) SpO_2 < 85% despite oxygen therapy 4) Unstable vital signs (e.g., fever > 38°C) 5) Arterial pH < 7.35 or venous pH < 7.32 with $PaCO_2$ > 60 mmHg 6) Use of bronchodilators or inhaled medications more frequently than every 4 hours 7) Inability of the patient or caregiver to maintain airway patency 8) At least three episodes of non-adherence to critical medications 9) Ineffective coughing or inability to clear secretions requiring suctioning or posing a life-threatening risk 10) New diagnosis of a life-threatening condition	**Action: Immediate hospital referral** • Immediate referral to the hospital upon identification of ≥2 alarm symptoms. • If the patient is alone, the nurse must arrange urgent EMS transfer (e.g., calling 115) and provide safety instructions. • **Post-discharge**: Telephone follow-up twice weekly until stabilization and transition to Yellow or Green Zone.

Notes: Some parameters in this table (e.g., ABG, acid-base parameters, SpO_2) were obtained from hospital medical records or from scheduled outpatient clinic visits (during follow-up). They were not assessed via telephone. During telephone follow-up, zone assignment was determined dynamically using all available data at each time point.

In practice, the calls lasted between 10 and 20 minutes, and zone-based frequencies were followed as described above, with call duration varying according to individual patient needs. All assessments, actions, and outcomes were fully documented in patient follow-up files. Monthly summary reports were submitted to the nursing manager. To ensure fidelity, a structured checklist was used for all communications, and the program was supervised monthly by the nursing manager (Supplementary File 1).

The control group

Patients in the control group received no structured nurse-led post-discharge follow-up beyond the routine hospital care described above. At the time of the study, the national structured post-discharge follow-up program had not yet been implemented as routine clinical practice in the hospital and was applied only within the context of this study for the intervention group. For ethical safety monitoring, the same study nurse conducted a single telephone call for all control participants 4–6 weeks after discharge using a standardized script consisting of three closed-ended questions:

1. "Do you currently have severe shortness of breath or chest pain?"
2. "Have you been admitted to hospital or visited the ED in the past two weeks?"
3. "Do you know the date of your next outpatient appointment?"

No education, counseling, self-management support, medication advice, or scheduled follow-up was provided. If a patient reported severe symptoms requiring immediate medical attention, the nurse advised the patient to seek appropriate medical care according to standard ethical practice. No additional monitoring or intervention was undertaken.

Outcomes

Primary outcomes

The primary outcomes were changes in dyspnea severity and COPD-related health status over the 3-month follow-up period, assessed using the Modified Borg Dyspnea Scale (MBDS) and the COPD Assessment Test (CAT), respectively. These patient-reported outcomes were selected because they are clinically relevant and sensitive indicators of changes in exacerbation status following hospital discharge (17). Together, these measures capture both the immediate and sustained effects of the post-discharge intervention.

Secondary outcomes

Secondary outcomes included unplanned ED visits, hospital readmissions, and post-discharge physical complications within 3 months. These events, representing more severe manifestations of exacerbation, were identified during follow-up and verified through medical records.

Measurements

Demographic and clinical characteristics questionnaire

This questionnaire included items on age, sex, marital status, income level, educational level, occupation, place of residence, smoking status, history of comorbidities, and duration of COPD**.**

Modified Borg Dyspnea Scale (MBDS)

The Borg Rating of Perceived Exertion Scale, developed by Gunnar Borg in the 1960s (18). Measures perceived effort, breathlessness, concentrating on COPD exacerbation therapy, and fatigue during physical activity. The modified version, known as the Borg CR10 or modified Borg dyspnea scale (19), rates breathlessness on a 0–10 scale, with scores categorized as low (0–3), moderate (4–6), and high effort (7–10) (20). A change of one point in the Borg dyspnea score is clinically meaningful for COPD patients (21). The Persian version has demonstrated strong psychometric properties. Dehghan et al. (22) confirmed criterion validity with a high correlation between Borg scores and heart rate (r= 0.847). Shariat et al. (23) reported acceptable face and content validity, excellent

test–retest reliability (ICC = 0.898), and strong concurrent validity with the Visual Analog Scale (r = 0.754).

The COPD Assessment Test

The CAT is a brief instrument for assessing health status and monitoring outcomes in COPD patients (24). It consists of eight items covering cough/phlegm, chest tightness, breathlessness, activity limitation, sleep, energy, and confidence leaving home. Items are scored from 0 to 5, yielding a total score of 0–40. Higher scores indicate greater disease impact. Scores of 10–20, 20–30, and >30 represent medium, high, and very high impact, respectively (25). A change of ≥2 points is considered clinically meaningful (26). The CAT has established validity and reliability, including in its Persian version (27).

Ethical approval and consent to participate

This study was approved by the Ethics Committee of Gonabad University of Medical Sciences (IR.GMU.REC.1401.006) and registered in the Iranian Registry of Clinical Trials (IRCT20191223045868N2). The research adhered to the Declaration of Helsinki. Participants received information on study objectives and procedures, confidentiality was assured, informed consent was obtained, and participants were free to withdraw at any time**.**

Statistical analysis

All analyses were performed using IBM SPSS Statistics 21.0 according to the per-protocol approach. There were no missing data. Continuous variables were summarized as mean and standard deviation (SD), and categorical variables as frequencies and percentages. Normality was assessed using the Kolmogorov–Smirnov test.

Baseline characteristics were compared using independent t-tests for continuous variables and Chi-square or Fisher's exact tests for categorical variables. Changes in MBDS and CAT scores over 3 months were analyzed using ANCOVA adjusted for baseline values. Unadjusted and adjusted means difference with 95% confidence intervals were reported. ANCOVA assumptions, including linearity, homogeneity of regression slopes, and homoscedasticity, were assessed; robust standard errors were used when homogeneity of variance was violated. Effect sizes were expressed as partial eta-squared, and observed power was calculated. Within-group changes were examined using paired t-tests.

For clinical interpretation, changes in MBDS and CAT scores were categorized into three clinically meaningful outcome categories based on established clinically important change thresholds: clinically meaningful exacerbation (an increase of ≥1 point in MBDS or ≥2 points in CAT), no clinically meaningful change, and clinically meaningful improvement (a decrease of ≥1 point in MBDS or ≥2 points in CAT). The distributions of these outcome categories were compared between groups using the Chi-square test. When the overall Chi-square test was statistically significant, post hoc pairwise comparisons of the clinically relevant outcome categories (clinically meaningful exacerbation and clinically meaningful improvement) were performed using Bonferroni-adjusted significance levels to identify the source of the overall association. The strength of the association was quantified using Cramer's V and interpreted as small (0.10), medium (0.30), and large (0.50), according to Cohen's guidelines (28).

COPD-related acute care events, including unplanned ED visits, hospital readmissions, and physical complications within 3 months of discharge, were compared using the Chi-square test. A two-sided p-value< 0.05 was considered statistically significant.

Results

A total of 157 patients were screened; 47 did not meet the inclusion criteria, and 12 declined participation. Ninety-eight eligible patients were randomized equally to the intervention (n = 49) and control (n = 49) groups. During follow-up, 6 participants in the intervention group (5 withdrawals, 1 death)

and 4 in the control group (2 withdrawals, 2 deaths) were discontinued from the study. Thus, 43 and 45 patients from the intervention and control groups, respectively, were included in the final analysis. The CONSORT diagram was shown in Figure 1.

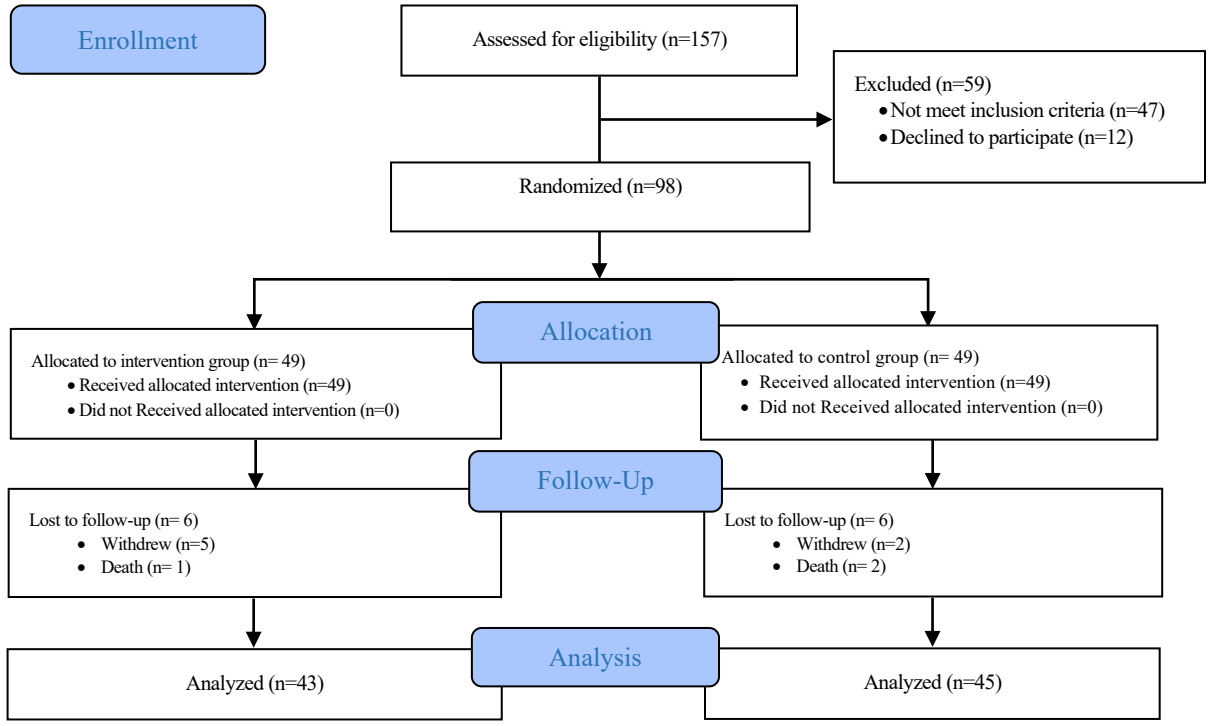

Figure 1. CONSORT diagram of the study

Baseline characteristics

Baseline demographic and clinical characteristics are summarized in Table 2. Females accounted for 41.9% of participants in the intervention group and 57.8% in the control group. The intervention group had a mean age of 64.02 years (SD = 13.36; range, 40-89 years), and 66.42 years (SD= 14.29; range, 39-92 years) in the control group. There were no statistically significant differences between groups regarding age, sex, marital status, occupation, educational level, residence place, or income level, underlying diseases, history of hospitalization, current smoking, and duration of COPD (all $p > 0.05$).

Table 2. Characteristics of the participants

Variables	Intervention group (n=43)	Control group (n=45)	*p*
Age, Mean (SD)	64.02 (13.36)	66.42 (14.29)	0.419*
Duration of COPD (years), Mean (SD)	4.86 (3.83)	5.69 (3.42)	0.287*
Sex, n (%)			
Female	18 (41.9)	26 (57.8)	0.135†
Male	25 (58.1)	19 (42.2)	
Marital status, n (%)			
Married	30 (69.7)	28 (62.2)	
Single	3 (7.0)	3 (6.7)	0.782**
Divorced/Widowed	10 (23.3)	14 (31.1)	
Occupation, n (%)			
Unemployed	13 (30.2)	14 (31.1)	
Retired	5 (11.6)	5 (11.1)	0.833**
Employee	7 (16.3)	7 (15.6)	
Farmer	6 (14.0)	3 (6.7)	
Housewife	12 (27.9)	16 (35.5)	
Educational level, n (%)			
Illiterate	17 (39.5)	22 (48.9)	
High school or less	23 (53.5)	21 (46.7)	0.645**
University	3 (7.0)	2 (4.4)	
Residence place, n (%)			
Urban	25 (58.1)	26 (57.8)	0.973†
Rural	18 (41.9)	19 (42.2)	

Variables	Intervention group (n=43)	Control group (n=45)	*p*
Income level, n (%)			
Low	19 (44.2)	16 (35.6)	0.568†
Moderate	17 (39.5)	18 (40.0)	
High	7 (16.3)	11 (24.4)	
Underlying diseases, n (%)			
Yes	31 (72.1)	27 (60.0)	0.232†
No	12 (27.9)	18 (40.0)	
History of hospitalization, n (%)			
Yes	43 (100.0)	45 (100.0)	1.00†
No	0 (0.0)	0 (0.0)	
Currently Smoking			
Yes	19 (44.2)	17 (37.8)	0.541†
No	24 (55.8)	28 (62.2)	

* Independent two samples T-test; ** Fisher exact test; † Chi-square

Primary outcomes

Table 3 presents the descriptive statistics and ANCOVA results for MBDS and CAT scores at baseline and after the 3-month follow-up.

MBDS score

At baseline, the intervention group had a slightly lower mean MBDS score (3.31, SD=2.32) than the control group (4.08, SD=2.56). After 3 months, the intervention group improved to a mean score of 2.71 (SD = 2.84), whereas the control group showed a slight deterioration with a mean score of 4.43 (SD=2.72).

Within-group analysis using paired t-tests showed a statistically significant improvement in the intervention group (t(42)=2.436, p=0.019) and a marginally significant deterioration in the control group (t(44)= −2.012, p= 0.050).

After adjusting for baseline scores using ANCOVA, the intervention group had a significantly lower adjusted mean MBDS score (3.09, SE= 0.22) compared with the control group (4.07, SE= 0.21). The adjusted mean difference was −0.98 (95% CI: −1.59 to−0.36), indicating a statistically significant effect of the intervention (F(1,85)=10.088, p=0.002). The Partial Eta² of 0.106 reflects a medium effect size.

CAT score

Baseline CAT scores were 14.91 (SD=10.91) in the intervention group and 16.27 (SD=11.22) in the control group. After the intervention, the intervention group improved to 12.65 (SD = 11.04), while the control group increased to 18.36 (SD = 11.70). Paired t-tests showed a significant improvement in the intervention group (t(44)=2.336, p= 0.024) and a non-significant increase in the control group (t(42)= −1.839, p= 0.073).

ANCOVA analysis revealed a significant adjusted mean difference favoring the intervention (−4.58 (95% CI: −7.47 to −1.69); F(1,85) = 9.916, p = 0.002), with a medium effect size (Partial Eta² = 0.104).

Table 3. Changes in modified Borg dyspnea and COPD assessment test scores at baseline and after 3-month follow-up in COPD patients

Outcome	Group	Baseline	End of trial	Within-group comparison using a paired t-test			Between-groups comparison using the ANCOVA test					
							Adjusted mean at the end of the trial[a]	Adjusted Mean Difference [b]	F (1,85)	*p*	Partial Eta²	Observed Power
		Mean (SD)	Mean (SD)	t	df	*p*	Mean (SE)	Mean (95% CI)				
MBDS score	Control (n=45)	4.08 (2.56)	4.43 (2.72)	-2.012	44	0.050	4.0 (0.21)	−0.98 (−1.59, −0.36)	10.08	0.002	0.106	0.881
	Intervention (n=43)	3.31 (2.32)	2.71 (2.84)	2.436	42	0.019	3.09 (0.22)					
CAT score	Control (n=45)	16.27 (11.22)	18.36 (11.70)	-1.839	42	0.073	17.81 (1.02)	−4.58 (−7.47, −1.69)	9.916	0.002	0.104	0.876
	Intervention (n=43)	14.91 (10.91)	12.65 (11.04)	2.336	44	0.024	13.22 (1.04)					

CAT, COPD Assessment Test; MBDS, Modified Borg Dyspnea Scale; SD, standard deviation; SE, Standard Error; CI, confidence interval.
a Adjusted for baseline scores using ANCOVA.
b Adjusted mean difference (Intervention – Control); negative values indicate greater improvement in the intervention group.

Clinically meaningful outcome categories of MBDS and CAT scores

The distributions of clinically meaningful MBDS and CAT outcome categories are presented in Table 4.

The distributions of clinically meaningful MBDS outcome categories differed significantly between groups ($\chi^2(2) = 8.64$, P = 0.013), with a moderate effect size (Cramer's V = 0.32). Clinically meaningful improvement occurred more frequently in the intervention group than in the control group (48.8% vs. 20.0%), while clinically meaningful exacerbation occurred less frequently (25.0% vs. 31.8%). Post hoc pairwise comparisons with Bonferroni adjustment demonstrated that the significant overall association was driven by the higher proportion of patients achieving clinically meaningful improvement (p=0.004), whereas no statistically significant difference was observed in the proportion of patients experiencing clinically meaningful exacerbation (p=0.408).

Similarly, the distributions of clinically meaningful CAT outcome categories differed significantly between the intervention and control groups ($\chi^2(2) = 9.91$, $P = 0.007$), with a moderate strength of association (Cramer's V = 0.34). Clinically meaningful improvement was observed more frequently in the intervention group than in the control group (48.8% vs. 17.8%), whereas clinically meaningful exacerbation occurred less frequently (23.3% vs. 31.1%). Post hoc pairwise comparisons with Bonferroni adjustment indicated that the overall difference was primarily attributable to the significantly higher proportion of patients achieving clinically meaningful improvement in the intervention group (p=0.002), whereas the difference in clinically meaningful exacerbation between groups was not statistically significant (p=0.408).

Table 4. Distribution of clinically meaningful outcome categories for MBDS and CAT scores after the 3-month follow-up

Outcome	Category	Intervention	Control	χ^2 (2)	*p*	Cramer's V
		n (%)	n (%)			
MBDS	Clinically meaningful exacerbation	10 (25.0)	14 (31.8)	8.644	0.013	0.321
	No clinically meaningful change	11 (27.5)	22 (50.0)			
	Clinically meaningful improvement	19 (47.5)	8 (18.2)			
CAT	Clinically meaningful exacerbation	10 (23.3)	14 (31.1)	9.911	0.007	0.336
	No clinically meaningful change	12 (27.9)	23 (51.1)			
	Clinically meaningful improvement	21 (48.8)	8 (17.8)			

CAT, COPD Assessment Test; MBDS, Modified Borg Dyspnea Scale.

Secondary outcomes

Post-discharge outcomes were compared between the intervention and control groups. There was no significant difference in the proportion of unplanned ED visits (30.2% vs. 22.2%, $\chi^2 = 0.731$, p= 0.393) or hospital readmissions (20.9% vs. 24.4%, χ^2= 0.155, p= 0.694). However, the incidence of post-discharge physical complications was significantly lower in the intervention group (25.6% vs. 48.9%, χ^2= 5.097, p= 0.024), indicating a beneficial effect of the nurse-led follow-up on patients' physical health after discharge (Table 5).

Table 5. Comparison of post-discharge outcomes between intervention and control groups

Variables	Intervention group (n=43)	Control group (n=45)	Chi-square test	
	n (%)	n (%)	χ^2 (1)	*p*
Unplanned Emergency Department visits			0.731	0.393
Yes	13 (30.2)	10 (22.2)		
No	30 (69.8)	35 (77.8)		
Post-discharge physical complications			5.097	0.024
Yes	11 (25.6)	22 (48.9)		
No	32 (74.4)	23 (51.1)		
Hospital readmission			0.155	0.694
Yes	9 (20.9)	11 (24.4)		
No	34 (79.1)	34 (75.6)		

Discussion

This trial provides the first scientific evaluation of a nationally designed pilot model of structured nurse-led follow-up care for COPD in Iran. The findings add to international evidence and inform policymakers on integrating nurse-led transitional care into routine COPD management.

Our study demonstrated that the nurse-led intervention significantly improved dyspnea (MBDS) and COPD-related health status (CAT) compared with usual care. Beyond statistical significance, the intervention also resulted in clinically meaningful benefits. Nearly half of the patients in the intervention group achieved clinically meaningful improvement in both dyspnea and health status, whereas substantially fewer patients in the control group experienced similar improvements. These findings indicate that the intervention produced benefits that were not only statistically significant but also meaningful from a clinical and patient-centered perspective.

Our findings are generally consistent with previous studies reporting beneficial effects of nurse-led follow-up after hospitalization for COPD. In a quasi-experimental study, an 8-week program consisting of four weekly home visits followed by four weekly telephone follow-ups improved dyspnea and health status (29). Similarly, Lavesen et al. (10) evaluated a nurse-led intervention comprising two scheduled telephone calls on days 2 and 30 after discharge, with additional calls provided when needed, and reported improvements in patients' disease mastery and self-management. In contrast, a telemedicine-based randomized trial used biweekly telephone contacts for six months primarily to administer a health-status questionnaire, identify clinical deterioration, and trigger physician assessment and management when required, but found no improvement in health status (11). Compared with these interventions, our 3-month program combined standardized patient education, individualized zone-based risk stratification, assessment of treatment adherence and self-care, psychosocial support, coordination of referrals to appropriate healthcare services, and flexible follow-up frequency according to patients' clinical status, which may explain the greater improvements observed in clinically meaningful dyspnea and health status.

In the present study, post-discharge unplanned ED visits and hospital readmissions did not differ significantly between groups, although physical complications were significantly reduced. Similar findings were reported by Aboumatar et al. (12), whose comprehensive 3-month transitional care program, including discharge support, individualized self-management support, and home or telephone follow-up, did not reduce COPD-related ED visits, and by Lavesen et al. (10), whose shorter telephone follow-up intervention also did not reduce hospital readmissions. In contrast, the PreCareKOL telehealth program (13) used telemonitoring with repeated nurse contacts and electronic monitoring of patients' clinical status for 90 days, while the Turkish multicenter trial (30) implemented a structured discharge and 90-day follow-up protocol, including detailed discharge education, in patients with chronic respiratory failure receiving long-term oxygen therapy and/or non-invasive ventilation; both reported reductions in hospital utilization. Differences in intervention duration, intensity, monitoring strategy, and patient characteristics may partly explain these inconsistent findings, consistent with the meta-analysis by Dou et al. (8), which found that nursing interventions improve several patient outcomes but have inconsistent effects on hospitalization.

Overall, the lack of a significant reduction in readmissions in our study may be related to the short follow-up period, inclusion of patients with varying disease severity, unmeasured barriers to healthcare access, and physician-driven hospital admission decisions. However, the observed improvements in dyspnea, COPD-related

health status, and post-discharge physical complications likely resulted from early problem detection, timely referral, and improved treatment adherence. The structured nature of the intervention, supported by standardized follow-up procedures, checklists, and regular supervision, may have further contributed to these improvements.

Strengths and limitations

This study has several strengths, including its randomized controlled design, use of validated outcome measures, and adequate sample size. However, blinding was not feasible because of the nature of the intervention, and the same nurse delivered the intervention and assessed outcomes, which may have introduced performance and detection bias. In addition, the single-center design may limit generalizability, and follow-up was limited to three months, precluding evaluation of long-term sustainability.

Implications

The findings suggest that a structured nurse-led post-discharge follow-up program can improve clinically meaningful patient outcomes after hospitalization for COPD. Because the intervention was implemented according to the national follow-up nurse protocol of the Iranian Ministry of Health, the results provide supportive evidence for its wider implementation in routine clinical practice. Incorporating standardized patient education, early telephone follow-up, and risk-stratified monitoring into post-discharge care may strengthen continuity of care and reduce post-discharge complications. These findings may also inform the development of similar nurse-led follow-up programs in other resource-limited healthcare settings.

Conclusion

This randomized controlled trial provides further evidence that nurse-led follow-up improves outcomes in patients with COPD. The high proportion of patients achieving clinically meaningful improvements in dyspnea and COPD-related health status, together with fewer post-discharge physical complications, supports the clinical value of this model and its planned national implementation in Iran. Future multicenter studies with longer follow-up should evaluate the optimal intensity and duration of follow-up, the contribution of other healthcare professionals, and the cost-effectiveness of this approach compared with usual care.

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Conflict of interest

The authors declare no conflicts of interest.

Author contributions

Concept and Design – E.S.N., F.M.; Data Collection and/or Processing - E.S.N.; Analysis and/or Interpretation - F.M.; Literature Search – E.S.N.; Writing Manuscript - F.M.; Reviewed and approved the final draft of the manuscript: E.S.N., F.M.

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Supplementary file 1

Checklist for evaluating the nurse-led follow-up program implementation

No.	Evaluation indicator	Yes	No	Comments
1	The follow-up nurse is a nursing expert with 5 years of experience or holds a master's degree in nursing with at least 3 years of clinical experience.			
2	The official appointment of the follow-up nurse has been issued and sealed by the head of the center and is available.			
3	A dedicated workspace has been allocated for the follow-up nurse.			
4	A dedicated phone line is available in the follow-up unit for contacting patients.			
5	Internet access is available in the follow-up nursing unit for communication with patients via virtual platforms.			
6	A computer system is available in the follow-up unit for patient data recording, preparation of educational materials, etc.			
7	The follow-up nurse possesses the necessary knowledge and skills regarding the diseases being followed up.			
8	Patients' educational, counseling, and intervention needs are assessed and recorded using the discharge summary.			
9	Each patient has an individual file.			
10	Telephone interview questionnaires are completed correctly.			
11	Follow-up frequency is determined based on the announced stratification level.			
12	All actions and interventions performed for the patient are documented.			
13	A copy of the patient's discharge summary exists in their file.			
14	Post-discharge follow-up is conducted for patients who are discharged against medical advice.			
15	Data obtained from patient interviews are summarized and analyzed.			
16	Monthly summaries, analyses, and records of actions taken are submitted to the nursing supervisor of the center.			
17	Monthly summaries, analyses, and records of actions taken are submitted to the Nursing Management of the Deputy for Treatment.			