

Original Research**Nurse-Led Pursed-Lip and Abdominal Breathing Training Improves Pulmonary Function and Functional Exercise Performance in Patients With Chronic Obstructive Pulmonary Disease: A Prospective Randomized Controlled Trial**

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Running Head: Nurse-Led Breathing Training in COPD

Keywords: COPD; pursed-lip breathing; abdominal breathing; nurse-led care; pulmonary function

Abbreviations: AB, abdominal breathing; CAT, COPD Assessment Test; COPD, chronic obstructive pulmonary disease; FEV₁, forced expiratory volume in 1 second; FVC, forced vital capacity; GOLD, Global Initiative for Chronic Obstructive Lung Disease; mMRC, modified Medical Research Council; PLB, pursed-lip breathing; SaO₂, peripheral oxygen saturation; 6MWD, 6-minute walk distance.

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Abstract

Background: Chronic obstructive pulmonary disease (COPD) causes dyspnea and impaired function. Evidence for structured nurse-led pursed-lip breathing (PLB) plus abdominal breathing (AB) in stable outpatients is limited.

Methods: In this single-center randomized controlled trial, 218 adults with Global Initiative for Chronic Obstructive Lung Disease (GOLD) stage II–IV stable COPD were randomized 1:1 to 12 weeks of nurse-led PLB plus AB or routine care. Co-primary outcomes were changes in forced expiratory volume in 1 second (FEV₁) and 6-minute walk distance (6MWD). Secondary outcomes were forced vital capacity (FVC), FEV₁/FVC, COPD Assessment Test (CAT) score, peripheral oxygen saturation (SaO₂), and modified Medical Research Council (mMRC) grade. Intention-to-treat analysis of covariance was performed, adjusting for baseline, age, sex, and GOLD stage, with multiple imputation for missing data.

Results: At week 12, adjusted differences favored the intervention for FEV₁ (0.14 L; 95% CI, 0.11–0.17), 6MWD (37.8 m; 95% CI, 31.5–44.1), FVC (0.16 L; 95% CI, 0.11–0.21), CAT score (–4.22 points; 95% CI, –4.90 to –3.54), and SaO₂ (1.33 percentage points; 95% CI, 1.10–1.56) (all $P < 0.001$). FEV₁/FVC change was not significant ($P = 0.095$). Adherence was 87.2%; no intervention-related adverse events were reported.

Conclusions: Nurse-led PLB plus AB improved spirometric outcomes, functional exercise performance, symptoms, and oxygenation. Multicenter trials with stronger adherence, medication, and mechanistic assessments are needed.

Trial registration: Chinese Clinical Trial Registry, ChiCTR2400000218.

Keywords: COPD; pursed-lip breathing; abdominal breathing; nurse-led care; pulmonary function; 6-minute walk distance; randomized controlled trial.

1. Introduction

Chronic obstructive pulmonary disease (COPD) is a leading cause of morbidity and mortality and is characterized by persistent respiratory symptoms and airflow limitation. Population aging and continued exposure to tobacco smoke, indoor pollutants, and outdoor pollutants are expected to sustain its global burden [1,2]. Progressive dyspnea, reduced daily function, and recurrent exacerbations erode health-related quality of life and increase health care use. Small-airway remodeling and dynamic hyperinflation contribute substantially to persistent symptoms in moderate-to-very-severe disease [3].

Pulmonary rehabilitation is a cornerstone of nonpharmacologic COPD management [4]. Breathing-retraining techniques such as pursed-lip breathing (PLB) and diaphragmatic or abdominal breathing (AB) are intended to lengthen expiration, reduce respiratory rate, and improve breathing mechanics [5]. PLB increases expiratory mouth pressure and may help maintain small-airway patency, whereas AB emphasizes diaphragmatic recruitment and reduced accessory-muscle use [6]. Short-term physiologic studies have reported favorable changes in tidal breathing and oxygen saturation during PLB [7], but the durability of these effects after structured outpatient training remains less certain.

Translation of breathing retraining into structured nurse-delivered programs remains heterogeneous. Trials differ in duration, supervision, daily dose, and outcome selection, and systematic reviews have called for more consistent randomized evidence [5,8]. Nurses have frequent longitudinal contact with COPD outpatients and are well positioned to teach and reinforce behavioral interventions, yet the effect of a standardized nurse-led program has not been well quantified at trial scale [9]. Prior studies have also varied in their use of patient-

reported outcomes such as the CAT [10] and field walking outcomes such as the 6-minute walk test [11].

We conducted a prospective parallel-group randomized controlled trial of a 12-week nurse-led PLB plus AB program in stable outpatients with GOLD stage II–IV COPD. We hypothesized that, compared with routine care, the program would improve the co-primary outcomes of FEV₁ and 6MWD at 12 weeks. We also assessed FVC, FEV₁/FVC, CAT score, resting SaO₂, and mMRC dyspnea grade. The design incorporated concealed allocation, blinded outcome assessment, intention-to-treat analysis, and prespecified control of familywise type I error for the co-primary outcomes, and reporting follows CONSORT 2025 [12].

2. Methods

2.1 Trial design and setting

This single-center, parallel two-group randomized controlled trial was conducted at Liyang People's Hospital between January 2024 and March 2025. Recruitment began in January 2024, and final follow-up was completed in March 2025. The protocol was approved by the institutional ethics committee of Liyang People's Hospital, and all participants provided written informed consent. The trial was registered in the Chinese Clinical Trial Registry (ChiCTR2400000218). Patients and members of the public were not involved in the design, conduct, reporting, or dissemination planning of the trial.

2.2 Participants

Eligible participants were adults aged 45–85 years with COPD confirmed according to the 2023 GOLD criteria (postbronchodilator FEV₁/FVC <0.70) [1] and clinically stable disease for at least 4 weeks. Exclusion criteria were an acute exacerbation within the preceding 4 weeks; coexisting interstitial lung disease, bronchiectasis, active tuberculosis, or lung cancer; New York Heart

Association class III–IV heart failure; inability to perform spirometry or the 6-minute walk test; or cognitive impairment precluding informed consent. Of 274 patients screened, 56 did not enter the trial: 38 did not meet eligibility criteria, 14 declined participation, and 4 were excluded for logistical reasons.

2.3 Randomization and blinding

Eligible participants were allocated 1:1 using a computer-generated sequence with permuted blocks of 4 and 6, stratified by GOLD stage (II vs III–IV). Sequentially numbered, opaque, sealed envelopes were prepared and opened by a research coordinator independent of recruitment. Recruiting personnel did not have access to the allocation sequence. Outcome assessors performing spirometry and the 6-minute walk test and the statistician conducting the primary analysis were blinded to allocation. Participants and treating nurses could not be masked because of the behavioral nature of the intervention.

2.4 Intervention and comparator

The nurse-led program combined PLB and AB in 30-minute sessions 3 times weekly for 12 weeks. The first 4 sessions were supervised face-to-face by a senior respiratory nurse; subsequent sessions were home-based with weekly telephone reinforcement and a structured paper diary, consistent with prior breathing-training protocols [8]. Each session comprised a 5-minute warm-up, 20 minutes of paced PLB plus AB cycles, and a 5-minute cool-down. Participants inhaled through the nose for 2 seconds and exhaled through pursed lips for 4–6 seconds while coordinating abdominal expansion and retraction. No metronome or electronic visual aid was used. During supervised sessions, the nurse standardized pacing by verbal counting; during home sessions, participants followed the same written timing instructions.

Both groups attended scheduled study assessment visits at baseline and week 12. The control group received routine outpatient pulmonary care, including pharmacotherapy review and standard health education, with additional clinical visits as medically indicated; it did not receive structured breathing training or weekly study telephone calls. Thus, nonspecific contact time was not matched between groups. Maintenance inhaler therapy was managed as part of routine care, but bronchodilator class and longitudinal medication changes were not captured with sufficient granularity for regimen-specific analysis.

2.5 Outcomes

The co-primary outcomes were 12-week changes in FEV₁ (liters) and 6MWD (meters). Spirometry and the 6-minute walk test were conducted according to European Respiratory Society/American Thoracic Society standards [11]. The 6-minute walk test was performed once at baseline and once at week 12 along a 30-m flat indoor corridor using standardized encouragement; it was treated as a measure of functional exercise performance rather than maximal exercise capacity. Secondary outcomes were FVC, FEV₁/FVC, CAT score (range, 0–40; higher scores indicate worse health status) [10], resting SaO₂ measured by finger pulse oximetry after 10 minutes of seated rest, and mMRC dyspnea grade [13]. A 2-point reduction was used as the CAT minimum clinically important difference [14]. Because a universally validated minimum clinically important difference for the categorical mMRC scale has not been established, mMRC was analyzed as an ordinal outcome without applying a responder threshold [15]. Adverse events were actively elicited at clinic visits and weekly intervention telephone contacts and recorded in a safety log.

2.6 Sample size

The sample-size calculation used an anticipated between-group difference in FEV₁ change of 0.12 L, a within-group standard deviation of 0.25 L, a 2-sided α of 0.05, and 90% power. This yielded 92 participants per group. Allowing for approximately 15% attrition, the target sample was 218 randomized participants.

2.7 Statistical analysis

Continuous variables were summarized as mean (SD) or median (interquartile range), and categorical variables as number (percentage). The primary analysis followed the intention-to-treat principle and included all 218 randomized participants. For each continuous outcome, an analysis of covariance model estimated the between-group difference in 12-week change while adjusting for the corresponding baseline value, age, sex, and GOLD stage. Missing values were addressed by fully conditional multiple imputation with 20 imputations, and estimates were pooled using Rubin rules [16].

Familywise type I error for the 2 co-primary outcomes was controlled at 0.05 with a fixed-sequence procedure specified as FEV₁ followed by 6MWD. FEV₁ was tested first at a 2-sided α of 0.05; only if that null hypothesis was rejected was 6MWD tested confirmatorily at the same α . Had FEV₁ not been significant, the 6MWD result would have been considered exploratory. Secondary outcomes were not adjusted for multiplicity and were interpreted as exploratory, with effect estimates and 95% CIs emphasized rather than dichotomous significance. Welch 2-sample t tests of raw change scores were sensitivity analyses. The mMRC distribution shift was evaluated with a Cochran–Mantel–Haenszel test for ordered categories. Standardized effects were expressed as Cohen d [17]. Tests were 2-sided, and analyses used Python 3.11 with NumPy, SciPy, pandas, statsmodels, and Matplotlib.

3. Results

3.1 Participant flow and baseline characteristics

Of 274 patients screened, 218 were randomized (109 per group). Four participants in the intervention group and 8 in the control group were lost to follow-up, leaving observed week-12 data for 105 and 101 participants, respectively. All randomized participants were retained in the intention-to-treat analysis with multiple imputation (Figure 1).

Baseline demographic and clinical characteristics are shown in Table 1. The proportion of male participants was 67.9% in the intervention group and 54.1% in the control group; sex was included as a covariate in the primary model. Age, body mass index, smoking exposure, GOLD stage, baseline spirometric indices, CAT score, 6MWD, resting SaO₂, and mMRC grade were similar between groups.

3.2 Pulmonary-function outcomes

From baseline to week 12, FEV₁ increased by 0.18 (0.10) L in the intervention group and 0.04 (0.10) L in the control group. The adjusted between-group difference was 0.14 L (95% CI, 0.11–0.17; P<0.001; Cohen d=1.35). FVC increased by 0.21 (0.21) L and 0.05 (0.17) L, respectively, for an adjusted difference of 0.16 L (95% CI, 0.11–0.21; P<0.001; d=0.89). FEV₁/FVC changed by 0.6 (1.8) and 0.2 (1.8) percentage points, respectively; the adjusted difference was 0.40 percentage points (95% CI, –0.07 to 0.87; P=0.095; d=0.22) (Table 2).

3.3 Functional exercise performance, symptoms, oxygenation, adherence, and safety

The 6MWD increased by 55.1 (24.3) m in the intervention group and 17.3 (21.7) m in the control group; the adjusted between-group difference was 37.8 m (95% CI, 31.5–44.1; P<0.001; d=1.64). CAT score changed by –5.05 (2.49) and –0.83 (2.44) points, respectively, for an adjusted difference of –4.22 points (95% CI, –4.90 to –3.54; P<0.001; d=–1.71). Resting SaO₂

changed by 1.52 (0.78) and 0.19 (0.90) percentage points, respectively; the adjusted difference was 1.33 percentage points (95% CI, 1.10–1.56; $P<0.001$; $d=1.58$) (Table 2). Intervention participants completed 87.2% of scheduled sessions. No intervention-related adverse events were reported.

3.4 Correlations of change scores

Within the intervention group, FEV₁ change correlated with FVC change (Pearson $r=0.61$) and 6MWD change ($r=0.34$). CAT change correlated with 6MWD change ($r=-0.42$) and SaO₂ change ($r=-0.31$). The complete lower-triangular correlation matrix is presented in Figure 2.

3.5 Dyspnea grade

The proportion of participants with mMRC grade 3 or 4 decreased from 56.9% at baseline to 21.0% at week 12 in the intervention group and from 54.1% to 47.5% in the control group. The between-group difference in the ordered grade shift was significant (Cochran–Mantel–Haenszel $\chi^2=27.4$; $df=1$; $P<0.001$). Observed grade distributions are shown in Figure 3.

4. Discussion

In this randomized trial, a 12-week nurse-led PLB plus AB program improved FEV₁, FVC, 6MWD, CAT score, and resting SaO₂ relative to routine care. The adjusted 6MWD difference of 37.8 m exceeded the approximately 30-m threshold commonly used for clinically important change in severe COPD [18], and the adjusted CAT difference exceeded the 2-point threshold [14]. The FEV₁ difference of 0.14 L also exceeded the 0.10-L benchmark commonly used to interpret bronchodilator trials [19]. These comparisons describe the magnitude of the observed effects but do not establish long-term clinical benefit.

The spirometric changes require cautious interpretation. Pulmonary rehabilitation and breathing retraining do not consistently improve resting spirometric measures [4,5], although PLB can alter

breathing pattern and chest-wall mechanics acutely [6,7]. The present trial did not include serial inspiratory-capacity measurements, exercise tidal loops, or cardiopulmonary exercise testing to determine whether dynamic hyperinflation occurred. In addition, detailed longitudinal bronchodilator regimens were not available for analysis; medication changes therefore cannot be excluded as a contributor to the spirometric findings. Replication with prespecified medication auditing and mechanistic measurements is needed.

The 6-minute walk test measures functional exercise performance under standardized conditions rather than maximal exercise capacity [11]. Because only 1 test was performed at each time point, the estimated change may include a learning component and has less precision than an assessment based on duplicate tests. Random allocation should reduce systematic between-group imbalance in this effect, but it does not eliminate measurement uncertainty. The observed 6MWD improvement should not be interpreted as evidence of improved prognosis because this interventional trial did not measure long-term clinical outcomes.

The correlations among changes in spirometry, 6MWD, CAT score, and SaO₂ suggest that responses occurred across several domains, but these within-group analyses were exploratory and do not identify a mechanism. The mean baseline SaO₂ was approximately 94% in both groups. Therefore, the 1.33-percentage-point adjusted improvement should not be generalized to patients with normal oxygenation or interpreted as an indication for altered oxygen therapy; no baseline-oxygenation subgroup analysis was prespecified.

The program used 4 face-to-face sessions followed by home practice and weekly telephone reinforcement. This low-resource format may be feasible where comprehensive pulmonary rehabilitation is unavailable [4,9]. However, the control group did not receive matched weekly study contact, so attention and behavioral reinforcement may have contributed to patient-

reported and performance outcomes. Objective assessment of intervention fidelity was also unavailable during the home phase.

Several limitations should be considered. The single-center setting limits external generalizability. Participants and treating nurses were not masked, creating potential performance bias. Twelve weeks was insufficient to evaluate exacerbations, hospitalizations, or mortality. Patients with GOLD stage I disease were not enrolled, and the requirement for clinical stability limits application to frequent exacerbators. The groups differed numerically in sex distribution, although adjusted analyses included sex. Bronchodilator regimens and changes were not characterized in sufficient detail. The 6-minute walk test was not performed in duplicate, and cardiopulmonary exercise testing, inspiratory capacity, arterial blood gases, and serial dynamic-hyperinflation measures were not collected. Finally, home adherence was based on diaries and telephone confirmation rather than an objective sensor or digital log.

The standardized effects were larger than those usually reported for breathing retraining. The observed SD of FEV₁ change was smaller than the value assumed for sample-size planning, which increased the standardized effect estimate. Selection of clinically stable participants, structured nurse support, and self-reported adherence may also have produced an efficacy estimate that will not be reproduced in less selected settings. Pragmatic multicenter trials are needed to estimate effectiveness across different clinical environments.

5. Conclusion

A 12-week nurse-led PLB plus AB program improved spirometric outcomes, functional exercise performance, symptoms, and resting oxygenation in stable outpatients with GOLD stage II–IV COPD. Confirmation in multicenter trials should include duplicate 6-minute walk tests, prespecified documentation of bronchodilator stability, objective adherence monitoring, and

cardiopulmonary exercise testing with serial assessment of inspiratory capacity and dynamic hyperinflation.

Pre-proof

Acknowledgments

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Author Contributions

Changfang Geng: Conceptualization, formal analysis, and writing—original draft. Quan Gao: Investigation and data curation. Jia Yu: Investigation and methodology. Wei Huang: Supervision, project administration, and writing—review and editing. All authors reviewed and approved the final manuscript.

Data Sharing

Deidentified individual participant data and a data dictionary may be made available by the corresponding author beginning 3 months and ending 5 years after publication to researchers whose methodologically sound proposal is approved by the institutional ethics committee and the study team, for the purposes specified in the approved proposal and subject to a data-use agreement. The study protocol is provided with the revision; no separate statistical analysis plan is available.

Funding

This study was supported by institutional resources from Liyang People's Hospital. No external funding was received.

Ethics Approval and Consent to Participate

The institutional ethics committee of Liyang People's Hospital approved the protocol. All participants provided written informed consent.

Clinical Trial Registration

Chinese Clinical Trial Registry: ChiCTR2400000218.

Declaration of Interest

Changfang Geng, Quan Gao, Jia Yu, and Wei Huang declare that they have no competing interests.

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Table 1. Baseline demographic, clinical, and physiologic characteristics.

Characteristic	Intervention (n=109)	Control (n=109)	P value
Age, y	68.5 (8.4)	68.1 (8.7)	0.78
Male, No. (%)	74 (67.9)	59 (54.1)	0.052
Body mass index, kg/m ²	23.4 (3.5)	23.7 (3.4)	0.59
Smoking exposure, pack-years	38.6 (14.5)	37.4 (13.8)	0.55
GOLD stage II/III/IV, No.	47/49/13	45/51/13	0.96
FEV ₁ , L	1.52 (0.42)	1.55 (0.41)	0.65
FVC, L	2.58 (0.55)	2.61 (0.54)	0.69
FEV ₁ /FVC, %	59.2 (7.8)	59.5 (7.6)	0.77
6MWD, m	312.4 (64.5)	317.8 (62.1)	0.53
CAT score	18.6 (4.1)	18.1 (4.3)	0.39
Resting SaO ₂ , %	94.3 (1.8)	94.4 (1.7)	0.68
mMRC grade ≥ 3 , No. (%)	62 (56.9)	59 (54.1)	0.69

Values are mean (SD) unless otherwise indicated. BMI indicates body mass index; CAT, COPD Assessment Test; FEV₁, forced expiratory volume in 1 second; FVC, forced vital capacity; GOLD, Global Initiative for Chronic Obstructive Lung Disease; mMRC, modified Medical Research Council; SaO₂, peripheral oxygen saturation; 6MWD, 6-minute walk distance.

Table 2. Between-group comparison of 12-week change scores.

Outcome	Intervention change	Control change	Adjusted difference (95% CI)	t	P value	Cohen d
FEV ₁ , L	0.18 (0.10)	0.04 (0.10)	0.14 (0.11 to 0.17)	10.05	<0.001	1.35
FVC, L	0.21 (0.21)	0.05 (0.17)	0.16 (0.11 to 0.21)	6.32	<0.001	0.89
FEV ₁ /FVC, percentage points	0.6 (1.8)	0.2 (1.8)	0.40 (−0.07 to 0.87)	1.68	0.095	0.22
6MWD, m	55.1 (24.3)	17.3 (21.7)	37.8 (31.5 to 44.1)	11.85	<0.001	1.64
CAT score	−5.05 (2.49)	−0.83 (2.44)	−4.22 (−4.90 to −3.54)	−12.36	<0.001	−1.71
SaO ₂ , percentage points	1.52 (0.78)	0.19 (0.90)	1.33 (1.10 to 1.56)	11.39	<0.001	1.58

Values are mean (SD) for raw change scores. Adjusted differences and 95% CIs are from analysis of covariance models adjusted for the baseline outcome value, age, sex, and GOLD stage. t statistics are from Welch 2-sample t tests reported as sensitivity analyses. All 218 randomized participants were included in the intention-to-treat models using multiple imputation. CAT indicates COPD Assessment Test; FEV₁, forced expiratory volume in 1 second; FVC, forced vital capacity; SaO₂, peripheral oxygen saturation; 6MWD, 6-minute walk distance.

Figure Titles and Legends

Figure 1. CONSORT participant flow diagram. All randomized participants were included in the intention-to-treat analysis; missing week-12 data were handled by multiple imputation.

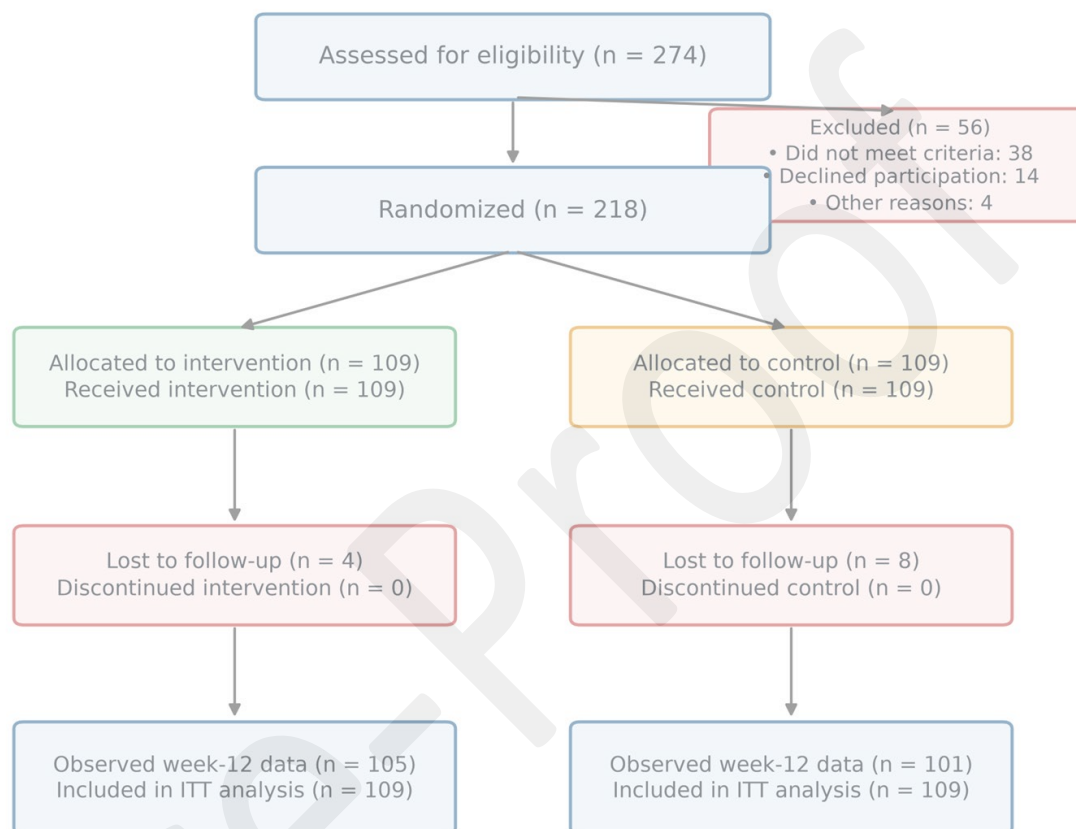


Figure 2. Lower-triangular Pearson correlation matrix of 12-week change scores within the intervention group. Color and numeric labels encode the same correlation coefficient on a symmetric -1 to 1 scale; the diagonal and duplicated upper triangle are omitted.

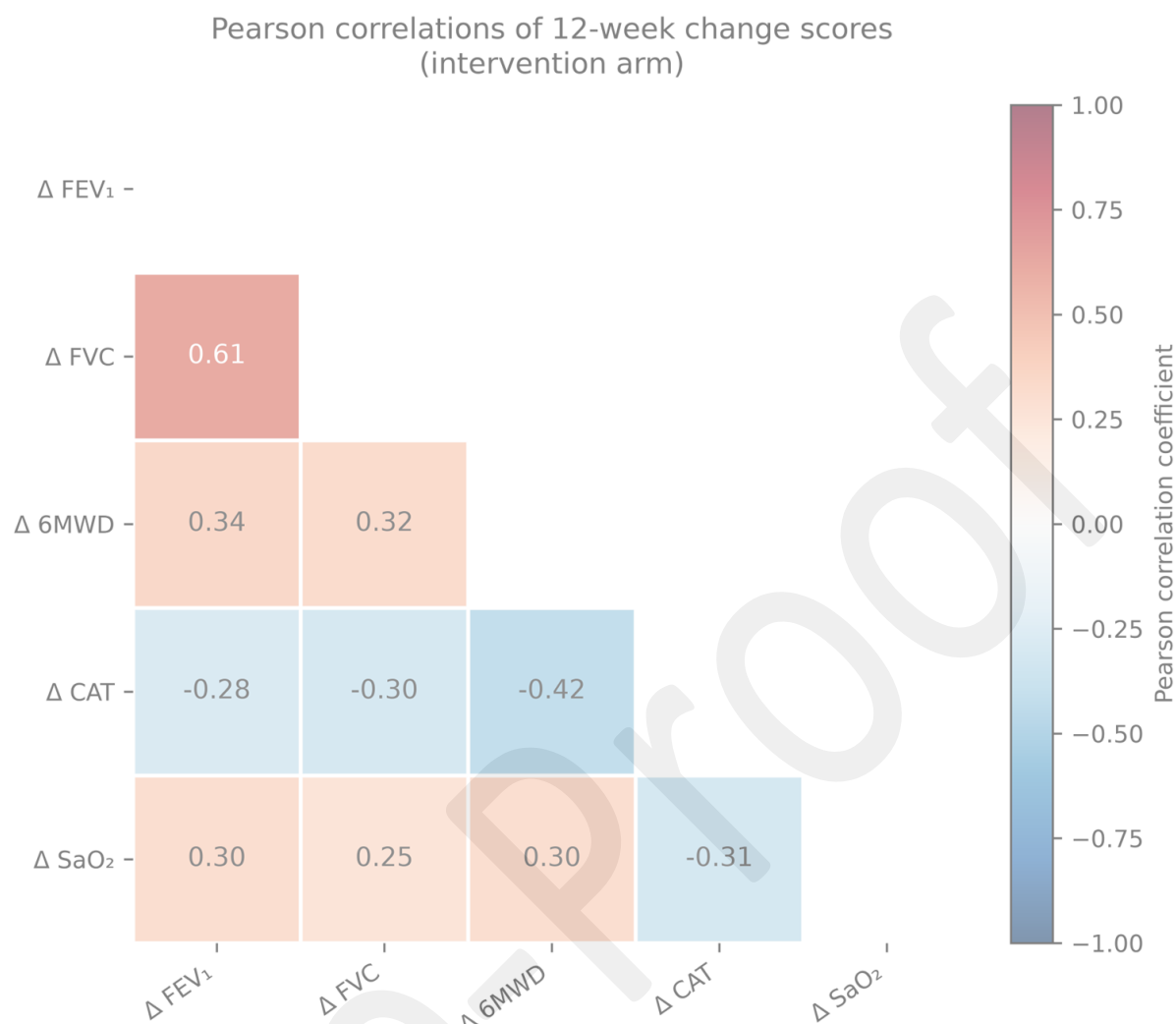
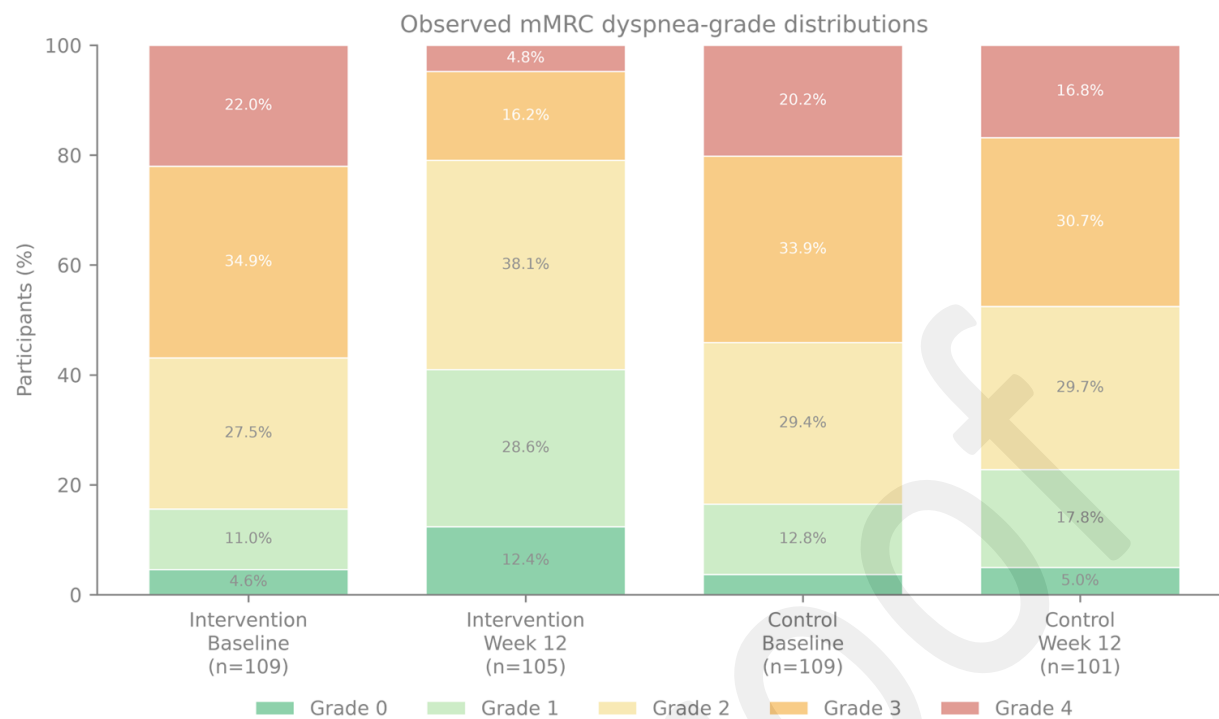


Figure 3. Observed modified Medical Research Council (mMRC) dyspnea-grade distributions at baseline and week 12 by group. Baseline denominators were 109 per group; observed week-12 denominators were 105 in the intervention group and 101 in the control group.



Online Supplement

Supplementary Appendix 1: Study Protocol

Nurse-Led Pursed-Lip and Abdominal Breathing Training Improves Pulmonary Function and Functional Exercise Performance in Patients With Chronic Obstructive Pulmonary Disease: A Prospective Randomized Controlled Trial

Protocol item	Details
Sponsor/center	Liyang People's Hospital
Protocol version	Version 1.0 (pre-enrollment protocol)
Trial registration	Chinese Clinical Trial Registry: ChiCTR2400000218
Design	Single-center, parallel two-group randomized controlled trial
Planned enrollment	218 participants
Intervention period	12 weeks
Study period	January 2024 through March 2025

1. 1. Background and Rationale

COPD is characterized by persistent airflow limitation, dyspnea, and reduced daily function. PLB can prolong expiration and modify breathing pattern, while AB emphasizes diaphragmatic recruitment. A standardized nurse-led program may improve physiologic and patient-centered outcomes while remaining feasible in outpatient care.

2. 2. Objectives and Hypotheses

The primary objective is to determine whether 12 weeks of nurse-led PLB plus AB improves FEV₁ and 6MWD compared with routine outpatient care. The prespecified hypothesis is that the intervention will improve both co-primary outcomes. Secondary objectives are to evaluate FVC, FEV₁/FVC, CAT score, resting SaO₂, mMRC dyspnea grade, adherence, and safety.

3. 3. Trial Design and Setting

This is a prospective, single-center, parallel two-group trial with 1:1 allocation at Liyang People's Hospital. Outcome assessors and the primary analyst are blinded. Participants and intervention nurses cannot be blinded because of the behavioral intervention.

4. 4. Eligibility

Inclusion criteria: age 45–85 years; COPD confirmed by postbronchodilator FEV₁/FVC <0.70; GOLD stage II–IV; clinical stability for at least 4 weeks; ability to consent and complete spirometry and the 6-minute walk test. Exclusion criteria: acute exacerbation in the preceding 4 weeks; interstitial lung disease, bronchiectasis, active tuberculosis, or lung cancer; NYHA class III–IV heart failure; inability to complete outcome testing; or cognitive impairment precluding consent.

5. 5. Intervention

Participants allocated to intervention complete 30-minute sessions 3 times weekly for 12 weeks. Each session contains a 5-minute warm-up, 20 minutes of PLB plus AB cycles, and a 5-minute cool-down. The breathing cycle uses nasal inspiration for 2 seconds and pursed-lip expiration for 4–6 seconds coordinated with abdominal movement. The first 4 sessions are supervised face to face by a senior respiratory nurse;

later sessions are home based with a paper diary and weekly reinforcement calls. No metronome or electronic visual aid is specified; supervised pacing uses verbal counting and home pacing uses written timing instructions.

6. 6. Comparator and Concomitant Care

Control participants receive routine outpatient pharmacotherapy review and standard health education without structured breathing training. Both groups attend baseline and week-12 assessment visits; additional outpatient visits occur as clinically indicated. Weekly study calls are limited to the intervention group. Prescribed clinical care remains under the treating clinician. Longitudinal inhaler-class changes are not a protocol outcome.

7. 7. Outcomes and Assessment Schedule

Outcome	Metric	Time points	Role
FEV ₁	Change in liters	Baseline; week 12	Co-primary (first in hierarchy)
6MWD	Change in meters; one test per time point	Baseline; week 12	Co-primary (second in hierarchy)
FVC	Change in liters	Baseline; week 12	Secondary
FEV ₁ /FVC	Change in percentage points	Baseline; week 12	Secondary
CAT	Change in 0–40 score	Baseline; week 12	Secondary
Resting SaO ₂	Change in percentage points after 10-min seated rest	Baseline; week 12	Secondary
mMRC	Ordered grade distribution	Baseline; week 12	Secondary
Adherence	Completed/scheduled sessions	Throughout	Process
Adverse events	Active elicitation and safety log	Visits; weekly intervention calls	Safety

8. 8. Sample Size

The calculation assumes an FEV₁ change difference of 0.12 L, within-group SD of 0.25 L, 2-sided $\alpha=0.05$, and 90% power, yielding 92 participants per group. With approximately 15% attrition, the planned randomized sample is 218.

9. 9. Randomization, Concealment, and Blinding

A computer-generated allocation sequence uses permuted blocks of 4 and 6 and stratification by GOLD stage II versus III–IV. Sequentially numbered, opaque, sealed envelopes implement allocation. A coordinator independent of recruitment opens envelopes after eligibility confirmation. Recruiting personnel do not have sequence access. Spirometry and field-walk assessors and the primary analyst remain blinded.

10. 10. Statistical Analysis

The primary population includes all randomized participants in their assigned groups. Each continuous outcome is analyzed with ANCOVA of 12-week change adjusted for baseline outcome value, age, sex, and GOLD stage. Missing values are handled with fully conditional multiple imputation using 20 datasets and Rubin pooling. The co-primary fixed sequence is FEV₁ followed by 6MWD. FEV₁ is tested first at 2-sided $\alpha=0.05$; only after rejection is 6MWD confirmatory at $\alpha=0.05$. If FEV₁ is not significant, 6MWD is exploratory. Secondary outcomes are exploratory without multiplicity adjustment. Welch tests of raw

changes are sensitivity analyses. mMRC is evaluated as an ordered distribution with a Cochran–Mantel–Haenszel test. Cohen d summarizes standardized effect size.

11. 11. Data Management and Quality Control

Eligibility, allocation, outcomes, adherence, missingness, and adverse events are recorded on trial forms. Spirometry uses calibrated equipment. Field-walk testing uses a 30-m indoor course and standardized encouragement. Data are checked for range, consistency, and completeness before database lock. The blinded analysis dataset retains randomized group codes until primary models are finalized.

12. 12. Safety

Adverse events are elicited at clinic visits and intervention telephone contacts and recorded in a safety log. Clinically important events are referred to the treating clinician. Participation may be paused or stopped for acute exacerbation, hemodynamic instability, chest pain, syncope, or other clinician-determined safety concerns.

13. 13. Ethics and Consent

The institutional ethics committee of Liyang People's Hospital approved the protocol. Written informed consent is obtained before study procedures. Data are handled as confidential research records. Participation is voluntary and may be withdrawn without affecting clinical care.

14. 14. Dissemination and Data Sharing

Results will be reported in accordance with CONSORT. Deidentified participant data and a data dictionary may be shared after publication under ethics approval, a methodologically sound proposal, and a data-use agreement. Authorship will follow ICMJE criteria.

15. 15. Protocol Deviations and Amendments

Protocol deviations are documented with date, reason, and impact. Any substantive amendment requires ethics review before implementation unless immediate action is needed to protect a participant. The co-primary hierarchy is not changed after outcome data review.

16. Protocol references

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