

Protocol

A study protocol for assessing the efficacy of add-on Brihatkataphaladi Vati, Vasadi Kashaya and polyherbal nebulization in the management of chronic obstructive pulmonary disease: a randomized placebo-controlled clinical trial

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ABSTRACT

Background: Chronic obstructive pulmonary disease (COPD), correlated with Tamaka Shwasa in Ayurveda, is a major global health concern characterized by persistent airflow obstruction. Conventional treatment provides symptomatic relief and reduces exacerbations but has limited effects on disease progression. Ayurveda interventions with potential anti-inflammatory, mucolytic, and broncho-dilatory properties may offer complementary benefits. This study aims to evaluate the efficacy and safety of add-on Brihatkataphaladi Vati, Vasadi Kashaya, and polyherbal nebulization alongside standard care in COPD.

Methods: This randomized, placebo-controlled, parallel-group clinical trial will include 50 clinically stable COPD patients classified as GOLD Grades I-III. Participants will be randomly allocated into two groups of 25 each. The intervention group will receive Brihatkataphaladi Vati, Vasadi Kashaya, and polyherbal nebulization alongside standard care, whereas the control group will receive placebo alongside standard care. Treatment will continue for 90 days, with weekly follow-ups and two post-treatment follow-up visits. The primary outcome will be the change in COPD symptom severity measured using the COPD assessment test (CAT) score. Secondary outcomes will include changes in forced expiratory volume in one second (FEV₁), FEV₁/FVC ratio, exacerbation and hospitalization frequency, rescue medication use, Ayurvedic symptom scores, and safety parameters assessed through clinical monitoring and laboratory investigations. Outcomes will be assessed at baseline and post-treatment. Appropriate statistical tests will be applied, with $p < 0.05$ considered statistically significant.

Conclusions: The study is expected to provide evidence regarding the efficacy and safety of this integrative therapeutic approach in improving symptoms and pulmonary function in COPD patients.

Trial Registration: The trial is registered with Clinical trial registry of India (CTRI) CTRI/2026/05/110230.

Keywords: Ayurveda, Brihatkataphaladi Vati, COPD, Polyherbal nebulization, Tamaka Shwasa, Vasadi Kashaya

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) (CA22) is a chronic lung disease that causes air flow limitation (less air in and out of the airways) and breathing-related symptoms.¹ COPD (CA22) is a heterogeneous lung condition characterized by chronic respiratory symptoms

(dyspnea, cough, expectoration, and/or exacerbations) due to abnormalities of the airways (bronchitis, bronchiolitis), and/or alveoli (emphysema) that cause persistent, often progressive, airflow obstruction.² Chronic bronchitis is a long-term inflammatory condition of the airways, characterized by a persistent productive cough without other identifiable underlying causes lasting at least 3 months per year for 2 consecutive years.³ while

emphysema is characterized by irreversible destruction of alveolar walls, resulting in air trapping, impaired gas exchange, and progressive airflow obstruction.⁴

In Charaka Samhita, Shwasa Roga (respiratory disease) has been mentioned as one of the most dreadful diseases.⁵ Acharya Sushruta also mentions it major and difficult to treat.⁶ Tamaka Shwasa (COPD) is a subtype of Shwasa Roga that primarily affects the Pranavaha Srotas (respiratory channels). It is primarily caused by the vitiation of Vata and Kapha Doshas. When excess Kapha accumulates in the Pranavaha Srotas (respiratory pathways), it obstructs the natural movement of Prana Vayu. This leads to aggravated and retrograde Vata movement, referred to as Pratiloma Vayu, resulting in labored and prolonged expiration. The patient experiences intense respiratory distress accompanied by Ghurghuraka-a characteristic wheezing or rattling sound produced due to obstructed airflow. The breathing becomes forceful and of high velocity, severely disturbing normal physiology and potentially endangering life. In Charaka Samhita, it has been mentioned that the patient has a profound cough and may even get fainting spells as the patient finds it difficult to expectorate.

Acharya Charaka further mentioned that when the patient of Tamaka Shwasa successfully expectorates sputum, he feels relieved for some time. The patient finds it difficult to lie down comfortably and thus finds it difficult to sleep. They often assume a sitting posture as it provides some comfort. The condition worsens in cold, damp, and night-time environments, and the patient finds relief from warmth, upright posture, and fresh air.⁷

COPD is currently one of the leading causes of morbidity and mortality worldwide, accounting for approximately 3.5 million deaths annually.⁸ Although current modern pharmacological management, including, bronchodilators and inhaled corticosteroids, provide symptomatic relief and reduce exacerbations, they have limited impact on disease progression and are often associated with long-term medication dependence. Therefore, there is a need to explore safe and effective integrative approaches that may improve symptom control, quality of life, and overall disease management. The present study evaluates a comprehensive Ayurvedic add-on therapeutic approach consisting of oral Ayurvedic formulations along with polyherbal nebulization administered in addition to standard medical care. The selected oral formulations are traditionally indicated in Tamaka Shwasa for Kapha-Vata Shamana, Shothahara, Shwasahara, and Rasayana actions, while polyherbal nebulization represents a localized drug delivery approach that enables direct delivery of herbal formulations into the respiratory tract, potentially enhancing local therapeutic action, promoting airway clearance, and providing rapid symptomatic relief. The integration of these interventions offers a multi-targeted therapeutic strategy with synergistic anti-inflammatory, mucolytic, bronchodilatory, and

immunomodulatory effects, thereby facilitating comprehensive management of COPD. Comparative clinical trials assessing the outcomes of such integrative approaches versus standard care alone are scarce. Most existing studies focus on oral or decoction-based formulations, with limited exploration of pulmonary drug delivery using Ayurvedic principles. The potential benefits of localized delivery through nebulization, such as enhanced bioavailability, rapid onset of action, and reduced systemic side effects, remain under-researched.

Aim

Aim of the study is to evaluate the improvement in clinical outcomes in COPD(CA22) patients receiving standard care with placebo and those receiving standard care with add-on Brihatkataphaladi Vati, Vasadi kasahaya, and polyherbal nebulization.

Objectives

The primary objective of this study is to assess the change in symptom severity in patients with COPD using the CAT score following the intervention. The secondary objectives are to evaluate changes in pulmonary function test parameters, including forced expiratory volume in one second (FEV₁) and the FEV₁/FVC ratio, and to assess the safety and tolerability of the Ayurvedic interventions through clinical evaluation and laboratory investigations.

Outcome

The primary outcome will be the change in COPD symptom severity from baseline to the end of treatment, assessed using the CAT score.⁹

Secondary outcomes will include changes in pulmonary function test (PFT) parameters including forced expiratory volume in one second (FEV₁) and the FEV₁/FVC ratio, frequency of exacerbations and hospitalizations, reduction in the use of rescue medication, improvement in signs and symptoms assessed using a structured Ayurvedic symptom scoring scale, and safety and tolerability assessed through clinical monitoring and laboratory investigations.¹⁰

METHODS

Trial design

This study is a randomized, controlled, parallel-group clinical trial with an allocation ratio of 1:1. It follows a superiority framework to compare the effectiveness of the intervention against the control. The method of randomization will be computer generated randomization using a random number table to ensure unbiased allocation.

The layout of the study i.e., from participant's screening to final assessment has been shown in Figure 1.

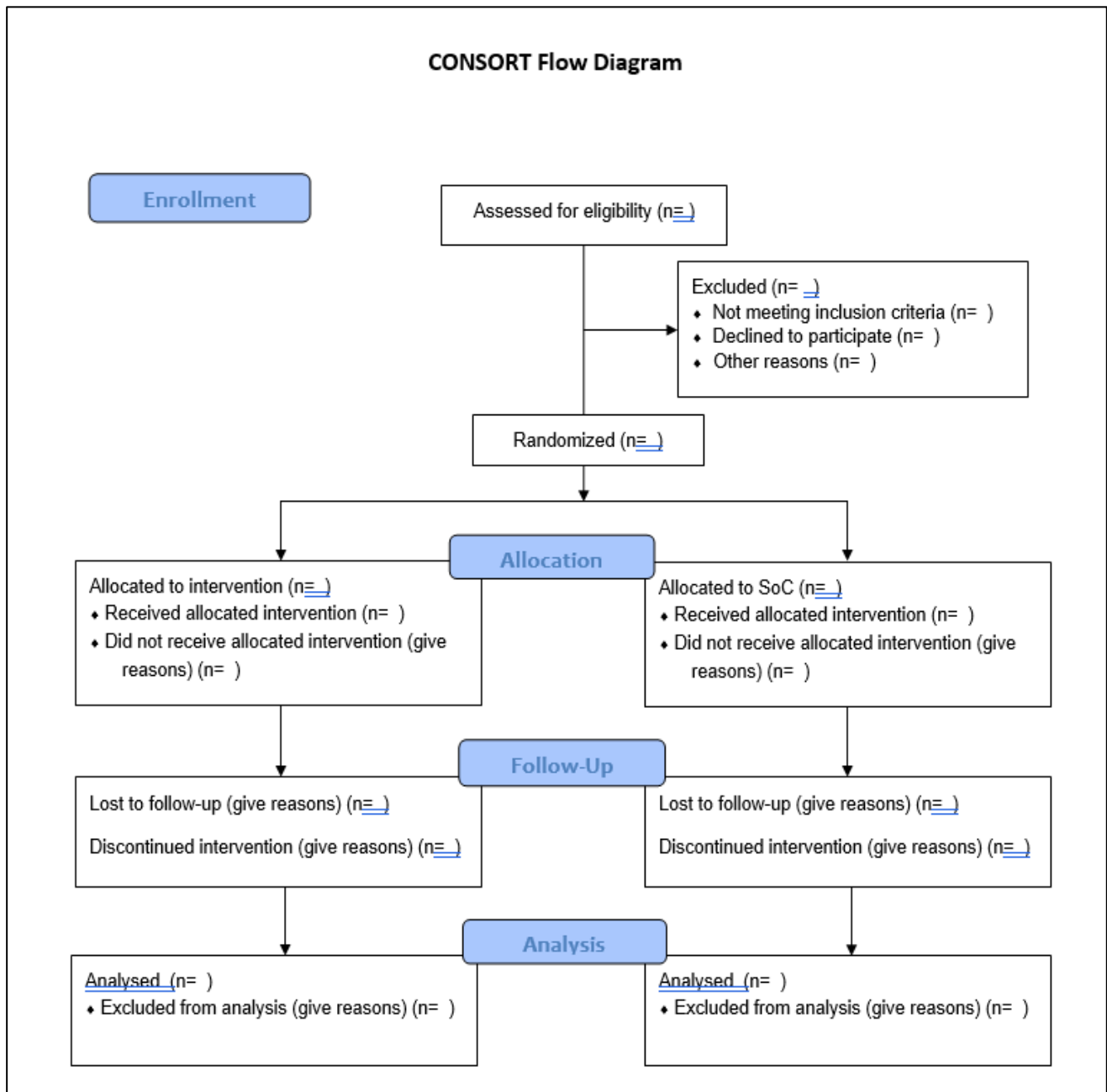


Figure 1: CONSORT flow chart.

Allocation

As this is an open-label study, neither the participants nor the investigators will be blinded to the allocated interventions; therefore, allocation concealment and blinding will not be implemented. Although the open-label design may introduce the potential for performance and detection bias, it has been adopted considering the practical and logistical feasibility of the study.

Sample size calculation

The sample size was calculated for a randomized clinical trial with a continuous primary outcome. The calculation

was based on a significance level (α) of 0.05 and a statistical power of 80%. Considering the expected mean difference ($\Delta=2$ points) in CAT score between the two groups and a standard deviation ($\sigma=2.4$) derived from previously published clinical studies on Ayurvedic inhalation therapy in COPD, the sample size was calculated using the following formula:

$$n = [2 \times (Z_{1-\alpha/2} + Z_{1-\beta})^2 \times \sigma^2] / \Delta^2$$

Based on the above parameters, the required sample size was 22 participants per group. Assuming a 10% dropout rate, the final sample size was rounded to 25 participants per group, making a total of 50 participants for the study.¹¹

Study setting

The study will be conducted at the department of Kayachikitsa, Institute of Teaching and Research in Ayurveda (ITRA), Jamnagar, in collaboration with the department of Respiratory Medicine, G.G. Hospital, Jamnagar. Eligible participants diagnosed with COPD will be recruited from the OPD/IPD of the Kayachikitsa, TB-Chest OPD of Kayachikitsa, or those referred from other departments of ITRA, and the Department of Respiratory Medicine, G. G. Hospital. For screening and diagnostic purposes, chest X-ray (PA view), spirometry, hematological investigations including hemoglobin, total leukocyte count, differential leukocyte count, absolute eosinophil count, and erythrocyte sedimentation rate (ESR) will be performed. Biochemical investigations will include blood urea, serum creatinine, serum lipid profile, aspartate aminotransferase (AST), alanine aminotransferase (ALT), serum bilirubin, and fasting blood glucose levels. Urine routine and microscopic examination will also be conducted. Safety will be monitored through liver function test including SGPT, SGOT and serum bilirubin levels. Baseline and post-intervention assessments will include hematological investigations (hemoglobin, total leukocyte count, total red blood cell count, erythrocyte sedimentation rate, absolute eosinophil count, and differential leukocyte count), biochemical investigations (fasting blood sugar, postprandial blood sugar, lipid profile including total cholesterol, triglycerides, HDL, LDL, VLDL, blood urea, serum creatinine, serum uric acid, liver function tests including AST, ALT, alkaline phosphatase, total serum bilirubin, and direct and indirect bilirubin), urine examination (routine and microscopic), pulmonary function test (FEV₁, FVC, and FEV₁/FVC ratio). These investigations will be performed at baseline and repeated after completion of the intervention to evaluate the safety and therapeutic efficacy of the treatment. Assessments will include CAT score and spirometric parameters (FEV₁, FVC, and FEV₁/FVC ratio).

Diagnostic criteria

Participants will be diagnosed based on clinical evaluation for chronic respiratory symptoms, including dyspnea, cough and wheeze consistent with COPD (CA22) (Tamaka Shvasa). Detailed history, physical examination, which will include use of accessory muscle of respiration, pursed-lip breathing, barrel shaped chest, dyspnoea relieving posture-Sitting in characteristic “tripod” position, Jugular venous distension during expiration, reduced bilateral chest expansion, chest hyperresonance, decreased intensity of breath sounds, early inspiratory crackles and wheezing will be conducted. Spirometry confirming FEV₁ <80% and FEV₁/FVC <0.7 post-bronchodilator is mandatory.¹² X-ray with marked or prominent broncho-vascular markings, enlarged cardiac shadow, hyper translucent lung field, increased intercostal spaces, low flat diaphragm, decreased broncho-vascular markings, narrow

or tubular heart, will be used to further confirm diagnosis and to rule out other respiratory conditions. Standardized tools such as the mMRC Dyspnea Scale, CAT, and Ayurvedic symptom scoring will be applied to assess baseline severity and eligibility before randomization.

Inclusion criteria

Patients of either gender, religion, or caste, aged 40-80 years, fulfilling diagnostic criteria for chronic obstructive pulmonary disease (COPD) GOLD grade I, II, and III will be included in this clinical trial. Only those who are willing to provide written informed consent and comply with the study protocol, including scheduled follow-up visits and outcome assessments, will be enrolled.

Exclusion criteria

Participants not willing for the trial will be excluded. Participants having bronchial asthma or other respiratory diseases like pulmonary tuberculosis, pneumothorax, pneumonia, cystic fibrosis, interstitial lung disorder, and lung cancer will be excluded. Individual with a history of myocardial infarction, heart failure, acute ischemic coronary disease, unstable angina, or severe cardiac arrhythmia within last 6 months, Participants suffering from accelerated hypertension (>160/100 mmHg), diabetes (FBS>150 mg/dl), GOLD grade IV (FEV₁% <30% of predicted), and not getting conventional treatment as per allopathic standards will not be eligible. Participants requiring long-term oxygen therapy, and suffering from major systemic illness necessitating long-term treatment or undergoing regular treatment for any other severe illness will be excluded from the study.

Intervention and comparator details

Intervention group (group A-Trial drugs along with standard care)

Participants allocated to the intervention group (Group A) will receive the study intervention in addition to standard COPD care. The intervention will commence with a preparatory phase consisting of Deepana-pachana using Trikatu Churna (3 g twice daily after meals). Along with this, all the participants will undergo Sthanika Abhyanga with Katu Taila and rock salt, followed by steam fomentation using plain water steam over the Urah Pradesha and Prishtha Pradesha for 3 days. On the following day, Koshtha Shodhana will be performed using Trivrita Avaleha 10-20 g administered early in the morning on an empty stomach with lukewarm water, according to the patient's Koshtha.

During the treatment phase, Brihatkatphaladi Vati (500 mg, two tablets) thrice daily after breakfast and dinner with lukewarm water as Anupana. and Vasadi Kashaya orally at a dose of 40 mL twice daily, will be administered on an empty stomach 30 minutes before breakfast and approximately 5 hours after lunch for 90

days. Along with this Polyherbal Arka nebulization (3 ml) will be administered twice daily for the initial 15 days, followed by nebulization during each follow-up visit(weekly) and SOS thereafter.

Comparator group (group B-placebo along with standard care)

Participants in the Group B (control group) will receive placebo capsules containing roasted semolina (250 mg) in a dose of 2 capsules twice daily with lukewarm water for 90 days and Placebo nebulization using distilled water (2.5 ml once) will be administered at weekly intervals for a total of 4 sittings.

Both groups will receive standard COPD treatment as per GOLD guidelines throughout the study period, including inhaled bronchodilators (with or without inhaled corticosteroids), rescue medication as needed, and other supportive management as advised by the treating pulmonologist/physician.

Procurement, authentication, and preparation of trial drugs

The raw drug Bharangi Moola, required for the preparation of both Vasadi Kashaya and polyherbal Arka for nebulization, have been procured from Krishna Ayurvedics, Thiruvananthapuram, Kerala, India, and was identified and authenticated through pharmacognostical evaluation prior to use. All other raw materials required for the preparation of Brihatkatphaladi Vati, Vasadi Kashaya and Polyherbal Arka (vasa, tulsi, shirisha) have been procured from the ITRA Pharmacy, Jamnagar, Gujarat, India. Vasadi Kashaya and Brihatkatphaladi Vati have been prepared at the ITRA Pharmacy, Jamnagar, Gujarat, India. The Arka formulation for nebulization has been prepared at the Pharmaceutical Chemistry Laboratory, Institute of Teaching and Research in Ayurveda (ITRA), Jamnagar, Gujarat, India, following standard pharmaceutical procedures.

Withdrawal criteria

Participants will be withdrawn from the study if they continue to show symptomatic deterioration despite two consecutive referrals to a higher center and/or appropriate readjustment of allopathic medication. Participants will also be withdrawn from the study if they experience any adverse event related to the oral or inhalational medications or study procedures. In addition, participants who voluntarily withdraw their informed consent at any stage of the study or are unable to comply with the study protocol and follow-up requirements will be discontinued from further participation.

Follow-up

Patients will be advised to visit the hospital every week during the treatment for 90 days and then 2 follow ups

after the completion of trial at 15 days interval. During these visits, outcomes related to assessment of signs and symptoms and any delayed adverse events will be recorded to assess durability and safety of intervention.

Participant timeline

Table 1 outlines the schedule of events throughout the clinical trial, from screening of the eligible participant to the end of the treatment period. Participants will undergo initial evaluations including informed consent, demographics, and baseline investigations. participants will undergo periodic assessments at weekly intervals (± 3 days), including physical examination, vital signs, and symptom assessment. Study drugs will be dispensed, and participants will be regularly monitor for safety, efficacy, and any adverse events. Final assessments and analysis will be conducted at the end of the treatment period.

Drug and diet compliance

Drug compliance will be ensured and assessed throughout the study period. The trial medications will be administered according to the prescribed dose and treatment schedule. Participants will receive detailed instructions regarding the dosage, frequency, and timing of drug administration. The trial medications will be dispensed at each scheduled follow-up visit, and compliance will be assessed by reviewing the returned medication and participant self report at every visit. All participants will also be advised to adhere to a standardized dietary regimen throughout the study period.

Treatment adherence

Treatment adherence will be assessed at each follow-up visit through participant interviews, review of medication intake records, pill counts of returned Brihatkataphaladi Vati, assessment of the remaining quantity of Vasadi Kashaya, treatment logs for polyherbal nebulization, and review of concomitant standard care medications. Participants with suboptimal adherence will receive appropriate counselling to reinforce the importance of compliance with the prescribed treatment regimen. Reasons for missed doses, missed nebulization sessions, treatment discontinuation, or withdrawal from the study will be documented in the case record form (CRF).

Data collection plan

The required data will be collected by the scholar using a structured CRF, which will include demographic details, presenting complaints, history of present illness, past, family, treatment and personal history, Ashtavidha Pariksha, Dashavidha Pariksha, Dosha and Srotas Pariksha, general physical examination, respiratory system examination, vital parameters, laboratory investigations, treatment details, follow-up assessments, adverse drug reactions, spirometry (FEV₁ and FEV₁/FVC), CAT, and overall treatment outcome.

Table 1: The timeline for participants enrolling in trial.

Periods	Screening	Intervention phase												Follow-up	
Visit number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Visit name	Screening period	Randomization	-	-	-	-	-	-	-	-	-	-	End of the treatment period	Can be telephonically	-
Visit window (in days)	1-7	7 days from screening	7±3	7±3	7±3	7±3	7±3	7±3	7±3	7±3	7±3	7±3	7±3	15±3	15±3
Informed consent	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Demographics	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Medical history	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Physical examination	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Vital signs	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Spirometry	√	-	-	√	-	-	-	-	-	-	-	-	√	-	-
Sign and symptoms (as per grading system)	√	√	√	√	√	√	√	√	√	√	√	√	√	-	-
Pulse oximetry	√	√	√	√	√	√	√	√	√	√	√	√	√		
CAT	√	-	-	-	-	-	-	-	-	-	-	-	√	√	√
Hematological and biochemistry test	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Urine routine and microscopic	√	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Dispense study drugs	-	√	√	√	√	√	√	√	√	√	√	√	√	-	-
Adverse events	-	-	√	√	√	√	√	√	√	√	√	√	√	√	-

Data management

Data from CRF will be entered into pre-specified excel-sheets by the scholar. The data entry will be verified with the double data entry methods. The data of the personal details of the participants will be kept confidential by the scholar.

Data analysis

The collected data will be analyzed using appropriate statistical methods and presented as mean, standard deviation (SD), and standard error (SE). Descriptive statistics will be used to summarize demographic and baseline characteristics. Associations between categorical baseline variables will be assessed using the Chi-square test or Z-test, as appropriate. For continuous variables, within-group comparisons will be performed using the paired t test, while between-group comparisons will be analyzed using the unpaired t-test. Non-parametric data will be analyzed using the Wilcoxon Signed-Rank Test for within-group comparisons and the Mann-Whitney U Test for between-group comparisons. Data will be compiled in Microsoft excel and analyzed using SPSS/Sigma-stat software. Statistical significance will be considered at $p < 0.05$, with $p < 0.01$ indicating high significance and $p < 0.001$ indicating very high significance.

Ethical clearance

Ethical clearance has been obtained (PGT/7-A/Ethics/2026-27/284) and the study has been registered with the Clinical Trials Registry-India (CTRI No.: CTRI/2026/05/110230).

Confidentiality

All the trial data recorded will be treated in strict confidence. During documentation and analysis of the trial, the individual participant is identified only by their enrolment number. The source documents and electronic data have restricted accessibility.

Trial status

The preparation of trial drug has been completed in month of July, 2026. The recruitment of participants has been initiated.

DISCUSSION

COPD remains a major global health burden and is associated with progressive airflow limitation, persistent respiratory symptoms, recurrent exacerbations, and impaired quality of life. Despite advances in pharmacological management, many patients continue to experience residual symptoms and functional limitations, highlighting the need for effective adjunctive therapeutic approaches.

The present study protocol outlines a randomized, placebo-controlled clinical trial to evaluate the efficacy and safety of Brihat Katphaladi Vati, Vasadi Kashaya, and Polyherbal Nebulization as an adjunct to standard conventional care in patients with COPD. COPD is a progressive airway disease characterized by persistent airflow limitation, recurrent exacerbations, and impaired quality of life. Although conventional therapy effectively reduces symptoms and exacerbations, disease progression remains a major challenge, and may be associated with long-term adverse effects, highlighting the need for safe and evidence-based complementary therapeutic approaches.

From the Ayurveda perspective, COPD closely resembles Tamaka Shwasa, a disorder predominantly caused by the vitiation of Vata and Kapha leading to obstruction of Pranavaha Srotas. Based on these principles, the study incorporates Deepana-Pachana, Urah prishtha Abhyanga-Swedana, and Koshtha Shodhana as preparatory procedures, followed by administration of Brihat Katphaladi Vati, Vasadi Kashaya, and Polyherbal Arka Nebulization. These interventions are expected to exert bronchodilator, mucolytic, anti-inflammatory, and antioxidant effects, while nebulization facilitates targeted delivery of herbal constituents directly to the respiratory tract.

The study employs a clearly defined inclusion and exclusion criteria to ensure recruitment of clinically stable COPD patients. An appropriate sample size has been determined to provide adequate statistical power, and all participants will continue to receive standard COPD management according to the GOLD guidelines, thereby ensuring ethical clinical practice while evaluating the additional benefit of the Ayurveda intervention.

The primary outcome of the study will be assessed by the change in CAT score, which reflects symptom burden and health-related quality of life. Secondary outcomes include changes in pulmonary function parameters (FEV_1 and FEV_1/FVC ratio), frequency of exacerbations, rescue medication use, improvement in Ayurveda signs and symptoms assessed using a structured Ayurvedic symptom scoring scale, and safety evaluation through clinical assessment and laboratory investigations. The combination of validated subjective and objective outcome measures is expected to provide comprehensive evidence regarding the clinical efficacy and safety of the proposed intervention.

Previous Ayurvedic clinical studies have evaluated oral formulations and inhalation therapies in the management of Tamaka Shwasa and COPD. However, randomized controlled trials evaluating the combined use of oral Ayurvedic formulations with polyherbal nebulization as an adjunct to standard care remain limited. Therefore, the present study aims to evaluate the efficacy and safety of this integrative approach in the management of COPD. If the study demonstrates favourable outcomes, it may

provide an effective adjunctive therapeutic strategy for improving symptom control, pulmonary function, and quality of life in COPD patients. Furthermore, the findings may strengthen the evidence base for Ayurveda in respiratory disorders and encourage future multicentric clinical trials integrating traditional Ayurvedic interventions with contemporary respiratory medicine.

CONCLUSION

The proposed clinical trial is expected to generate robust evidence regarding the efficacy and safety of an integrative Ayurvedic treatment protocol in COPD. By employing a randomized placebo-controlled design with standardized clinical and functional outcome measures, the study may contribute to evidence-based integration of Ayurveda into COPD management.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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