

Cover letter

Unique Protocol ID: INPATIENT COPD REHABILITATION

**Official Title: Efficacy Of Inpatient Pulmonary Rehabilitation Program In
Elderly Patients with Acute Exacerbation Of COPD**

Release date:8-5-2025

EFFICACY OF INPATIENT PULMONARY REHABILITATION PROGRAM IN ELDERLY PATIENTS WITH ACUTE EXACERBATION OF COPD: A RANDOMIZED CONTROL TRIAL.

Introduction

Chronic Obstructive Pulmonary Disease (COPD) is now one of the top three causes of death worldwide, and 90% of these deaths occur in low- and middle-income countries (LMICs) [1, 2] . Previous studies illustrated that older adults with COPD have a high risk of experiencing AECOPD, which typically leads to decreased lung function, an increased incidence of respiratory failure, and even death [3]. Acute exacerbation (AE) of COPD (AECOPD) is defined as episodes of acute worsening of respiratory symptoms (such as dyspnea, coughing, and sputum production) that require additional therapy [4]. AECOPD is responsible for patients' clinical deterioration.

Patients requiring hospitalisation are associated with poor outcomes, including accelerated declines in muscle strength and lung function, a reduced health status and quality of life (QOL), accelerated disease progression, a significant risk of recurrent exacerbation, and an increased risk of mortality [5] . Increase population ageing, in addition to a large percentage of elderly experiencing AECOP, will lead to extra efforts in healthcare systems, in addition to high costs of medical care services. Seeking cost-effective ways is the aim of international societies concerning COPD.

The study aimed to identify the effect of early pulmonary rehabilitation in elderly patients with Acute exacerbation (AE) of COPD (AECOPD) on exercise tolerance, dyspnea, sleep quality, fatigue, and time from hospital admission till discharge from the hospital.

Methods

Participants

A prospective, supervised, blinded randomised controlled trial (RCT) will be conducted at Alzahraa University Hospital, in the inpatient department of Chest disease, Cairo, Egypt. Participants were allocated to the two groups using computer-generated random allocation sequences. The codes were determined by using serially numbered block sizes will be kept in sealed and opaque envelopes in a locked office. Participants' healthcare providers were blinded to the group assignment.

Sample size calculation.

Before the participants were included in the study, the sample size was measured using Epi Info™ program version 7. 2. Based on the previous study [6].

Inclusion criteria

Patients with mild to moderate acute exacerbation of COPD in both genders 2) were older than 65 years, 3) were in clear consciousness, 4) had been diagnosed with shortness of breath or dyspnea that was not caused by heart disease, pneumothorax, or pulmonary oedema

Exclusion criteria were 1) systolic blood pressure lower than 90 mmHg, 2) an unstable psychological status, hemoptysis, pneumothorax, pulmonary oedema, and the use of a respirator

Ethical considerations

The study was approved by the ethical committee of the Faculty of Medicine for Girls- Al-Azhar University, Cairo, Egypt, number (2723). The principal investigator explained to the patients the objectives, the implementation process,

Inclusion criteria, and exclusion criteria of the study. In addition, the patients were informed that they could withdraw from the study at any time if they felt unwell, and they were enrolled only after signing informed consent forms

Assessment

Diagnosis of COPD

The presence of non-fully reversible airflow obstruction ($FEV_1/FVC < 0.7$ post-bronchodilation) measured by spirometry confirms the diagnosis of COPD [7]. The patients were admitted to the hospital for over 24 hours and diagnosed with COPD based on the Global Initiative for Obstructive Lung Disease guideline. The presence of non-fully reversible airflow obstruction ($FEV_1/FVC < 0.7$ post-bronchodilation) measured by spirometry confirms the diagnosis of COPD [7]. Patients medically controlled by medication recommended by GOLD2024.

The diagnostic approach to AECOPD is confirmed based on the clinical setting and severity of the exacerbation. After history and examinations, including oximetry, sputum culture, chest X-ray [8].

Fatigue Severity Scale (FSS)

The Fatigue Severity Scale (FSS) is a nine-item self-administered questionnaire. Each item is scored between 1 and 7, and a lower total score indicates a decrease in fatigue [9].

Exercise Program

Group A: They will Perform a physical therapy program that will be completed two daily sessions till discharge from the hospital, starting from randomization until hospital discharge. Administered twice per day, seven times per week,

Group B: A control group will only receive medical treatment from hospital admission until discharge.

REFERENCES

1. Halpin, D.M.G., et al., *The GOLD Summit on chronic obstructive pulmonary disease in low- and middle-income countries*. The International Journal of Tuberculosis and Lung Disease, 2019. **23**(11): p. 1131-1141.
2. Meghji, J., et al., *Improving lung health in low-income and middle-income countries: from challenges to solutions*. The Lancet, 2021. **3G7**(10277): p. 928-940.
3. Jurado Gámez, B., et al., *Home intervention and predictor variables for rehospitalisation in chronic obstructive pulmonary disease exacerbations*. Arch Bronconeumol, 2013. **4G**(1): p. 10-4.
4. Wedzicha, J.A.E.C.-C., et al., *Management of COPD exacerbations: a European Respiratory Society/ American Thoracic Society guideline*. Eur Respir J, 2017. **4G**(3).
5. Tung, L.F., et al., *Effect of high-flow nasal therapy during early pulmonary rehabilitation in patients with severe AECOPD: a randomized controlled study*. Respir Res, 2020. **21**(1): p. 84.
6. Mohammed, M., et al., *Efficacy of threshold inspiratory muscle trainer versus diaphragmatic plus pursed lip breathing in occupational COPD*. Beni-Suef University Journal of Basic and Applied Sciences, 2023. **12**.
7. Report, G., *GLOBAL STRATEGY FOR PREVENTION, DIAGNOSIS AND MANAGEMENT OF COPD*. 2024 GOLD Report, 2024.
8. Ko, F.W., et al., *Acute exacerbation of COPD*. Respiriology, 2016. **21**(7): p. 1152-65.
9. Armutlu, K., et al., *The validity and reliability of the Fatigue Severity Scale in Turkish multiple sclerosis patients*. Int J Rehabil Res, 2007. **30**(1): p. 81-5.

Informed Consent

I freely and voluntarily consent to participate in the research program under the direction of researcher/ Marwa Mohammed. A thorough description of the procedure has been provided, and I understand that I can withdraw my consent and discontinue my participation in this research at any time without prejudice.

Date..... Participant's signature.....