

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Investigating the effect of supportive treatments on lung function indicators and fatigue in patients with chronic obstructive pulmonary disease that referred to subspecialty lung clinic

Protocol summary

Study aim

Determining the effect of supportive treatments on lung function indicators and fatigue in chronic obstructive pulmonary disease patients

Design

The clinical trial has 3 intervention groups and a control group, triple blind, randomized, with factorial design, on 60 patients, the second phase.

Settings and conduct

The study was conducted on chronic obstructive pulmonary disease patients by assigning the patients to groups of 15 and performing the rehabilitation intervention of respiratory physiotherapy, breathing exercises and a combination of the two on the patients.

Participants/Inclusion and exclusion criteria

entering : Willingness of the patient to participate in the study. Definitive diagnosis of copd by a lung specialist. Stage 2 to 3 copd. Confirmation of respected lung specialist the ability to perform breathing exercises and lung physiotherapy. Not suffering from other chronic and debilitating diseases such as HF. Exclusion : Severity of the disease. Irregular participation . Death of the patient. Absence of severe respiratory infections in the last 6 months. Changing the doctor's order.

Intervention groups

group 1: breathing exercises, diaphragmatic breathing training, lip bud breathing and effective coughing will be done for 20 sessions (3 times a week) for 45 minutes. group 2: chest percussion, vibration and chest compressions will be used for 20 sessions (3 times a week) for 45 minutes. group 3, a combination of breathing exercises and chest physiotherapy will be performed for 20 sessions (3 times a week) for 45 minutes. group, 4 : control group

Main outcome variables

Lung volumes, fatigue intensity

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20230528058322N1**

Registration date: **2023-07-01, 1402/04/10**

Registration timing: **prospective**

Last update: **2023-07-01, 1402/04/10**

Update count: **0**

Registration date

2023-07-01, 1402/04/10

Registrant information

Name

Sakineh Ghaffari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 44 4223 0593

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sakine.ghafari777@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2023-10-22, 1402/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	the study with full knowledge and consent. They did not know which group they were in and were not in contact with other groups. The outcome evaluator did not know which evaluation group was in which rehabilitation group. The data analyst was also unaware.
Scientific title Investigating the effect of supportive treatments on lung function indicators and fatigue in patients with chronic obstructive pulmonary disease that referred to subspecialty lung clinic	Placebo Not used
Public title "Investigating the effect of supportive treatments in patients with chronic obstructive pulmonary disease"	Assignment Factorial
Purpose Supportive	Other design features
Inclusion/Exclusion criteria Inclusion criteria: Willingness of the patient to participate in the study Definitive diagnosis of chronic obstructive pulmonary disease by a lung specialist Stage 2 to 3 chronic obstructive pulmonary disease Confirmation of respected lung specialist regarding the ability to perform breathing exercises and lung physiotherapy Being 40 to 80 years old Not suffering from other chronic and debilitating diseases such as heart failure Exclusion criteria: Severity of the disease Irregular participation in lung rehabilitation and breathing exercises (not attending more than two sessions) Non-cooperation in breathing exercises and physiotherapy Death of the patient Absence of severe respiratory infections in the last 6 months Changing the doctor's order	Secondary Ids empty
Age From 40 years old to 80 years old	Ethics committees 1 Ethics committee Name of ethics committee Ethics committee of Najafabad Islamic Azad University Street address university street City esfahan Province Isfahan Postal code 5915764575
Gender Both	Approval date 2023-06-12, 1402/03/22
Phase N/A	Ethics committee reference number IR.IAU.NAJAFABAD.REC.1402.050
Groups that have been masked • Outcome assessor • Data analyser	Health conditions studied 1 Description of health condition studied Chronic obstructive pulmonary disease ICD-10 code J44 ICD-10 code description Other chronic obstructive pulmonary disease
Sample size Target sample size: 60	Primary outcomes 1 Description Lung volumes - patient fatigue Timepoint Measurement of lung volumes by spirometry before and end of interventions Method of measurement spirometry and fatigue Severity Scale(fss)
Randomization (investigator's opinion) Randomized	Secondary outcomes empty
Randomization description In this study, 60 available patients with chronic obstructive pulmonary disease, whose disease was confirmed by a lung specialist, were assigned to groups using a table of random numbers. In this way, numbers 1-15 (intervention group 1) group of breathing exercises, numbers 16-30 (intervention group 2) group of respiratory physiotherapy, numbers 31-45 (intervention group 3) combined group of physiotherapy and breathing exercises and numbers 46-60 were selected as the control group.	
Blinding (investigator's opinion) Double blinded	
Blinding description Pulmonary rehabilitation and the types of rehabilitation and its effectiveness on lung volumes were explained to the patients participating in the study, who were fully aware of their disease, and the patients participated in	

Intervention groups

1

Description

The first intervention group: Breathing exercises: Diaphragmatic breathing, bud lip breathing and effective cough training will be done for 20 sessions (3 times a week) in the clinic for the patient. - The second intervention group: respiratory physiotherapy: chest percussion, vibration and chest compression will be used for 20 sessions (3 sessions per week) for 45 minutes. - The third intervention group: combination of breathing exercises and respiratory physiotherapy for 20 sessions (three times a week)-The control group is taught routine breathing exercises

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Dabaghian's subspeciality lung clinic , Behnam Bulding ,West Salahedin Aiubi Avenue

Full name of responsible person

sakineh ghaffari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

mahdi rafie

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

20

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

sakineh ghaffari

Position

Nurse

Latest degree

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Other areas of specialty/work

Nursery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable