Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Nov 2026

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

Phone

+98 44 4223 0593

Email address

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

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

Public title
"Investigating the effect of supportive treatments in patients with chronic obstructive pulmonary disease"

Purpose
Supportive

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

Age
From **40 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

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 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.

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Najafabad Islamic Azad University

Street address
university street

City
esfahan

Province
Isfehan

Postal code
5915764575

Approval date
2023-06-12, 1402/03/22

Ethics committee reference number
IR.IAU.NAJAFABAD.REC.1402.050

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

Primary outcomes

1

Description
Lung volumes - patient fatigue

Timepoint
Measurement of long volumes by spirometry before and end of interventions

Method of measurement
spirometry and fatigue Severity Scale(fss)

Secondary outcomes

empty

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
Bachelor

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