

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

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 subspecialty 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

Isfahan

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 lung 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

Street address

No.13,Azadegan Square ,yasaman avenue

City

Mahabad

Province

West Azarbaijan

Postal code

5915764575

Phone

+98 44 4222 4056

Email

sakine.ghafari777@gmail.com

Web page address

<https://www.paziresh24.com>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

mahdi rafie

Street address

university street, Azad niversity Najafabad Branch

City

Najafabad

Province

Isfahan

Postal code

3142291111

Phone

+98 31 4229 1111

Email

m.rafeei@pmt.iaun.ac.ir

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

Street address

No.13 ,yasaman 3 alley ,azadegan square

City

mahabad

Province

West Azarbaijan

Postal code

5915764575

Phone

+98 44 4223 0593

Email

sakine.ghafari777@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr .fatemeh salmani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

chahar bagh street

City

Isfahan

Province

Isfahan

Postal code

81737363611

Phone

+98 31 3627 0134

Email

ft_salmani@yahoo.com.au

Province

Isfahan

Postal code

81737363611

Phone

+98 31 3627 0134

Email

sakine.ghafari777@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

sakine ghafari

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

university street

City

esfahan

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