

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 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

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#### 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

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#### Province

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#### Postal code

3142291111

#### Phone

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#### 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

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No.13 ,yasaman 3 alley ,azadegan square

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## 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

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**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