

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 2026

### Investigating the effect of adding pulmonary rehabilitation to respiratory physiotherapy in patients with COPD exacerbation, referring to Masih Daneshvari Hospital

#### Protocol summary

##### Study aim

Investigating the effect of adding the pulmonary rehabilitation to respiratory physiotherapy in patients with COPD exacerbation referring to Masih Daneshvari Hospital

##### Design

A controlled, parallel-group, single-blind, randomized, phase 3 clinical trial on 82 patients, using a random number table for randomization.

##### Settings and conduct

The present study is a clinical trial on patients with chronic obstructive pulmonary disease (COPD) exacerbation referred to Masih Daneshvari Hospital in Tehran. In the control group, patients perform breathing exercises along with upper limb stretching. In the intervention group, in addition to the control group exercises, patients perform aerobic exercise on a stationary bike or treadmill. Then, they perform strengthening exercises on the muscles of the upper and lower limbs.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria included COPD grade 3 and higher (FEV1% predicted<sup>30-49</sup> and <sup>30</sup>, post bronchodilator FEV1/FVC<sup>0.7</sup>), no comorbidities, no separate medication outside the prescribed line of therapy, patients undergoing oxygen therapy and line of therapy including antibiotics, corticosteroids, bronchodilators (spray) at the same dose, and exclusion criteria included acute cardiac problems, pneumothorax, embolism, musculoskeletal problems, severe distress, and the patient's inability to perform tests.

##### Intervention groups

In the control group, the patient is initially taught breathing exercises and stretching exercises on the bed by a specialist physiotherapist. In the intervention group, in addition to respiratory physiotherapy, the patient performs an aerobic exercise program on a stationary

bike or treadmill, followed by light strengthening exercises.

##### Main outcome variables

Sit-to-stand test results, 6-minute walk test distance, quality of life, results of the hospital anxiety and depression questionnaire

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240413061474N3**

Registration date: **2025-08-25, 1404/06/03**

Registration timing: **prospective**

Last update: **2025-08-25, 1404/06/03**

Update count: **0**

##### Registration date

2025-08-25, 1404/06/03

##### Registrant information

##### Name

Abouzar Mojbian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2610 9946

##### Email address

dr.a.mojbians@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-10-23, 1404/08/01

##### Expected recruitment end date

2026-04-21, 1405/02/01  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Investigating the effect of adding pulmonary rehabilitation to respiratory physiotherapy in patients with COPD exacerbation, referring to Masih Daneshvari Hospital

**Public title**  
Investigating the effect of pulmonary rehabilitation along with respiratory physiotherapy in COPD exacerbation patients

**Purpose**  
Other

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

post bronchodilator FEV1/FVC less than 0.7 Predicted FEV1 percentage 30-49 and less than 30(Edited)Restore original Absence of comorbidities Non-receipt of a separate medication outside the prescribed treatment line Patients receiving oxygen therapy Treatment includes antibiotics, corticosteroids, and bronchodilators (spray) at the same dose.

**Exclusion criteria:**

Acute cardiac problems pneumothorax embolism musculoskeletal problems severe distress patient inability to perform tests

**Age**  
No age limit

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Outcome assessor

**Sample size**  
Target sample size: 82

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
For randomization, a simple randomization method is used with the help of a random number table. For this purpose, two groups are named as A and B. We choose one of the rows of the random number table at will, and the numbers in each row will be between 0 and 9. We assign the numbers 0-4 to treatment A and the numbers 5-9 to treatment B.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
The clinical outcome assessor will not have access to patient grouping and will remain blinded throughout the study. Patients and therapists will not be blinded.

**Placebo**  
Not used

**Assignment**  
Parallel  
**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of the School of Medicine, Shahid Beheshti University of Medical Sciences

**Street address**

Darabad, Masih Daneshvari Hospital

**City**

Tehran

**Province**

Tehran

**Postal code**

1956944413

**Approval date**

2025-07-29, 1404/05/07

**Ethics committee reference number**

IR.SBMU.MSP.REC.1404.262

**Health conditions studied**

1

**Description of health condition studied**

Chronic obstructive pulmonary disease

**ICD-10 code**

J44.1

**ICD-10 code description**

Chronic obstructive pulmonary disease with (acute) exacerbation

**Primary outcomes**

1

**Description**

6-minute walk test distance

**Timepoint**

Before and after rehabilitation

**Method of measurement**

6-minute walk test

2

**Description**

Number of sit-ups in 30 seconds

**Timepoint**

Before and after rehabilitation

**Method of measurement**

Sit to stand test

### 3

**Description**

Dyspnea

**Timepoint**

Before and after rehabilitation

**Method of measurement**

Modified Borg Scale

## Secondary outcomes

### 1

**Description**

Quality of life

**Timepoint**

Before and after rehabilitation

**Method of measurement**

St. George Questionnaire, Chronic Respiratory Disease Questionnaire, Activities of Daily Living Questionnaire

### 2

**Description**

Anxiety and depression

**Timepoint**

Before and after rehabilitation

**Method of measurement**

Hospital anxiety and depression scale

## Intervention groups

### 1

**Description**

Intervention group: Initially, the patient is taught breathing exercises and stretching exercises on the bed by a specialist physiotherapist. Breathing exercises include pursed lip breathing with diaphragmatic breathing and deep breathing with upper limb stretching. Then, an aerobic exercise program and strengthening exercises are performed.

**Category**

Rehabilitation

### 2

**Description**

Control group: Patients perform breathing exercises, diaphragmatic breathing, and deep breathing along with upper limb stretching.

**Category**

Rehabilitation

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Masih Daneshvari Hospital

**Full name of responsible person**

Mina Fereydouni

**Street address**

Masih Daneshvari Hospital, Darabad

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**Phone**

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**Email**

zahirireyhane@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Afshin Zarghi

**Street address**

Yemen St, Shahid Chamran Highway

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**Province**

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zarghi@sbmu.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mohsen Abedi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Abouzar Mojbian

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

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**Full name of responsible person**

Reyhaneh Zahiri

**Position**

Researcher

**Latest degree**

Master

**Other areas of specialty/work**

Biotechnology

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reyhanehzahiri@sbmu.ac.ir

**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**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available