

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of implementing an exercise program with blood flow restriction on clinical and functional factors of chronic obstructive pulmonary disease

#### Protocol summary

##### Study aim

The effect of implementing an exercise program with blood flow restriction on clinical and functional factors of chronic obstructive pulmonary disease patients at Masih Daneshvari Hospital

##### Design

A clinical trial with a control group, with parallel groups, without blinding, randomized, phase 3 on 20 patients. A table of random numbers was used for randomization.

##### Settings and conduct

The current study is a clinical trial on chronic obstructive pulmonary disease (COPD) patients referred to Masih Daneshvari Hospital in Tehran. Patients are randomly divided into two groups. A six-minute walk test, sit to stand and dynamometry were performed, then the patients of the intervention group were given breathing exercises, including diaphragmatic breathing and chest expansion, and then for 20 minutes with BFR with low load intermittently from a stationary bicycle. In the control group, patients only do breathing exercises.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include patients with stable chronic obstructive pulmonary disease, able to perform aerobic exercise, between the ages of 40 and 65 years, and exclusion criteria include • sickle cell anemia, history of venous thromboembolism, patients with cancer (mass), patients with hemoptysis, Patients with pulmonary abscess, patients with fibrosis, immunocompromised patients, patients with cardiovascular system instability.

##### Intervention groups

In the intervention group, training of breathing exercises including diaphragmatic breathing and chest expansion and then intermittently using a stationary bike for 20 minutes along with blood flow restriction (BFR) with low load. In the control group, patients only do breathing exercises.

##### Main outcome variables

Quadriceps strength; Shortness of breath; sports capacity; Blood oxygen saturation percentage

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240203060888N1**

Registration date: **2024-05-28, 1403/03/08**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-05-28, 1403/03/08**

Update count: **0**

##### Registration date

2024-05-28, 1403/03/08

##### Registrant information

##### Name

Mohsen Abedi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2712 1000

##### Email address

mohsenabedi110@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-04-20, 1403/02/01

##### Expected recruitment end date

2024-10-22, 1403/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The effect of implementing an exercise program with blood flow restriction on clinical and functional factors of chronic obstructive pulmonary disease

**Public title**  
Exercise program with blood flow restriction in chronic obstructive pulmonary disease patients

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Sustained chronic obstructive disease Ability to do aerobic exercise Age 40 to 65 years  
**Exclusion criteria:**  
History of venous thromboembolism History of cancer Patients with hemoptysis Patients with pulmonary abscess Patients with fibrosis patients with immune system deficiency Patients with instability of the cardiovascular system

**Age**  
From **40 years** old to **65 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **20**

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

**Randomization description**  
The randomization method is Random Permuted Blocks. For this purpose, two treatment groups A and B are defined as groups AB and BA. Then random table numbers are defined in the range of 0 to 9. We consider numbers 0 to 4 for block AB and numbers 5 to 9 for group BA. Then random numbers are selected from the table. The number 0 is related to block AB, and after that two people enter this block, the first person receives treatment A and the second person receives treatment B. In the same way, for other people, groups are treated. Although in this method, the number of observations of both groups will be the same, but due to the small size of the blocks, the possibility of predicting the treatment group by the person performing it is high. To solve this problem: the randomization list will be done bilaterally before the start of the study by a person outside the treatment staff. It also increased the block size. In the example, blocks with two treatments and 20 patients are designed.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

The Ethics Committee of the Rehabilitation Faculty of Shahid Beheshti University

##### Street address

Damavand Street (New Tehran), Imam Hossein (AS) Square

##### City

Tehran

##### Province

Tehran

##### Postal code

1616913111

#### Approval date

2024-02-04, 1402/11/15

#### Ethics committee reference number

IR.SBMU.RETECH.REC.1402.692

## Health conditions studied

### 1

#### Description of health condition studied

Chronic obstructive pulmonary disease

#### ICD-10 code

J44.9

#### ICD-10 code description

Chronic obstructive pulmonary disease, unspecified

## Primary outcomes

### 1

#### Description

Dyspnea

#### Timepoint

Before and after rehabilitation

#### Method of measurement

Borg scale

### 2

#### Description

Quadriceps strength

#### Timepoint

Before and after rehabilitation

#### Method of measurement

Dynamometer

### 3

#### **Description**

Sports capacity

#### **Timepoint**

Before and after rehabilitation

#### **Method of measurement**

Six-minute walk and sit to stand tests

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

#### **Description**

At first, six-minute walking tests, assessment of the Borg standard questionnaire (to measure dyspnea and fatigue), 30-second sit-and-stand test, and evaluation of quadriceps muscle strength with the help of a dynamometer are performed. Pulse oximetry is also used to determine the percentage of oxygen saturation. Diaphragmatic breathing and chest expansion are taught to patients at the beginning of each cycle. Then the patients use a stationary bike for 20 minutes with BFR intermittently and with a low load. The duration of this exercise is 4 periods of 5 minutes.

#### **Category**

Rehabilitation

#### 2

#### **Description**

Control group: Patients perform breathing exercises including diaphragmatic breathing and chest expansion.

#### **Category**

Rehabilitation

### **Recruitment centers**

#### 1

#### **Recruitment center**

##### **Name of recruitment center**

Masih Daneshvari Hospital

##### **Full name of responsible person**

Mohsen Abedi

##### **Street address**

Masih Daneshvari Hospital, Darabad

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1956944413

##### **Phone**

+98 21 2610 1000

##### **Email**

mohsenabedi110@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

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1983969411

##### **Phone**

+98 21 2243 1920

##### **Email**

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**

Assistant Professor

##### **Latest degree**

Ph.D.

##### **Other areas of specialty/work**

Physiotherapy

##### **Street address**

Masih Daneshvari Hospital, Darabad

##### **City**

Tehran

##### **Province**

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##### **Postal code**

1983969411

##### **Phone**

+98 21 2610 1000

**Email**

mohsenabedi110@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mohsen Abedi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

Masih Daneshvari Hospital, Darabad

**City**

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**Province**

Tehran

**Postal code**

1983969411

**Phone**

+98 21 2610 1000

**Email**

mohsenabedi110@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Reyhaneh Zahiri

**Position**

Researcher

**Latest degree**

Master

**Other areas of specialty/work**

Biotechnology

**Street address**

Masih Daneshvari Hospital, Darabad

**City**

Tehran

**Province**

Tehran

**Postal code**

1983969411

**Phone**

+98 21 2610 1000

**Email**

zahirireyhane@gmail.com

## 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