# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 2026

## Investigating the effect of using the inspiratory muscle training device (IMT) on the thickness and excursion of the diaphragm of COPD patients undergoing lung rehabilitation

## Protocol summary

**Study aim**
Investigating the effect of using the inspiratory muscle training device (IMT) on the thickness and excursion of the diaphragm of COPD patients undergoing lung rehabilitation

**Design**
A controlled, single-blind, randomized, phase 3 clinical trial with parallel groups on 22 patients, using a random number table for randomization.

**Settings and conduct**
Two groups of patients hospitalized in the Pulmonary Rehabilitation Department of Masih Hospital perform rehabilitation exercises, with the difference that in the intervention group, patients also use the IMT device. The radiologist who performs and evaluates the patients' ultrasound is blind.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria included age over 18 years, diagnosis of COPD based on GOLD, literacy, and exclusion criteria included hemoptysis, embolism, lung cancer, pneumothorax, acute cardiovascular problems, diaphragmatic paralysis, severe shortness of breath preventing testing, patient unwillingness to continue participating in the research project, and not having a smartphone.

**Intervention groups**
In the intervention group, patients perform daily pulmonary rehabilitation exercises along with aerobic exercise during 2 weeks of hospitalization. Patients use the IMT device. Patients continue the rehabilitation process at home as remote rehabilitation with the IMT device (for 6 weeks). In the control group, patients perform daily breathing exercises and stretching exercises along with aerobic exercise during 2 weeks of hospitalization. Then they continue their rehabilitation program at home for 6 weeks.

**Main outcome variables**
Exercise capacity, dyspnea, health-related quality of life, sit to stand test, S-index derived from IMT, diaphragm excursion and thickness

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20200611047727N7**
Registration date: **2025-06-23, 1404/04/02**
Registration timing: **prospective**

Last update: **2025-06-23, 1404/04/02**
Update count: **0**

**Registration date**
2025-06-23, 1404/04/02

**Registrant information**

**Name**
Maryam Sadat Mirenayat

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2025-07-23, 1404/05/01

**Expected recruitment end date**
2026-01-21, 1404/11/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Investigating the effect of using the inspiratory muscle training device (IMT) on the thickness and excursion of the diaphragm of COPD patients undergoing lung rehabilitation

**Public title**
The effect of using the inspiratory muscle training device (IMT) on the thickness and excursion of the diaphragm of COPD patients
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Age over 18 years Diagnosis of COPD based on GOLD
**Exclusion criteria:**
Hemoptysis embolism lung cancer pneumothorax acute cardiovascular problems diaphragmatic paralysis severe dyspnea preventing testing patient's unwillingness to continue participating in the research project
**Age**
From **18 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Outcome assessor

**Sample size**
Target sample size: **221**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Randomization method: Simple, Randomization unit: Individual, Randomization tool: Random number table. Simple randomization method is used for randomization with the help of a random number table. For this purpose, two groups are named A and B. We choose one of the rows of the random number table at will and the numbers of 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**
Ultrasound scans of patients are performed by an experienced radiologist blind to the patient's other tests (on two occasions before the start of rehabilitation and at the end of the rehabilitation period).
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Shahid Beheshti University of Medical Sciences
**Street address**
Shahid Abbas Arabi St., Yemen St., Shahid Chamran Highway
**City**
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**Postal code**
1956944413
**Approval date**
2025-05-27, 1404/03/06
**Ethics committee reference number**
IR.SBMU.MSP.REC.1404.114

## 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**
Diaphragmatic excursion
**Timepoint**
At the beginning of hospitalization, after two weeks (at discharge), and also after 6 weeks of tele-rehabilitation
**Method of measurement**
Ultrasound

### 2

**Description**
Diaphragmatic thickness
**Timepoint**
At the beginning of hospitalization, after two weeks (at discharge), and also after 6 weeks of tele-rehabilitation
**Method of measurement**
Ultrasound

### 3

**Description**

Forced vital capacity (FVC)

**Timepoint**

At the beginning of hospitalization, after two weeks (at discharge), and also after 6 weeks of tele-rehabilitation

**Method of measurement**

Spirometry

**4**

**Description**

Forced expiratory volume in one second (FEV1)

**Timepoint**

At the beginning of hospitalization, after two weeks (at discharge), and also after 6 weeks of tele-rehabilitation

**Method of measurement**

Spirometry

**5**

**Description**

Predicted FVC

**Timepoint**

At the beginning of hospitalization, after two weeks (at discharge), and also after 6 weeks of tele-rehabilitation

**Method of measurement**

Spirometry

## Secondary outcomes

**1**

**Description**

Six minute walk test distance

**Timepoint**

At the beginning of hospitalization, after two weeks (at discharge), and also after 6 weeks of tele-rehabilitation

**Method of measurement**

Six minute walk test

**2**

**Description**

Dyspnea

**Timepoint**

At the beginning of hospitalization, after two weeks (at discharge), and also after 6 weeks of tele-rehabilitation

**Method of measurement**

Based on modified medical research council dyspnea scale questionnaire

**3**

**Description**

Quality of life

**Timepoint**

At the beginning of hospitalization, after two weeks (at discharge), and also after 6 weeks of tele-rehabilitation

**Method of measurement**

Based on the St. George questionnaire

## Intervention groups

**1**

**Description**

Intervention group: Patients are hospitalized for 2 weeks and during this time they perform daily pulmonary rehabilitation exercises including diaphragmatic breathing, pursed lip breathing and respiratory stretching exercises along with aerobic exercise. In addition, patients use the IMT device. After 2 weeks, patients are discharged after receiving a home pulmonary rehabilitation program and exercise training. Patients continue their rehabilitation process at home as remote rehabilitation with the IMT device (for 6 weeks). To use the IMT device, the patient performs 30 repetitions in the morning and 30 repetitions in the afternoon every day, and the resistance of the device is gradually increased. At the end of 6 weeks, the patient returns to the hospital (rehabilitation department) and the desired evaluations will be performed.

**Category**

Treatment - Other

**2**

**Description**

Control group: Patients are hospitalized for 2 weeks and during this period, they perform daily breathing exercises including diaphragmatic breathing, pursed lip breathing, and respiratory stretching exercises for 20 minutes on the bed and under the direct supervision of a physiotherapist, along with aerobic exercise including at least 15 minutes of walking on a treadmill at a maximum speed equivalent to 80% of the six-minute walk test. After two weeks, patients are discharged after receiving a remote rehabilitation program and continue their rehabilitation program at home (under the supervision of the hospital rehabilitation team) for 6 weeks.

**Category**

Treatment - Other

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Masih Daneshvari Hospital

**Full name of responsible person**

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## Sponsors / Funding sources

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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**
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
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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**

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