

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### The assessment of effectiveness of respiratory muscle training (I M T) and aerobic training on quality of life in patients with chronic obstructive pulmonary disease (C O P D)

#### Protocol summary

##### Study aim

Comparison of the Effect of Two Methods of Dementia Respiratory Muscle Exercise and Aerobic Exercise in Patients with C.O.P.D in Imam Hussein Hospital in 2016

##### Design

The first group (n = 16) treated with the I.M.T method in the second group (n = 14) received the aerobic exercise method in the third group (n = 15) in the fourth group (n = 15) (control group)

##### Settings and conduct

Hospital but Hussein Department of Physiotherapy

##### Participants/Inclusion and exclusion criteria

Satisfaction to participate in the study, Getting Grade 2 or 3 Based on GOLD Criteria, Age 40 to 70 years, Lack of other pulmonary diseases, Lack of severe limb limbs, Lack of pulmonary surgery in the last 12 months, Recent fracture failure at the level of ribs (6 months), No history of psychotropic disease and related drugs and alcohol and psychotropic substances.

##### Intervention groups

The first group (n = 16) was treated by IMT: the intensity of training was 40-60% (S-Index 40-60%), 2 days per week, and 5 sessions of dermal muscle training with repeat 50 (5 Repeat 10) for about 15 minutes per session. The second group (n = 14) was treated with aerobic exercise method: with a treadmill and foot pedometer, 2 times a week, with 40 to 60% HRR for 40 minutes per session. The third group (n = 15) received combined therapy (in each session, breathing exercises were performed first and then aerobic exercises were performed on the lower extremities) The fourth group (n = 15) did not take any special intervention other than the usual treatments (control group)

##### Main outcome variables

Evaluation of pulmonary function according to spirometry (FEV1); Testing of respiratory muscles with the IMT Test Power Breath device to determine the S-

index; Dyspnea severity: based on the MMRC classification; 6-minute walk test (6MWD); The severity of COPD was assessed by two methods: A-GOLD BODE INDEX. Health-related quality of life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180205038633N1**

Registration date: **2019-03-17, 1397/12/26**

Registration timing: **retrospective**

Last update: **2019-03-17, 1397/12/26**

Update count: **0**

##### Registration date

2019-03-17, 1397/12/26

##### Registrant information

##### Name

Saeid Rezaei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8823 0532

##### Email address

saeedrezaee1394@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-03-21, 1396/01/01

##### Expected recruitment end date

2017-05-21, 1396/02/31

##### Actual recruitment start date

2017-05-22, 1396/03/01  
**Actual recruitment end date**  
2017-07-23, 1396/05/01  
**Trial completion date**  
empty

#### Scientific title

The assessment of effectiveness of respiratory muscle training (I M T)and aerobic training on quality of life in patients with chronic obstructive pulmonary disease(C O P D)

#### Public title

The assessment of effectiveness of respiratory muscle training (I M T)and aerobic training in patients with pulmonary disease

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Satisfaction to participate in the study Getting Grade 2 or 3 Based on GOLD Criteria Age 40 to 70 years Failure to have previous known disease, such as heart disease (such as C.H.F and coronary artery disease), or disease of the lungs (E.S.R.D and C.R.F), and liver (cirrhosis of the liver, cancer, etc.) Lack of other pulmonary diseases, such as lung cancer, plural disease, or musculature involvement. The lack of extreme limbs that prevent aerobic exercise Lack of pulmonary surgery in the last 12 months Recent fracture failure at the level of ribs (6 months) No history of psychotropic disease and related drugs and alcohol and psychotropic substances

##### Exclusion criteria:

Failure to have previous known disease, such as heart disease (such as C.H.F and coronary artery disease), or disease of the lungs (E.S.R.D and C.R.F), and liver (cirrhosis of the liver, cancer, etc.)

#### Age

From **30 years** old to **70 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **68**

Actual sample size reached: **60**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

block randomization

#### 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

Ethics committee of Shahid beheshti University of Medical Sciences

##### Street address

Shahid Beheshti University of Medical Sciences, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

#### Approval date

2016-06-21, 1395/04/01

#### Ethics committee reference number

IR.SBMU. MSP.REC.1395.146

## Health conditions studied

### 1

#### Description of health condition studied

Chronic bronchitis-emphysema

#### ICD-10 code

J41-J43

#### ICD-10 code description

Emphysema Excl.: emphysema-Simple and mucopurulent chronic bronchitis

## Primary outcomes

### 1

#### Description

Spirometric FEV 1 Index - Quality of Life Indicator score

#### Timepoint

Beginning of study - Week 4 - Week 8

#### Method of measurement

Lung Spirometry - St. George's Quality of Life Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Intervention group: -

#### Category

Rehabilitation

## 2

### **Description**

Exercise group and respiratory training

### **Category**

Rehabilitation

## 3

### **Description**

Intervention group: Respiratory training group

### **Category**

Rehabilitation

## 4

### **Description**

Control group: no intervention

### **Category**

Rehabilitation

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Imam Hossein Hospital

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

Saeed Razaee

##### **Street address**

Shahid Madani Avenue Nizam Abad Tehran

##### **City**

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##### **Postal code**

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##### **Phone**

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##### **Web page address**

<http://www.ehmc.ir>

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

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

Dr seyed ali ziyayi

##### **Street address**

elenjak taleghani hospital

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#### **Grant name**

Deputy of Research of Shahid Beheshti University of Medical Sciences

#### **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**

Dr amirhosseion abedi yekta

##### **Position**

Assistant Professor

##### **Latest degree**

Specialist

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

Sport Medicine

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## **Person responsible for scientific inquiries**

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Resident  
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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**  
Yes - There is a plan to make this available

**Statistical Analysis Plan**  
Yes - There is a plan to make this available

**Informed Consent Form**  
Yes - There is a plan to make this available

**Clinical Study Report**  
No - There is not a plan to make this available

**Analytic Code**  
Yes - There is a plan to make this available

**Data Dictionary**  
Yes - There is a plan to make this available

**Title and more details about the data/document**  
Dissertation and some with information about the consequences of patients without mentioning patients' characteristics

**When the data will become available and for how long**  
Possibility of post-publication of the article

**To whom data/document is available**  
Researchers and students from all over the country

**Under which criteria data/document could be used**  
Clinical research similar to the direction of relevant researchers

**From where data/document is obtainable**  
Theses and articles of research deputy of Shahid Beheshti University of Medical Sciences

**What processes are involved for a request to access data/document**  
Through a reputable service center at a different country and adhering to the principles of copyright

**Comments**