

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### **Comparison of two methods of routine breathing exercises (pursed lip breathing and diaphragmatic breathing) and the simultaneous use of routine breathing and breathing-stretching exercises on respiratory indicators (oxygen saturation percentage and carbon dioxide pressure), disease severity and exercise capacity in patients with chronic obstructive pulmonary disease**

#### **Protocol summary**

##### **Study aim**

Determining and comparing two methods of routine breathing exercises (pursed lip breathing and diaphragmatic breathing) and the simultaneous use of routine breathing and breathing-stretching exercises on respiratory indicators (oxygen saturation percentage and carbon dioxide pressure), disease severity and exercise capacity in patients with Chronic obstructive pulmonary disease

##### **Design**

A clinical trial with a control group, with Parallel groups, one-sided blind, randomized using a table of random numbers, on 32 patients.

##### **Settings and conduct**

After approving the project in the ethics and research registration committee, the researcher goes to Imam Reza clinic with a written letter of introduction. Participants will be informed of their presence in the intervention or control group only after the intervention is completed.

##### **Participants/Inclusion and exclusion criteria**

Patients with chronic obstructive pulmonary disease/  
Including criteria: Not suffering from a known mental disorder and Absence of acute and chronic diseases affecting the respiratory system. Excluding criteria: Occurrence of any complication or exacerbation of the disease (patients whose disease worsens due to causes such as pneumonia, pneumothorax or heart failure or patients who need to be hospitalized) that requires intervention

##### **Intervention groups**

The control group will only receive routine breathing exercises (pursed lip and diaphragmatic breathing) and

the intervention group, in addition to routine breathing exercises, will receive stretching-breathing exercises for 5 days.

##### **Main outcome variables**

The oxygen saturation percentage, the amount of carbon dioxide pressure, the score that people receive from the chronic obstructive pulmonary disease assessment test and the distance that people will travel in 6 minutes.

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20240502061629N1**

Registration date: **2024-05-08, 1403/02/19**

Registration timing: **prospective**

Last update: **2024-05-08, 1403/02/19**

Update count: **0**

##### **Registration date**

2024-05-08, 1403/02/19

##### **Registrant information**

##### **Name**

Fatemeh Zare

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

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 71 3722 7476

##### **Email address**

fateme.zare@jums.ac.ir

##### **Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**  
2024-06-06, 1403/03/17

**Expected recruitment end date**  
2024-08-07, 1403/05/17

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of two methods of routine breathing exercises (pursed lip breathing and diaphragmatic breathing) and the simultaneous use of routine breathing and breathing-stretching exercises on respiratory indicators (oxygen saturation percentage and carbon dioxide pressure), disease severity and exercise capacity in patients with chronic obstructive pulmonary disease

**Public title**  
the effect of two methods of routine breathing exercises and the simultaneous use of routine breathing and breathing-stretching exercises in patients with chronic obstructive pulmonary disease

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
patient will to participate in the study Not suffering from a known mental disorder (such as psychotic and depressive disorders that do not cooperate) Absence of acute and chronic diseases affecting the respiratory system (such as colds and flu) The ability to talk in Persian Not suffering from other chronic diseases that interfere with the rehabilitation program (such as skeletal-motor disorders) patients with stage 2 and 3 of the disease based on Global Initiative for Chronic Obstructive Lung Disease classification Obtaining lung fellowship approval

**Exclusion criteria:**  
Non-cooperation or unwillingness of the patient to continue participating in the study Occurrence of any complication or exacerbation of the disease (patients whose disease worsens due to causes such as pneumonia, pneumothorax or heart failure or patients who need to be hospitalized) that requires intervention

**Age**  
No age limit

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant

**Sample size**  
Target sample size: 32

**Randomization (investigator's opinion)**

Randomized

**Randomization description**  
At first, by using the available sampling method, inpatients with entry criteria are identified and based on the Global Initiative for Chronic Obstructive Lung Disease criteria, grade 2 and 3 chronic obstructive pulmonary disease patients are selected. In the next step, random allocation is done using a table of random numbers and patients are divided into two control groups (breathing exercises) and intervention (simultaneous use of breathing and breathing-stretching exercises).

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

**Blinding description**  
After the necessary information regarding conducting the research is provided to the patients, written informed consent is obtained from the patients; And after random allocation, patients are divided into two control groups (breathing exercises) and intervention (simultaneous use of breathing and breathing-stretching exercises). Participants will be informed of their presence in the intervention or control group only after the intervention is completed.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**  
Ethics Committee of Jahrom University of Medical Sciences

**Street address**  
Jahrom University of Medical Sciences, after Nursing College, Ostad Motahari Street, Jahrom

**City**  
Jahrom

**Province**  
Fars

**Postal code**  
7414846199

**Approval date**  
2024-04-29, 1403/02/10

**Ethics committee reference number**  
IR.JUMS.REC.1403.008

## Health conditions studied

### **1**

**Description of health condition studied**  
chronic obstructive pulmonary disease

**ICD-10 code**

J43

**ICD-10 code description**

Emphysema

**2**

**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**

Oxygen saturation percentage

**Timepoint**

before the start of the intervention and 5 days after the start of the intervention

**Method of measurement**

Pulse oximeter

**2**

**Description**

Carbon dioxide pressure

**Timepoint**

before the start of the intervention and 5 days after the start of the intervention

**Method of measurement**

Venous blood gases

**3**

**Description**

The score that people will get from the chronic obstructive pulmonary disease assessment test

**Timepoint**

before the start of the intervention and 5 days after the start of the intervention

**Method of measurement**

chronic obstructive pulmonary disease assessment test

**4**

**Description**

The distance that people travel in 6 minutes

**Timepoint**

before the start of the intervention and 5 days after the start of the intervention

**Method of measurement**

6-Minute walk test

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: this group receives breathing-stretching exercises, in addition to routine breathing exercises (pursed lip and diaphragmatic breathing). Stretching exercises with breathing control will be performed for the intervention group for 5 days and twice a day (at 10 am and 6 pm). Stretching exercises are done by controlling deep breathing exercises, inhaling through the nose and exhaling through the mouth. The stretching time will be with the inhaling and the tension releasing time will be with the exhaling. On the first day, the patient stretches his hands, wrists and ankles with breathing control while lying on the bed. On the second day, he repeats the exercises of the first session while sitting on the bed and with his legs extended. On the third day, while sitting on the bed, he performs the exercises of the first day along with neck stretching exercises. On the fourth day, the patient gets out of bed and walks and performs arm and shoulder stretching exercises while walking. On the fifth day, the patient tries to walk by raising the knee as much as possible and repeats the stretches of the fourth day.

**Category**

Rehabilitation

**2**

**Description**

Control group: The control group only receives routine breathing exercises (pursed lip and diaphragmatic breathing).

**Category**

Rehabilitation

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Imam Reza Clinic

**Full name of responsible person**

Fatemeh Zare

**Street address**

Imam Reza Clinic, Peymaniye Hospital, Vali Asr St, Jahrom

**City**

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**Phone**

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**Email**

paymaniehbimeh@yahoo.com

**Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Jahrom University of Medical Sciences

**Full name of responsible person**

Dr. Amir Abdoli

**Street address**

Deputy of Research and Technology, Jahrom  
University of Medical Sciences, Ostad Motahari St,  
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**Phone**

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pshora2014@gmail.com

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

Yes

**Title of funding source**

Jahrom 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**

Jahrom University of Medical Sciences

**Full name of responsible person**

Fatemeh Zare

**Position**

Nursing master's student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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No. 2, Sadr Shirazi St., Forsat Shirazi Blvd

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### Person responsible for scientific inquiries

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**Latest degree**

Bachelor

**Other areas of specialty/work**

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### Person responsible for updating data

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**Full name of responsible person**

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**Position**

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**Latest degree**

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**Phone**

+98 71 3722 7476

**Fax****Email**

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### Sharing plan

#### Deidentified Individual Participant Data Set (IPD)

Yes - There is 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**  
Yes - There is 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**  
.All data is potentially shareable after individuals become incognito.  
**When the data will become available and for how long**

The beginning of the access period is 6 months after the results are published.

**To whom data/document is available**

The data will be available for students, professors and researchers working in academic and scientific institutions.

**Under which criteria data/document could be used**

Sending a request through the researcher's email is to access data or documents. The use of data is subject to strict compliance with literary rights and confidentiality.

**From where data/document is obtainable**

Send a request through the following email to receive data/documents. fateme.zare@jums.ac.ir Fatemeh Zareh, nursing master of science student

**What processes are involved for a request to access data/document**

After the request for data/document via the researcher's email, your email will be answered within 7 days at most.

**Comments**