

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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	Randomized
Funding source	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).
Expected recruitment start date 2024-06-06, 1403/03/17	Blinding (investigator's opinion) Single blinded
Expected recruitment end date 2024-08-07, 1403/05/17	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.
Actual recruitment start date empty	Placebo Not used
Actual recruitment end date empty	Assignment Parallel
Trial completion date empty	Other design features
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	Secondary Ids empty
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	Ethics committees
Purpose Supportive	1
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	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
Age No age limit	Approval date 2024-04-29, 1403/02/10
Gender Both	Ethics committee reference number IR.JUMS.REC.1403.008
Phase N/A	Health conditions studied
Groups that have been masked Participant	1
Sample size Target sample size: 32	Description of health condition studied chronic obstructive pulmonary disease
Randomization (investigator's opinion)	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 oximetr

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
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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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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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Full name of responsible person

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Latest degree

Bachelor

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Person responsible for updating data

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Full name of responsible person

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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