Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+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 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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Phone

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Jahrom University of Medical Sciences

Full name of responsible person
Dr. Amir Abdoli

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

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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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Person responsible for scientific inquiries

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Position
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Latest degree
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Person responsible for updating data

Contact

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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