Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of active cycle breathing technique on health status, sleep quality, and health-related quality of life of people with chronic obstructive pulmonary disease

Protocol summary

Study aim

Effects of active cycle breathing technique on health status, sleep quality, and health-related quality of life of people with chronic obstructive pulmonary

Design

This study is a randomized, single-phase, and unblinded clinical trial.

Settings and conduct

This study is being conducted at the medical and educational centers of Shahrekord University of Medical Sciences, and due to the nature of the study, blinding was not performed.

Participants/Inclusion and exclusion criteria

Participants completed a written consent form to participate in the study. The age range of patients with chronic obstructive pulmonary disease was 20 to 70 years. The participants' disease was diagnosed by a pulmonologist and confirmed according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria, which are as follows: • Having symptoms of shortness of breath, cough, and increased sputum production or a history of exposure to risk factors • The ratio of forced expiratory volume in 1 second (FEV1) to forced vital capacity (FVC) was less than 0.7 (FEV1/FVC ratio < 70%). (54, 55). The subjects were free of physical and mental problems that would interfere with the learning process. The subjects were free of severe respiratory problems and respiratory failure that would lead to intolerance to the breathing technique.

Intervention groups

The control group received only routine care, and the intervention group, in addition to receiving routine care, performed the active cycle breathing technique for 3 months, twice a day, for 15 to 20 minutes each time.

Main outcome variables

The effect of the active breathing cycle technique on sleep quality is measured using the Pittsburgh Sleep Quality Questionnaire, health-related quality of life with the St. George Questionnaire, and health status with the Chronic Obstructive Pulmonary Assessment Test (CAT) questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240630062284N2**
Registration date: **2025-12-06, 1404/09/15**
Registration timing: **prospective**

Last update: **2025-12-06, 1404/09/15**
Update count: **0**

Registration date

2025-12-06, 1404/09/15

Registrant information

Name

Komeil Zamani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3776 4013

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-22, 1404/10/01

Expected recruitment end date

2026-03-11, 1404/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of active cycle breathing technique on health status, sleep quality, and health-related quality of life of people with chronic obstructive pulmonary disease

Public title

Effects of active cycle breathing technique on health status, sleep quality, and health-related quality of life of people with chronic obstructive pulmonary disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Participants complete written consent to participate in the study. The age range of patients with chronic obstructive pulmonary disease is 20 to 70 years. The participants' disease was diagnosed by pulmonology specialists and confirmed based on the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria, which are as follows: • Having symptoms of shortness of breath, cough, and increased sputum production or a history of exposure to risk factors • The ratio of forced expiratory volume in 1 second (FEV1) to forced vital capacity (FVC) should be less than 0.7 (FEV1/FVC ratio < 70%).

Exclusion criteria:

People with physical and mental problems that interfere with the learning process. People with severe respiratory problems and respiratory failure that lead to intolerance to the breathing technique

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of assigning samples to groups will be in the form of random blocks with different numbers without permutation. For this purpose, first the letter A is considered for the control group and the letter B for the experimental group, and different states of the two groups will be written on the card, and each will be placed in a sealed and opaque envelope. To cover the assignment, blocks with different numbers will be used, that is, blocks of 6 and 2 will be included in the blocks. The block of 6 can be a combination of ABBABA and ... The block of 2 can also include AB, BA. These envelopes are placed in a box and the researcher will not know which group the units under study will be in until the card is selected. Before facing the research units, the ward nurse (unaware of the study and the groups) will determine which group the patients who will enter the study will be in, respectively, by removing one of the envelopes from the box. This process will continue until all the cards are removed from the box, and the cards will be returned to the box again, and this random selection will be repeated until the desired sample size is provided.

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 Shahrekord University of Medical Sciences

Street address

Shahrekord, Kashani Blvd., University Headquarters

City

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Province

Chahar-Mahal-va-Bakhtiari

Postal code

۸۸۱۵۷۱۳۴۷۱

Approval date

2025-11-10, 1404/08/19

Ethics committee reference number

IR.SKUMS.NUMHE.REC.1404.002

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

Health status

Timepoint

before the start of the intervention, one week and 3

months after the start of the intervention

Method of measurement

The COPD Assessment Test (CAT)

2

Description

Sleep quality

Timepoint

before the start of the intervention, one week and 3 months after the start of the intervention

Method of measurement

Pittsburgh Sleep Quality Index (PSQI)

3

Description

Health-related quality of life

Timepoint

before the start of the intervention, one week and 3 months after the start of the intervention

Method of measurement

St George's Respiratory Questionnaire (SGRQ)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Perform the active cycle breathing technique independently and without supervision, twice a day (morning and evening), each time for 15 to 20 minutes (preferably before meals or 1 hour after) at home for 3 months. It includes rest periods between other parts of this cycle and continues until the person feels ready to perform other parts of the cycle or start a new cycle. By relaxing his shoulders and using the lower parts of the chest, the person tries to perform diaphragmatic breathing at a natural depth and speed. 2- Thoracic Expansion Exercises (TEE): In this stage, by increasing lung volume, air flow and clearing secretions from narrow airways and air diffusion in healthy lung parts are improved. To do this, the patient holds the air for 2 to 3 seconds by taking a deep and active breath and then exhales the air slowly and completely with a passive exhalation. This stage is performed following the BC stage and is repeated up to 3 times. 3- Forced expiratory technique (FET): This stage is a combination of one or two forced exhalations (huffs) along with the (BC) stage. By suddenly contracting the respiratory and abdominal muscles and huffing or coughing, the speed of air exiting the small airways increases and helps clear secretions.

Category

Rehabilitation

2

Description

Control group: Routine treatment and care methods will be used, and the researcher will not have any role in providing this training and care to this group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar Hospital

Full name of responsible person

Nasser Khosravi

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Sponsors / Funding sources

1

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Name of organization / entity

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Full name of responsible person

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shahre-kord 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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not 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

No - There is not a plan to make this available

Title and more details about the data/document

Biographical data such as age and gender are essential for better presentation of research results, and since this data is anonymous, there is no reason not to publish it.

When the data will become available and for how long

Due to the anonymity and coding of the data, they will be available after the study is completed.

To whom data/document is available

This data will be accessible to various health professionals and researchers.

Under which criteria data/document could be used

No analysis of this data is permitted and it will only be used for comparison with and citation of results from other studies

From where data/document is obtainable

The download of the resulting article will be done according to the policy of the journal that publishes it. Therefore, the use of biographical data tables and other sections of the journal is possible after downloading. The email address of the responsible author included in the article will be available for communication with other authors and for guidance.

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

For this purpose, the applicant can contact the office of the journal that published the article, the corresponding author, and the Vice President for Research of Shahrekord University of Medical Sciences. The duration of access depends on the policy of the journal and the Vice President for Research of the university, but the corresponding author will respond to the request of colleagues within a week.

Comments