# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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**


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**Name of organization / entity**

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Iran (Islamic Republic of)

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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**

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**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**

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## Sponsors / Funding sources

**1**

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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**