# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## Effects of of breathing techniques on pulmonary function and quality of life in adults with chronic obstructive pulmonary diseases (COPD)

### Protocol summary

**Study aim**
Comparing the effects of breathing techniques on diagnostic indicators and changing the quality of life of COPD patients

**Design**
Each group has 55 people and two groups with 1 to 1 allocation, a total of 110 samples. Allocation of samples in the intervention and control groups is done with random blocks and using online software.

**Settings and conduct**
Blinding of the patients, the doctor and the evaluator of the results will be implemented. 2 training sessions of routine treatment and training of breathing exercises along with routine treatment individually by a specialist. In addition, this group has the requirements of the control group in addition to its own requirements.

**Participants/Inclusion and exclusion criteria**
Participants: adult patients with chronic obstructive pulmonary disease (COPD) referring to Bahonar Hospital and the private department of Alborz University professors Entry requirements for people: 1) Patients diagnosed with moderate and severe COPD (GOLD=2 and GOLD=3) 2) Age over 18 years After obtaining the informed consent of the subjects, they enter the study and based on random allocation in each of the intervention groups are under control. Conditions for exiting people: 1) Patients needing hospitalization 2) Severe obesity (BMI equal to and above 35) .3) Patients who are not trainable

**Intervention groups**
1) Intervention group: 2 sessions of regular treatment training and breathing exercise training (including 2 diaphragmatic breathing techniques, compressed lip breathing) along with regular individual treatment by a specialist. Along with the training DVD including these 2 techniques, each person is required to do these exercises at home 3 times a day for 10 minutes each time. 2) Control group: 2 training sessions of usual treatment

**Main outcome variables**
The effect of respiratory physiotherapy exercises on respiratory indices and quality of life of COPD patients

### General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20110509006416N2**
Registration date: **2023-05-22, 1402/03/01**
Registration timing: **prospective**

Last update: **2023-05-22, 1402/03/01**
Update count: **0**

**Registration date**
2023-05-22, 1402/03/01

**Registrant information**
**Name**
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
**Phone**
02614314400
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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2023-06-05, 1402/03/15
**Expected recruitment end date**
2025-01-04, 1403/10/15
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Effects of of breathing techniques on pulmonary function and quality of life in adults with chronic obstructive pulmonary diseases (COPD)

**Public title**
Effect of breathing techniques on COPD

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Patients with age over 18 years old Patients are diagnosed with moderate and severe COPD (gold=2 and gold=3)

**Exclusion criteria:**
Patients requiring hospitalization Patients with presence of pulmonary infection Patients with severe obesity (BMI equal to or above 35) Patients that need to artificial oxygen Patients have performed the respiratory physiotherapy before entering into the study Patients with mild disease (gold=1) Patients with very severe disease (gold=4) Patients who are not trainable Patients with obstructive sleep apnea disorder Patients with cancer Patients with neuromuscular weakness

**Age**
From **18 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**
Target sample size: **110**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
The daily list of samples will be introduced to the intervention group by the doctor (principal researcher) after checking the conditions for entering the study and obtaining informed consent. Allocation of samples in the intervention and control groups is done with random blocks. Random blocks of 4 (28 blocks) and randomization is done using Sealed Envelope online service. Allocation of samples to two intervention and control groups is done by another person from the plan (random block) and sent to the interventionists by SMS.

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

**Blinding description**
Double blinding will be used in this study. The patients in both control and intervention groups will be given an educational DVD, and training sessions will be held for both groups, but the difference between the two groups is that in the intervention group, in addition to the usual treatment, breathing exercises will also be taught, but for The control group will only receive the usual treatment. Also, for double-blinding, the recipient of the spirometry test must be unaware of the patients' history.

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Research Ethics Committees of Alborz University of Medical Sciences

**Street address**
Secretariat of the Research Ethics Committee of the University, 2nd Floor,Alborz University of Medical Sciences Research and Technology Vice-Chancellor Building, Shahid Safarian St., Golshahr forty-five meters, Karaj

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**Province**
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3154686695

**Approval date**
2023-04-29, 1402/02/09

**Ethics committee reference number**
IR.ABZUMS.REC.1402.028

## Health conditions studied

### 1

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

**ICD-10 code**
J44.0

**ICD-10 code description**
Chronic obstructive pulmonary disease with acute lower respiratory infection

## Primary outcomes

### 1

**Description**
quality of life

**Timepoint**
The beginning of the study, two months after the start of the study

**Method of measurement**
Quality of life Questionnaire (Clinical COPD Questionnaire)

**2**

**Description**
respiratory indicators
**Timepoint**
The beginning of the study, two months after the start of the study
**Method of measurement**
Spirometry

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: patients with COPD who receive breathing techniques. 2 sessions of regular treatment training and breathing exercise training (including 2 diaphragmatic breathing techniques, compressed lip breathing) along with regular individual treatment by a specialist. Along with the training DVD including these 2 techniques, each person is required to do these exercises at home 3 times a day for 10 minutes each time. In addition, this group has the requirements of the control group in addition to its own requirements. Follow-up and evaluation of patients will be done at the beginning of the study and 2 months after the intervention. Patients are examined once at the beginning of the study and again after 2 months (the end of the study). Patients are contacted by phone every week to ensure that breathing exercises are performed.
**Category**
Rehabilitation

**2**

**Description**
Control group: patients with COPD who received 2 sessions of regular treatment training (including how to use drugs and short-acting sprays and other recommendations) individually by a specialist. Along with an educational DVD containing the same drug recommendations and a series of basic training. Follow-up and evaluation of patients will be done at the beginning of the study and 2 months after the intervention. Patients are examined once at the beginning of the study and again after 2 months (the end of the study). Patients are contacted by phone every week to ensure attendance at the usual treatment.
**Category**
Other

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Karaj Imam Ali Hospital
**Full name of responsible person**
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## Sponsors / Funding sources

**1**

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**Grant name**
Research Council of Alborz university of medical sciences
**Grant code / Reference number**
5343
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Karaj 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**
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Karaj University of Medical Sciences
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be 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**
No - There is not a plan to make this available
**Clinical Study Report**
No - There is not a plan to make this available
**Analytic Code**
No - There is not a plan to make this available
**Data Dictionary**
No - There is not a plan to make this available