Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 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

Email address
kabir.kourosh@yahoo.com

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

City
Karaj

Province
Alborz

Postal code
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
Shokoofe Zamani
Street address
karaj. shora boulvard, valiasr boulvard, Karaj Imam Ali Hospital
City
Karaj
Province
Alborz
Postal code
3154686695
Phone
+98 912 318 2477
Fax
+98 26 3256 3318
Email
imamali@abzums.ac.ir
Web page address
https://emamali.abzums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Kourosh Kabir
Street address
Dr. Hamed Mohammadi (research assistant), Faculty of Medicine, University of Medical Sciences campus, above Art University, West Buali end, Nebubot Square, Karaj
City
Karaj
Province
Alborz
Postal code
3149969415
Phone
+98 26 3428 7359
Email
Kabir.kourosh@yahoo.com
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
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Kourosh Kabir
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Public Health/Community Medicine
Street address
University of Medical Sciences campus, Faculty of Medicine, above Art University, west end of Buali, Nebubot Square, Karaj
City
Karaj
Province
Alborz
Postal code
3149969415
Phone
009834287359
Email
kabir.kourosh@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Kourosh Kabir
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Epidemiology
Street address
Faculty of Medicine, University of Medical Sciences campus, above Art University, west end of Buali, Nebubot Square, Karaj
City
Karaj
Province
Alborz
Postal code
3149969415
Phone
009834287359
Email
kabir.kourosh@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Kourosh Kabir
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Epidemiology
Street address
Faculty of Medicine, University of Medical Sciences campus, above Art University, west end of Buali, Nebubot Square, Karaj
City
Karaj
Province
Alborz
Postal code
3149969415
Phone
009834287359
Email
kabir.kourosh@yahoo.com

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