Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effect of diaphragmatic and pursed-lip breathing exercises on sleep quality of older adults with chronic obstructive pulmonary disease

Protocol summary

Study aim
Determination and comparison of the effect of diaphragmatic and pursed-lip breathing exercises on sleep quality of older adults with chronic obstructive pulmonary disease

Design
Cross-over clinical trial without blinding

Settings and conduct
The research setting will include all public hospitals of Guilan province with lung / internal ward. Elderly people with inclusion criteria will be randomly divided into two intervention groups 1 and 2.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 60 and over; diagnosis of chronic obstructive pulmonary disease based on physician diagnosis; normal cognitive status; patients with low or moderate disease stage based on CAT ؛ Score 2 or lower from STOP-BANG Obstructive Sleep Apnea Questionnaire; Scores of 6 or more of the Pittsburgh Sleep Quality Index. Non-entry criteria: unstable clinical condition; Inability to read and write Persian texts; History of participating in pulmonary rehabilitation programs; Taking sleeping and sedatives drugs; BMI above 35.

Intervention groups
Intervention group: In this intervention group breathing exercises will be performed. Intervention is a combination of diaphragmatic and pursed-lip breathing exercises that are performed after randomly dividing the subjects into intervention groups (1 and 2) using a Cross-over method. First, the intervention group will perform diaphragmatic breathing exercises for the first 4 weeks, and the second intervention group will have pursed-lip breathing exercises. After one week of wash out period, in the next 4 weeks of the study, the diaphragmatic breathing exercises and the pursed-lip breathing will be changed.

Main outcome variables
sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190315043062N2**
Registration date: **2020-07-05, 1399/04/15**
Registration timing: **prospective**

Last update: **2020-07-05, 1399/04/15**
Update count: **0**

Registration date
2020-07-05, 1399/04/15

Registrant information

Name
Azar Darvishpour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 13 4256 5060

Email address
darvishpour@gums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-22, 1399/05/01

Expected recruitment end date
2021-03-18, 1399/12/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of diaphragmatic and pursed-lip breathing exercises on sleep quality of older adults with chronic obstructive pulmonary disease

Public title
The Effect of Breathing Exercises on the Sleep Quality of Older Adults with Chronic Lung Disease

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age 60 and older Diagnosis of chronic obstructive pulmonary disease based on the diagnosis of a physician Obtain a score of 7 and above (natural cognition) from the AMTS Cognitive Status Questionnaire Patients with low or moderate disease (score of 20 and below) based on CAT (CAT) test Acquire 2 or lower (low risk) score on STOP-BANG Obstructive Sleep Apnea Questionnaire Volunteering to participate in the study Obtain a Score of 6 or more of the Pittsburgh Sleep Quality Index (having poor quality sleep)

Exclusion criteria:
unstable clinical condition (High and uncontrolled high blood pressure with or without medication, acute symptoms of congestive heart failure or coronary heart disease, another chronic illness that disrupts sleep, health problem that interferes with breathing exercise). Inability to read and write Persian texts History of participating in pulmonary rehabilitation programs Taking sleeping and sedatives drugs BMI above 35

Age
From **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Subjects are divided into intervention groups (1 and 2) using random allocation method. First, the names of the treatment centers are written on separate sheets and then put in a packet and removed as one in the middle of the envelope and placed in intervention groups 1 and 2. (3 centers for intervention group 1 and 3 centers for intervention group 2)

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Guilan University of Medical Sciences

Street address
Vice Chancellor for Research and Technology., in front of the 17 Shahrivar Hospital., Shahid Siadati Street., Namjo Street

City
Rasht

Province
Guilan

Postal code
41466 -66949

Approval date
2020-06-10, 1399/03/21

Ethics committee reference number
IR.GUMS.REC.1399.111

Health conditions studied

1

Description of health condition studied
Chronic obstructive pulmonary disease

ICD-10 code
J44.9

ICD-10 code description
Chronic obstructive pulmonary disease, unspecified

Primary outcomes

1

Description
sleep quality

Timepoint
Before the intervention and after the intervention

Method of measurement
Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: This group will first perform diaphragmatic breathing exercises for 4 weeks. After one week of wash out period, in the next 4 weeks of the study, they will do the pursed-lip breathing exercise.

Category
Rehabilitation

2

Description
Intervention group2: This group will first perform pursed-lip breathing exercises for 4 weeks. After one week of wash out period, in the next 4 weeks of the study, they will do the diaphragmatic breathing exercise.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
All Guilan Public Hospitals have Lung and Internal ward
Full name of responsible person
Azar Darvishpour
Street address
Vice Chancellor for Research and Technology., in front of the 17 Shahrivar Hospital., Shahid Siadati Street., Namjo Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
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?
Yes
Title of funding source
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Azar Darvishpour
Position
Assistant Professor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable