

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

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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

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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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

Ph.D.

Other areas of specialty/work

Nursery

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School of Nursing and Midwifery., Shahid Yaghoub Sheikhi Street., LeylakooH road., Langeroud

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street addressSchool of Nursing and Midwifery., Shahid Yaghoub
Sheikhi Street., LeylakooH road., Langeroud**City****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 FormUndecided - 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