

# 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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**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**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

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

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**Position**

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**Position**

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**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**School 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 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