

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Determinate quality of sleep in patients with chronic obstructive pulmonary disease before and after Breathing Exercise training compared to cases without intervention

#### Protocol summary

##### Summary

Objective: The aim of this study is to investigate the effects of controlled breathing exercises on the sleep quality of in patient with chronic obstructive pulmonary disease. Design: Quasi-experimental pretest - posttest study with experimental and control groups. Study population: the population of the study, all patients will be diagnosed with Chronic Obstructive Pulmonary Disease during the years 2013-2014 who have History of Imam Khomeini and Shariati hospitalization. Inclusion criteria: diagnosis of Chronic Obstructive Pulmonary Disease based on medical history and clinical findings, without a history of Participate in Pulmonary rehabilitation program and exclusion criteria: severity of disease induced by breathing exercise, lack of motivation to continue cooperation. Sample size: 64 patients with Chronic Obstructive Pulmonary Disease. Methods: Samples in the experimental group (32 patients) were selected from Imam Khomeini hospital and samples in the control group (32 patients) were selected from Shariati Hospital. Experiment group, in relation to the breathing exercises consist of pursed lip breathing, diaphragmatic breathing and effective cough will be trained by the researcher. The exercises 2 times a day for 7 consecutive weeks will be. The control group was not given any training. To measure sleep quality used the Pittsburgh Sleep Quality Index that was completed by the patients in the two groups before and after the intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014060717989N1**

Registration date: **2015-06-01, 1394/03/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-06-01, 1394/03/11

##### Registrant information

###### Name

Yaghub Hame khezri

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8272 3295

###### Email address

khezriy@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Research Council of Tehran University of Medical Sciences

##### Expected recruitment start date

2014-07-23, 1393/05/01

##### Expected recruitment end date

2015-01-21, 1393/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Determinate quality of sleep in patients with chronic obstructive pulmonary disease before and after Breathing Exercise training compared to cases without intervention

**Public title**

Controlled breathing and sleep quality in patient with Chronic Obstructive Pulmonary Disease

**Purpose**

Health service research

**Inclusion/Exclusion criteria**

Inclusion criteria: Diagnosis of chronic obstructive pulmonary disease based on medical history and clinical findings, Stable clinical condition (absence of severe pulmonary disease, normal blood pressure with or without use the drugs, no signs of heart failure or coronary disease, the absence of health problems that interfere with the doing exercises), absence of other chronic disease, ability to read and write, the lack of cognitive problems, without a history of Participate in Pulmonary rehabilitation program. Exclusion criteria: Age above 85 years, severity of disease induced by breathing exercise, lack of motivation to continue cooperation.

**Age**

From **25 years** old to **85 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **64**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Health services research

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

**Street address**

Sixth Floor, Central Organization of University, Qods Street, Keshavarz Blvd.

**City**

Tehran

**Postal code****Approval date**

2014-07-15, 1393/04/24

**Ethics committee reference number**

130/918/93/5

**Health conditions studied****1****Description of health condition studied**

COPD

**ICD-10 code**

J44

**ICD-10 code description**

Other chronic obstructive pulmonary disease

**Primary outcomes****1****Description**

Sleep Quality

**Timepoint**

Before training and after seven weeks of training

**Method of measurement**

Pittsburgh Sleep Quality Index (PSQI)

**Secondary outcomes****1****Description**

Added at 2016-11-15: Re-hospitalization

**Timepoint**

Added at 2016-11-15: 2 months after education

**Method of measurement**

Added at 2016-11-15: Questioning from patient

**Intervention groups****1****Description**

Experiment group in relation to the breathing exercises will be trained by the researcher. The exercise consists of a series of pursed lip breathing, each time, 5 to 10 times, diaphragmatic breathing each time, 5 to 15 times, and effective cough, each time 2 to 3 times. These exercises are done for seven weeks, and every day in the morning and the evening.

**Category**

Rehabilitation

**2****Description**

The control group did not receive the intervention

**Category**

N/A

**Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Imam Khomeini Hospital

**Full name of responsible person**

Yaghub Hame khezri

**Street address**

Imam Khomeini Hospital, Tehran

**City**

Tehran

## 2

### Recruitment center

**Name of recruitment center**

Shariati Hospital

**Full name of responsible person**

Yaghub Hame khezri

**Street address**

Shariati Hospital, North Kargar Avenue, Tehran

**City**

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Research Council of Tehran University of Medical Sciences

**Full name of responsible person**

Doctor M. Younesian - Vice President of Research and Technology

**Street address**

Sixth Floor, Keshavarz Blvd., Qods street, Central Building of Tehran University of Medical Sciences, Tehran

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research Council of Tehran University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Yaghub Hame khezri

**Position**

MSc student of Medical-Surgical Nursing

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*