

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 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

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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

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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

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

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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

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

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Full name of responsible person

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Position

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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