Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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/د

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

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

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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