

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effect of Progressive Muscle Relaxation Technique of Fatigue and Quality of Sleep in Patients with Chronic Obstructive Pulmonary Disease

Protocol summary

Summary

This study is a double-blind randomized clinical trial. Inclusion criteria: patients with stage 3 or 4 COPD (according to the GOLD system ; Having degrees of moderate to severe fatigue and sleep disturbance based on questionnaire of fatigue and sleep quality index; Exclusion criteria: cognitive disorders; viral infections; participation in pulmonary rehabilitation Sample size is 100 patients who are assigned into two intervention and control groups (each 50 person). Subjects will be selected using probability random sampling method. In pre-test, data is collected using self-report responses to questionnaire of sleep quality PSQI and questionnaire of fatigue index FSS . Then for patients in the intervention group Progressive muscle relaxation program will be performed. Steps of progressive relaxation exercises include Breathing Exercises, lower extremity exercises ,upper extremity exercises and exercise of respiratory muscles .In the post-test stage, 8 weeks after the completion of their education, patients will be asked to come to the Lung clinic and complete the FSS and PSQI by the researcher. Also in the control group they will receive usual care and at the end of 8 weeks questionnaire of sleep quality PSQI and questionnaire of fatigue index FSS Will be completed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016080124080N3**
Registration date: **2017-03-11, 1395/12/21**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-11, 1395/12/21

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Lorestan University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Progressive Muscle Relaxation Technique of Fatigue and Quality of Sleep in Patients with Chronic Obstructive Pulmonary Disease

Public title

Effect of Progressive Muscle Relaxation Technique of Fatigue and Quality of Sleep in Patients

Purpose

Supportive

Inclusion/Exclusion criteria

The inclusion criteria include: COPD Diagnosed by a physician of at least duration of 6 months or longer; residence in the city; patients with stage 3 or 4 COPD

(according to the GOLD system, 2007); absence of a disease diagnosis additional to COPD; ability to read and write and willingness to collaborate ; Having degrees of moderate to severe fatigue and sleep disturbance; based on questionnaire of fatigue and sleep quality index; The absence of disease of the nervous system , Acute myocardial Infarction And Cancer In addition to copd; Age 45 to 70 years.BMI less than 30 ; Lack of psychiatric disorders such as anxiety . The exclusion criteria include: cognitive disorders;viral infections; participation in pulmonary rehabilitation

Age

From **45 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Lorestan University of Medical Sciences

Street address

School of Nursing and Midwifery, Kamalvand, Campus of Lorestan University of Medical Sciences.

City

Khorramabad

Postal code

6814993165

Approval date

2016-07-11, 1395/04/21

Ethics committee reference number

LUMS.REC.1395.107

Health conditions studied

1

Description of health condition studied

Chronic Obstructive Pulmonary Disease

ICD-10 code

J44

ICD-10 code description

Chronic Obstructive Pulmonary Disease, unspecified

Primary outcomes

1

Description

Fatigue

Timepoint

Immediately before intervention and 8 week after intervention

Method of measurement

Fatigue severity scale(fss)

Secondary outcomes

1

Description

Quality of sleep

Timepoint

Immediately before intervention and 8 week after intervention

Method of measurement

Pittsburgh Sleep Quality Index (PSQI)

Intervention groups

1

Description

for patients in the intervention group will perform Progressive muscle relaxation program.steps of progressive relaxation exercises include Breathing Exercises, lower extremity exercises ,upper extremity exercises and exercise of respiratory muscles - PMRT will give by using a handbook including relaxation exercises (including information about how to perform relaxation, respiration control, and progressive relaxation exercises) and a PMRT CD (educational CD prepared by the Iranian Association of Psychologists). After the education, each patient will give a handbook and CD containing PMRT and will ask to listen to and perform the exercises at home by following the instructions in the CD once a day for 8 weeks at hours when they feel themselves the least tired .

Category

Rehabilitation

2

Description

Also in the control group they will receive usual care

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Lorestan University of Medical Sciences

Full name of responsible person

Pouya Seydi Chegeni

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Lorestan University Of Medical Sciences

Full name of responsible person

Research Department

Street address

Kamalvand , Technology Research Department of Lorestan University Of Medical Sciences.

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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

Lorestan 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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Full name of responsible person

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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