Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

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

Public title

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

Purpose

Supportive

Inclusion/Exclusion criteria

The inclusion criteria includ: 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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Khorramabad

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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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