

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of Progressive Muscle Relaxation Technique of Fatigue and Quality of Sleep in Patiens 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

##### Name

Mohammad Gholami

##### Name of organization / entity

Lorestan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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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 Patiens with Chronic Obstructive Pulmonary Disease

#### Public title

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

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

**City**

Khorramabad

## 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.

**City**

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

**Contact****Name of organization / entity**

Lorestan University Of Medical Sciences

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Pouya.Seydi Chegeni

**Position**

Undergraduated Student

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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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*