

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Investigating the effect of pulmonary rehabilitation on sexual satisfaction and sexual self-efficacy of patients with chronic obstructive pulmonary disease

#### Protocol summary

##### Study aim

Investigating the effect of pulmonary rehabilitation on sexual satisfaction and sexual self-efficacy of patients with chronic obstructive pulmonary disease

##### Design

This is a randomized clinical trial with a parallel design, non-blinded, and a control group. The research population will include all chronic obstructive pulmonary disease patients referred to Dasht Azadegan Clinic in Isfahan. A total of 40 eligible people will be selected conveniently. A simple random method is used for randomization and the participants are assigned to two intervention and control groups.

##### Settings and conduct

This study, which will be conducted in Dasht Azadegan Clinic in Isfahan City, is not blinded. Both groups will first complete sexual satisfaction and sexual self-efficacy questionnaires. After implementing the protocol for the intervention group, the questionnaires will be provided to both groups again.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent; A definitive diagnosis of COPD by a doctor; A physically and sexually healthy wife  
Exclusion criteria: History of suffering from sexual problems and diseases; Smoking history; History of heart disease

##### Intervention groups

The intervention group will undergo pulmonary rehabilitation training for 8 weeks (one hour per session).  
The control group will not receive any intervention.

##### Main outcome variables

Sexual satisfaction, sexual self-efficacy

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20130812014333N205**

Registration date: **2023-07-19, 1402/04/28**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-07-19, 1402/04/28**

Update count: **0**

#### Registration date

2023-07-19, 1402/04/28

#### Registrant information

##### Name

Feizollah Foroughi

##### Name of organization / entity

kermanshah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 1821 4653

##### Email address

fforoughi@kums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2023-07-15, 1402/04/24

#### Expected recruitment end date

2023-08-20, 1402/05/29

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Investigating the effect of pulmonary rehabilitation on

sexual satisfaction and sexual self-efficacy of patients with chronic obstructive pulmonary disease

### Public title

Investigating the effect of pulmonary rehabilitation on sexual satisfaction and sexual self-efficacy of patients with chronic obstructive pulmonary disease

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Informed consent A definitive diagnosis of COPD by a doctor A physically and sexually healthy wife

#### Exclusion criteria:

History of suffering from sexual problems and diseases  
Smoking history History of heart disease

### Age

No age limit

### Gender

Both

### Phase

N/A

### Groups that have been masked

No information

### Sample size

Target sample size: 40

### Randomization (investigator's opinion)

Randomized

### Randomization description

Randomization will be done in a simple random method, after identifying eligible patients, they will be randomly assigned a three-digit dedicated code. The last digit on the right determines the patient group. If this number is 0, 1, 2, 3, 4, it will be assigned in the intervention group, and if this number is 5, 6, 7, 8, 9, it will be assigned in the control group

### Blinding (investigator's opinion)

Not 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 of Islamic Azad University

##### Street address

Vice Chancellor for Research Affairs, University Blvd.,  
Arghwanieh, J Sharghi Street

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8155139998

##### Approval date

2022-06-25, 1401/04/04

##### Ethics committee reference number

IR.IAU.KHUISF.REC.1402.131

## Health conditions studied

### 1

#### Description of health condition studied

Chronic Obstructive Pulmonary Disease

#### ICD-10 code

J44.9

#### ICD-10 code description

Chronic obstructive pulmonary disease, unspecified

## Primary outcomes

### 1

#### Description

Sexual satisfaction

#### Timepoint

The beginning of the study and the end of the study (one month later)

#### Method of measurement

Sexual satisfaction questionnaire

### 2

#### Description

sexual self-efficacy

#### Timepoint

The beginning of the study and the end of the study (one month later)

#### Method of measurement

Sexual self-efficacy questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The intervention group will undergo pulmonary rehabilitation training for 8 weeks (one hour per session).

#### Category

Behavior

### 2

#### Description

The control group will not receive any intervention.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Dasht Azadegan Clinic

**Full name of responsible person**

Mahdi Jalali

**Street address**

Azadegan Dental Clinic, 12th Alley, Freiburg Str,  
Mordavij Streeteet,

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8155139998

**Phone**

+98 31 3670 0792

**Email**

mahdi.jalali@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Islamic Azad University, Khorasgan branch

**Full name of responsible person**

Dr. Majid Meshkini

**Street address**

Faculty of Nursing and Midwifery, University Blvd.,  
Arghwanieh, J Sharghi Street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8155139998

**Phone**

+98 31 3535 4001

**Email**

meshkini@miums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Islamic Azad University, Khorasgan branch

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Islamic Azad University, Khorasgan branch

**Full name of responsible person**

Mahdi Jalali

**Position**

Islamic Azad University, Khorasgan branch

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Faculty of Nursing and Midwifery, University Blvd.,  
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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Islamic Azad University, Khorasgan branch

**Full name of responsible person**

Mahdi Jalali

**Position**

Nursing master's student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Islamic Azad University, Khorasgan branch

**Full name of responsible person**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available