

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Effect of online aerobic and breathing exercises on serum level of lysine and ornithine in Chronic Obstructive Pulmonary Disease Patients

#### Protocol summary

##### Study aim

Investigating the effect of telerehabilitation on amino acid metabolism

##### Design

A prospective pre-experimental design based on one group pre-test and post-test

##### Settings and conduct

Patients with COPD undergo regular online aerobic supervised exercises for eight weeks, three times a week, 60 minutes per session with moderate intensity. Serum levels of lysine and ornithine in arterial plasma and physical fitness parameters are measured before and after the intervention in each patient.

##### Participants/Inclusion and exclusion criteria

1. Men patients with COPD
2. Providing informed consent
3. Absence of special disease and recent surgery and hospitalization

##### Intervention groups

8-weeks aerobic and breathing exercises through online platforms

##### Main outcome variables

Serum levels of lysine and ornithine

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201205049609N1**

Registration date: **2023-07-11, 1402/04/20**

Registration timing: **retrospective**

Last update: **2023-07-11, 1402/04/20**

Update count: **0**

##### Registration date

2023-07-11, 1402/04/20

##### Registrant information

##### Name

Nazanin Shahabi Nezhad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3212 1282

##### Email address

n.shahabi@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-01, 1400/10/11

##### Expected recruitment end date

2022-07-23, 1401/05/01

##### Actual recruitment start date

2022-01-21, 1400/11/01

##### Actual recruitment end date

2022-06-20, 1401/03/30

##### Trial completion date

empty

##### Scientific title

Effect of online aerobic and breathing exercises on serum level of lysine and ornithine in Chronic Obstructive Pulmonary Disease Patients

##### Public title

Investigating the effect of online exercise training on the serum level of amino acids

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

##### Inclusion criteria:

Male COPD patients Stable condition

##### Exclusion criteria:

##### Age

From **40 years** old

##### Gender

Male

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: 24

Actual sample size reached: 24

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Single

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of kerman University of Medical Sciences

##### Street address

Ebn-e-Sina St.,Jahad Blvd., Kernan,Iran

##### City

Kerman

##### Province

Kermanshah

##### Postal code

7619813159

#### Approval date

2022-02-22, 1400/12/03

#### Ethics committee reference number

IR.KMU.AH.REC.1400.362

## Health conditions studied

### 1

#### Description of health condition studied

Chronic Obstructive Pulmonary Disease Patients (copd)

#### ICD-10 code

Z82.5

#### ICD-10 code description

Family history of asthma and other chronic lower respiratory diseases

## Primary outcomes

### 1

#### Description

serum level of amino acid

#### Timepoint

Before and after 8 weeks of intervention

#### Method of measurement

high-performance liquid chromatography

## Secondary outcomes

### 1

#### Description

Physical fitness parameters

#### Timepoint

Before and after 8 weeks of intervention

#### Method of measurement

fitness tests

## Intervention groups

### 1

#### Description

Intervention group: male COPD patients Selected patients with Chronic Obstructive Pulmonary Disease (COPD) undergo regular online aerobic supervised exercises for eight weeks, three times a week, 60 minutes per session with moderate intensity. The exercise focuses on diaphragmatic strengthening breathing which is called "Diaphragmatic Breathing Exercise". Serum levels of lysine and ornithine in arterial plasma, anthropometric parameters, and physical fitness parameters will analyze before and after the intervention in each patient. The amino acid concentrations are measured by ion-exchange, high-pressure liquid chromatography with fluorometric detection.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Afzalipour hospital

##### Full name of responsible person

Rostam Yazdani

##### Street address

Imam Khomeini Highway, Next to the Shahid bahonar uni, Afzalipor medical education center, Kerman, Iran

##### City

Kerman

##### Province

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##### Postal code

7616913355

##### Phone

+98 34 3132 8000

##### Email

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Rostam yazdani

**Street address**

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

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**Phone**

+98 34 3132 5829

**Email**

VCR@KMU.AC.IR

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

Yes

**Title of funding source**

Kerman University of Medical Sciences

**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**

Kerman University of Medical Sciences

**Full name of responsible person**

Rostam Yazdani

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

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31328000

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drryazdani@yahoo.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

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**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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## Person responsible for updating data

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31328000

**Email**

drryazdani@yahoo.com

**Sharing plan**

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

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available