

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

The effects of high intensity interval training, interval training and continuous training on systemic inflammatory and respiratory factors in patients with chronic obstructive pulmonary disease

Protocol summary

Study aim

Comparison of the effect of intermittent high-intensity exercise, moderate-intensity intermittent exercise, and continuous exercise on blood inflammatory indices and respiratory indices in patients with chronic obstructive pulmonary disease.

Design

The current clinical trial study has three intervention groups and one control group, with parallel and double-blind groups, randomized and with a sample size of 45 patients.

Settings and conduct

This study is conducted as a clinical trial in COPD patients referred to Masih Deneshvari Hospital in Tehran. Based on the results obtained from the laboratory tests, the clinical conditions of the patients before and after performing each group of exercises are compared with each other. Randomization will be done with the help of codes assigned to patients and based on their file numbers. Blinding is for patients and laboratory personnel, and the rehabilitation person who is a physiotherapist cannot be blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria included ages between 20-70 years, and patients with COPD grades 2 and 3. Exclusion criteria included moderate to severe learning difficulties, movement problems, confusion, disorientation or terminal illness, and congestive heart failure.

Intervention groups

In the control group, patients perform moderate-intensity continuous exercises. In the first intervention group, high-intensity interval training, activity duration of 4 hours and duration recovery for 3 minutes, in the second intervention group, high-intensity interval training, activity duration of 2 minutes and duration recovery of 1 minute, and in the third intervention group, high-intensity interval training, activity duration for 30

seconds and duration recovery for 30 seconds.

Main outcome variables

FVC, FEV1, oxygen saturation, dyspnea, health-related quality of life, Interleukin 8, TNF- α

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210813052172N2**

Registration date: **2023-01-16, 1401/10/26**

Registration timing: **prospective**

Last update: **2023-01-16, 1401/10/26**

Update count: **0**

Registration date

2023-01-16, 1401/10/26

Registrant information

Name

Masoumeh ZoghAli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3662 4225

Email address

masoumezoghali@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-10-23, 1402/08/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effects of high intensity interval training, interval training and continuous training on systemic inflammatory and respiratory factors in patients with chronic obstructive pulmonary disease

Public title
The effect of high-intensity intermittent exercise, moderate-intensity intermittent exercise and continuous exercise in patients with chronic obstructive pulmonary disease.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with COPD grades 2 and 3 Age between 20-70 years
Exclusion criteria:
 Moderate to severe learning difficulties Mobility problems
 Confusion Disorientation or terminal illness Congestive heart failure

Age
From **20 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: simple. Randomization Unit: Individual. Randomization tool: table of random numbers. Based on the codes assigned to each patient (using the file number), the patients are divided into 4 groups under the desired treatments.

Blinding (investigator's opinion)
Double blinded

Blinding description
Blinding is done for patients and laboratory technician. A rehabilitation person who is a physiotherapist cannot be blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Arabi St, Shahid Yemeni St., Chamran Highway,

City

Tehran

Province

Tehran

Postal code

1956944413

Approval date

2022-11-27, 1401/09/06

Ethics committee reference number

IR.SBMU.NRITLD.REC.1401.097

Health conditions studied

1

Description of health condition studied

Chronic obstructive pulmonary disease

ICD-10 code

J44

ICD-10 code description

Other chronic obstructive pulmonary disease

Primary outcomes

1

Description

Maximum expiratory volume in the first second

Timepoint

Before and after exercises

Method of measurement

Spirometry

2

Description

FVC

Timepoint

Before and after exercises

Method of measurement

Spirometry

3

Description

Oxygen saturation

Timepoint

Before and after exercises

Method of measurement

Pulse oximetry

4

Description

Dyspnea

Timepoint

Before and after exercises

Method of measurement

Borg scale

Secondary outcomes

1

Description

Interleukin 8

Timepoint

Before and after exercises

Method of measurement

ELISA test

2

Description

TNF- α

Timepoint

Before and after exercises

Method of measurement

ELISA test

Intervention groups

1

Description

Intervention group: Patients perform high-intensity intermittent exercises with a duration of 4 hours and a recovery period of 3 minutes.

Category

Rehabilitation

2

Description

Intervention group: Patients perform high-intensity intermittent exercises for 2 minutes of activity and 1 minute of recovery.

Category

Rehabilitation

3

Description

Intervention group: Patients perform high-intensity intermittent exercises, activity diversion for 30 seconds and recovery diversion for 30 seconds.

Category

Rehabilitation

4

Description

Control group: Patients do moderate intensity continuous exercises.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Masoumeh Zoghali

Street address

Masih Daneshvari Hospital, Daar Abad

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masoumezoghali@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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Arabi St, Yemen St., Shahid Chamran Highway

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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

Shahid Beheshti 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

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Email

mohsenabedi110@gmail.com

Person responsible for general inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Masoumeh Zoghali

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Researcher

Latest degree

Master

Other areas of specialty/work

Biotechnology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Mohsen Abedi

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Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Phone**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

Not applicable

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