Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 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)

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+98 21 3662 4225

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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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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

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
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Person responsible for updating data

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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