

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

The effect of interval exercises on heart rate variability in hospitalized patients with chronic obstructive pulmonary disease (COPD)

Protocol summary

Study aim

The effect of different interval training protocols on the clinical and cardiorespiratory index in patients with COPD

Design

A controlled, parallel-group, double-blind, randomized, phase 2 clinical trial on 48 patients.

Settings and conduct

This study is conducted as a clinical trial on patients with COPD referred to Masih Deneshvari Hospital in Tehran. Patients who meet the inclusion criteria will be placed in one of the three study groups after providing full explanations and signing a written consent form.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: COPD patients in Grades 2, 3, and 4, age over 18 years. Exclusion criteria: Patient dissatisfaction to participate in the study, underlying diseases such as diabetes, nervous system diseases affecting cardiac rhythm

Intervention groups

In the first intervention group, after warming up, the patients perform 30 seconds of activity with an intensity of 85% of the maximum oxygen peak, then they perform 30 seconds of recovery with 40% of the maximum oxygen peak. Patients will have 4 minutes of passive recovery after doing 8 sets. After 4 minutes of recovery, they will perform the same as above for another 8 minutes. After finishing the activity, the patients will perform cooling movements for 5 minutes. The second group also performs peak oxygen for 4 minutes with 85% intensity after 5 minutes of warming up. Then they perform 3 minutes of recovery with 40% of the maximum oxygen peak. Patients perform this protocol in 3 sets for 21 minutes. The third group (control group) received only routine treatments and did not receive any exercise intervention. The total duration of the rehabilitation process will be 2 weeks.

Main outcome variables

Six-minute walk test distance, resting oxygen saturation, anaerobic threshold VO₂, maximum heart rate,

maximum VO₂, SDRR, RMSSD, HF, LF, LF/HF

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200611047727N6**

Registration date: **2023-03-14, 1401/12/23**

Registration timing: **prospective**

Last update: **2023-03-14, 1401/12/23**

Update count: **0**

Registration date

2023-03-14, 1401/12/23

Registrant information

Name

Maryam Sadat Mirenayat

Name of organization / entity

Country

Iran (Islamic Republic of)

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mirenayat@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	The effect of interval exercises on heart rate variability in hospitalized patients with chronic obstructive pulmonary disease (COPD)
Public title	The effect of various types of interval exercises in patients with COPD
Purpose	Supportive
Inclusion/Exclusion criteria	
Inclusion criteria:	Patients with COPD in Grade 2, 3 and 4 Age more than 18
Exclusion criteria:	Dissatisfaction to participate in the study Underlying diseases such as diabetes Nervous system diseases affecting cardiac rhythm
Age	From 18 years old
Gender	Both
Phase	2
Groups that have been masked	Data analyser
Sample size	Target sample size: 48
Randomization (investigator's opinion)	Randomized
Randomization description	Simple randomization method, individual randomization unit and random number table randomization tool. For randomization, we use a table consisting of random digits from 0 to 9. Each of the figures in this table is repeated the same on average. We start from the first row of the table and move down row by row. For three treatments, we put numbers 1 to 3 for treatment A, numbers 4 to 6 for treatment B, and numbers 7 to 9 for treatment C. We continue the above process until three groups are completed.
Blinding (investigator's opinion)	Single blinded
Blinding description	In order to prevent any possible complications, the doctor and clinical caregiver are fully aware of the assignment of treatment groups. Researchers responsible for data collection and analysis are not aware of the allocation of different study groups.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address	Shahid Abbas Arabi St., Yemen St., Shahid Chamran Highway
City	Tehran
Province	Tehran
Postal code	1956944413
Approval date	2023-02-21, 1401/12/02
Ethics committee reference number	IR.SBMU.NRITLD.REC.1401.134

Health conditions studied	
<u>1</u>	
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	
<u>1</u>	
Description	Distance of 6-minute walk test
Timepoint	Before rehabilitation and 2 week after rehabilitation
Method of measurement	6-minute walk test
<u>2</u>	
Description	Resting heart rate
Timepoint	Before rehabilitation and 2 weeks after rehabilitation
Method of measurement	Cardiopulmonary exercise test
<u>3</u>	
Description	VO2 at anaerobic threshold
Timepoint	Before rehabilitation and 2 weeks after rehabilitation
Method of measurement	Cardiopulmonary exercise test

4

Description

Maximum heart rate

Timepoint

Before rehabilitation and 2 weeks after rehabilitation

Method of measurement

Cardiopulmonary exercise test

5

Description

VO2 max

Timepoint

Before rehabilitation and 2 weeks after rehabilitation

Method of measurement

Cardiopulmonary exercise test

6

Description

Standard deviation of ventricular contraction wave period

Timepoint

Before rehabilitation and 2 weeks after rehabilitation

Method of measurement

Heart rate variability holter

7

Description

The root mean square of successive differences between normal heartbeats

Timepoint

Before rehabilitation and 2 weeks after rehabilitation

Method of measurement

Heart rate variability holter

8

Description

High frequency

Timepoint

Before rehabilitation and 2 weeks after rehabilitation

Method of measurement

Heart rate variability holter

9

Description

Low frequency

Timepoint

Before rehabilitation and 2 weeks after rehabilitation

Method of measurement

Heart rate variability holter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After warming up, the patients do 30 seconds of activity with an intensity of 85% of the maximum oxygen peak, then they do 30 seconds of recovery with 40% of the maximum oxygen peak. Patients will have passive recovery after doing 8 sets of 4 minutes. After 4 minutes of recovery, they will perform the same as above for another 8 minutes. After finishing the activity, the patients will perform cooling movements for 5 minutes.

Category

Rehabilitation

2

Description

Intervention group: After warming up for 5 minutes, the patients perform 4 minutes with an intensity of 85% of the maximum oxygen peak. Then they perform 3 minutes of recovery with 40% of the maximum oxygen peak. Patients perform this protocol in 3 sets for 21 minutes.

Category

Rehabilitation

3

Description

Control group: Patients receive only routine treatments and no exercise intervention.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Maryam Sadat Mirenayat

Street address

Masih Daneshvari Hospital, Daarabad

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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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Shahid Abbas 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

Mohsen Abedi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Full name of responsible person

Arezoo Mohamadifar

Position

Non-faculty specialist doctor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Person responsible for updating data

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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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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