

# 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 VO<sub>2</sub>, maximum heart rate,

maximum VO<sub>2</sub>, 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)

##### Phone

+98 21 2610 5050

##### Email address

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                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Scientific title</b>                       | The effect of interval exercises on heart rate variability in hospitalized patients with chronic obstructive pulmonary disease (COPD)                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Public title</b>                           | The effect of various types of interval exercises in patients with COPD                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Purpose</b>                                | Supportive                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Inclusion/Exclusion criteria</b>           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Inclusion criteria:</b>                    | Patients with COPD in Grade 2, 3 and 4 Age more than 18                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Exclusion criteria:</b>                    | Dissatisfaction to participate in the study Underlying diseases such as diabetes Nervous system diseases affecting cardiac rhythm                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Age</b>                                    | From <b>18 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Gender</b>                                 | Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Phase</b>                                  | 2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Groups that have been masked</b>           | <ul style="list-style-type: none"> <li>Data analyser</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Sample size</b>                            | Target sample size: <b>48</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Randomization (investigator's opinion)</b> | Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Randomization description</b>              | 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. |
| <b>Blinding (investigator's opinion)</b>      | Single blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Blinding description</b>                   | 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.                                                                                                                                                                                                                                                             |
| <b>Placebo</b>                                | Not used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Assignment</b>                             | Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Other design features</b>                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Secondary Ids</b>                          | empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

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

|                                                |                                                    |
|------------------------------------------------|----------------------------------------------------|
| <b>Health conditions studied</b>               |                                                    |
| <b><u>1</u></b>                                |                                                    |
| <b>Description of health condition studied</b> | Chronic obstructive pulmonary disease              |
| <b>ICD-10 code</b>                             | J44.9                                              |
| <b>ICD-10 code description</b>                 | Chronic obstructive pulmonary disease, unspecified |

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

#### **City**

Tehran

#### **Province**

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#### **Postal code**

1956944413

#### **Phone**

+98 21 2612 5050

#### **Email**

MirenayaT\_M@yahoo.com

## **Sponsors / Funding sources**

## 1

### **Sponsor**

Name of organization / entity

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Afshin Zarghi

**Street address**

Shahid Abbas Arabi St., Yemen St., Shahid Chamran Highway

**City**

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**Email**

zarghi@sbmu.ac.ir

**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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Masih Daneshvari Hospital, Daarabad

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**Province**

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**Email**

mohsenabedi110@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**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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arezoomohamadifar@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Reyhaneh Zahiri

**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