Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the Effects of 6-weeks Interval Aerobic Exercise and Respiratory Muscle Training on some of Cardiopulmonary and Muscular Indicators of Chronic Obstructive Pulmonary Disease Patients (Case Study).

Protocol summary

Study aim

Evaluating the effect of 6-weeks combined respiratory with aerobic interval training on some of the Cardiopulmonary and muscular Indicators of chronic obstructive pulmonary disease (COPD) patients.

Design

This is an interventional study that there isn't pharmacological intervention in the study phase, Includes both genders, the range of age: 18 to no age limit. randomization does not apply because there is one group and the intervention is the same for everyone. no placebo and no blinding. Its main purpose is to rehabilitate patients.

Settings and conduct

The study will run at a sports therapy center in the hospital. all exercise programs will be performed under the supervision of a Sports medicine specialist with constant monitoring of the vital signs, through the Vital Signs Monitor.

Participants/Inclusion and exclusion criteria

the participants: Patients with chronic obstructive pulmonary disease (COPD). Inclusion criteria: COPD Stages 3 & 4. exclusion criteria: Having active heart disease or symptoms such as chest pain, Uncontrolled high blood pressure, Motor restriction, Musculoskeletal disorder, exacerbation of COPD.

Intervention groups

include 5 COPD patients stage 3 and 4. for 6 weeks, they'll take part in the exercise rehab intervention, 3 days per week; Including interval aerobic exercise and inspiratory muscle training. before and after end of the study, Related tests to Cardiopulmonary and muscular function, will be taken and finally these individuals are compared to pre-test and post-test.

Main outcome variables

FEV_1 or Forced Expiratory Volume in the first Second refers to the amount of air that can forcibly be blown out in the first second, after full inspiration.

General information

Reason for update

Acronym

COPD

IRCT registration information

IRCT registration number: **IRCT20190702044075N1**
Registration date: **2019-12-27, 1398/10/06**
Registration timing: **retrospective**

Last update: **2019-12-27, 1398/10/06**
Update count: **0**

Registration date

2019-12-27, 1398/10/06

Registrant information

Name

Mohammad Javad Fallahi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-11, 1398/08/20

Expected recruitment end date

2019-12-11, 1398/09/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the Effects of 6-weeks Interval Aerobic Exercise and Respiratory Muscle Training on some of Cardiopulmonary and Muscular Indicators of Chronic Obstructive Pulmonary Disease Patients (Case Study).

Public title
Evaluating the Effects of 6-weeks Interval Aerobic Exercise and Respiratory Muscle Training on some of Cardiopulmonary and Muscular Indicators of Chronic Obstructive Pulmonary Disease Patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Chronic Obstructive Pulmonary Disease Stage 3 and 4
Exclusion criteria:
Uncontrolled cardiovascular disease (decompensated CHF, uncontrolled arrhythmia, myocardial infarction or unstable angina during recent 6 weeks) uncontrolled hypertension (systolic blood pressure more than 180 mm-Hg / diastolic blood pressure more than 110 mm Hg) any musculo-skeletal disease and Motor restriction which preclude exercise program moderate to severe COPD exacerbation leading to hospital admission during recent 6 weeks performing regular exercise or participation in cardiac or pulmonary rehabilitation during recent 6 months
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **5**
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 Shiraz University of Medical Sciences
Street address
Vice-Chancellor for Research, Central building of Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran
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Postal code
71348-14336
Approval date
2019-05-15, 1398/02/25
Ethics committee reference number
IR.SUMS.REHAB.REC.1398.014

Health conditions studied

1

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

1

Description
FEV_1 (Forced Expiratory Volume in the first Second): is the volume of air that can forcibly be blown out in the first second, after full inspiration. In another words, this indicator shows the volume of expiratory air in the first second of vital capacity. (Vital Capacity; The maximum volume of air that can be blown out after a very deep inspiration).
Timepoint
Before and after the 6th and final week of the intervention, as a Pulmonary Function Test (PFT).
Method of measurement
Using spirometry, measured in Liters.

Secondary outcomes

1

Description
FVC (Forced vital capacity): is the volume of air that can be blown out of the lungs with more intensity and maximum power, after full inspiration.
Timepoint

Before and after the 6th and final week of the intervention, as a Pulmonary Function Test (PFT).

Method of measurement

Using spirometry, measured in Liters.

2

Description

TLC (Total lung capacity): is the maximum volume of air that can be placed in the lungs and is about 5800 ml.

Timepoint

Before and after the 6th and final week of the intervention, as a Pulmonary Function Test (PFT).

Method of measurement

Using Plethysmograph or "body box", measured in Liters.

3

Description

RV (Residual volume): the volume of air remaining in the lungs at the end of a very deep exhalation.

Timepoint

Before and after the 6th and final week of the intervention, as a Pulmonary Function Test (PFT).

Method of measurement

Using Plethysmograph or "body box", measured in Liters.

4

Description

FRC (Functional Residual Capacity): The volume of air that remains in the lungs after a normal exhalation, when the lungs and chest are resting.

Timepoint

Before and after the 6th and final week of the intervention, as a Pulmonary Function Test (PFT).

Method of measurement

Using Plethysmograph or "body box" or Indirect spirometry with helium dilution method, measured in Liters.

5

Description

HRR index (Heart rate recovery): Is the rate of return heart rate to rest mode In the first minute after stopping exercise, Which reflects the reactivation of the parasympathetic system, and a delay in its decline indicates impaired cardiac function.

Timepoint

Before and after the 6th and final week of the intervention; 1 minute after the end of the exercise test.

Method of measurement

Usin the Electrocardiography or Polar™ Heart rate sensor.

6

Description

RPP index (Rate Pressure Product): Indicates the amount of internal Cardiac muscle work and it's used to showing the workload and oxygen consumption of myocardium, and obtained by multiplying the systolic blood pressure in the heart rate. [RPP = SBP × HR/1000]

Timepoint

Before and after the 6th and final week of the intervention; Immediately upon stopping the cardiac exercise (stress) testing.

Method of measurement

Using the Sphygmomanometer and Electrocardiography or Polar™ Heart rate sensor.

7

Description

CRF (Cardio respiratory Fitness): Refers to the capacity of the respiratory and cardiovascular systems to provide muscles oxygen during sustained or intense exercise.

Timepoint

Before and after the 6th and final week of the intervention; during exercise testing.

Method of measurement

Using gas analyzer and Calculating Vo2max.

8

Description

Muscle strength: refers to the ability of the muscle to generate the force (power).

Timepoint

Before and after the 6th and final week of the intervention.

Method of measurement

Using hand grip or handheld dynamo meter.

9

Description

Muscle endurance: Refers to the ability of the muscle to maintain or repeat a particular task over time.

Timepoint

Before and after the 6th and final week of the intervention.

Method of measurement

Using Sit-up and Inverted Row (Supine row) tests.

10

Description

Flexibility index: The Level of ability to move or mobilize a joint around its entire range of motion and maintaining it facilitates joint movements.

Timepoint

Before and after the 6th and final week of the intervention.

Method of measurement

Using sit and reach test.

11

Description

Body composition: It means the ratio of fat (adipose) tissue to free fat tissue and percentage of muscle mass.

Timepoint

Before and after the 6th and final week of the intervention.

Method of measurement
Using body composition analyzer.

Intervention groups

1

Description
Intervention group: The intervention group will include 5 COPD patients at Stage 3 & 4. First, Informed consent form will be provided for Participants and will be completed by Patient or in the case of necessity, with the supervision of the witness or legal guardian of the patient. then the patients will participate in two pre-test and post-test steps. to determine peak exercise capacity and cardio-respiratory fitness (CRF), or the risk of heart disease and the hidden ischemia; Cardio Pulmonary Exercise Testing and the health screening tests before activity based on the American College of Sports Medicine (ACSM) guidelines, will be taken with supervision of Sports medicine physician. Pulmonary function tests (PFTs) will be done at the hospital or Medical center. Muscle functional tests (Muscular strength and endurance, Body Composition, and flexibility) will be done In partnership with Nursing staff In the Sports Science department laboratory. After completing the above steps, Patients will take part in the 6-week exercise rehab intervention, 3 days per week; Including the interval aerobic exercise and inspiratory muscle training (IMT). 24 to 48 hours after the end of the Exercise intervention, the above mentioned tests will be carried out as a post-test to assess the changes and adaptations created in the pulmonary, cardiac and muscular indicators. Interval aerobic exercise program; will be performed as walking or cycling on a treadmill or cycle ergometer. during this period; Heart rate and ECG, Arterial oxygen saturation percentage (SaO2), and blood pressure will be monitored using the Vital signs monitor and Pulse Oximeter. the intensity of the aerobic exercise program: 30 to 40% (low intensity) and 60 to 80% (high intensity) peak heart rate achieved during cardiopulmonary exercise testing. the high-intensity stage time is 2 minute and the low-intensity stage is 3 minutes. Interval exercise time for the first and second weeks, 20 minutes; Third and fourth weeks, 25 minutes; and the fifth and sixth weeks, will be 30 minutes. Inspiratory muscle training (IMT) program: 3 days per week with the 30% of maximal inspiratory pressure (MIP) resulted from plethysmography test, for 15 minutes per session using inspiratory muscle training device POWERbreathe™. duration of each training session respectively in the first and second weeks 50 minutes, 3rd and 4th weeks 55 minutes, and in the 5th and 6th weeks will be 60 minutes.

Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Internal clinic of the Shahid Faghihi Hospital
Full name of responsible person
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2

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Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Shiraz University
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
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Javad Fallahi
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Internist, Sub-specialist of Pulmonology and ICU. Assistant Professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The results of primary and secondary outcomes will be shared.
When the data will become available and for how long
two months after the publication of the results.
To whom data/document is available
academic researchers.
Under which criteria data/document could be used
Once accessed, individuals have the right to use the study protocol for rehabilitation purposes.
From where data/document is obtainable
Mr. Mohammad Amin Bahrami will be responsive through email: aminjoangamper@gmail.com
What processes are involved for a request to access data/document
After receiving the request and mentioning the reasons for data requirement, will be answered within a maximum of one month.
Comments