Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

The effect of respiratory and peripheral muscles training on pulmonary and physiological performance in COVID-19 patient

Protocol summary

Study aim
The effect of respiratory and peripheral muscles training on pulmonary and physiological performance in COVID-19 patient

Design
Clinical trial with control group, with parallel groups, randomized, on 36 patients. In order to randomize, a simple randomization method using a table of random numbers was used.

Settings and conduct
All patients who meet the inclusion criteria and have completed the consent form to participate in the project are invited to participate in the test. The tests include tests related to pulmonary function and CBC test. After the tests, the patients are randomly divided into three groups. In the first group, breathing exercises such as diaphragmatic breathing and pursed-lip breathing are performed. In the second group, breathing, muscle, balance, aerobic and stretching exercises are given. In the third group, they have no training during the intervention period. Patients do exercises for 6 weeks. Then the tests are repeated again.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Pneumonia confirmed by Pulmonologist (having signs and radiographic evidence of pneumonia); stable clinical condition regular participation in the treatment process (before participating in the research); being interested in participating in training courses. Non-entry criteria: pulmonary resection; neurological disease; mental illness; COPD disease; history of orthopedic and neurological disease that prevents exercise; uncontrolled blood pressure; cardiovascular disease; pregnancy and breastfeeding status.

Intervention groups
Respiratory muscle training group: six weeks of training, two sessions per week, 1 hour per session. Peripheral muscle training group: six weeks of training, two sessions per week, 1 hour per session. Control group: not doing any sports and training activities during the intervention period.

Main outcome variables
Pulmonary function; physiologic variables

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230305057618N1**
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
Hossein Nabavinik

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 935 355 2864

Email address
hossein.nabavinik@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-19, 1401/12/28

Expected recruitment end date
2023-07-22, 1402/04/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of respiratory and peripheral muscles training on pulmonary and physiological performance in COVID-19 patient

Public title

The effect of respiratory and peripheral muscles training on pulmonary and physiological performance in COVID-19 patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Pneumonia confirmed by Pulmonologist (having signs and radiographic evidence of pneumonia) Stable clinical condition regular participation in the treatment process (before participating in the research) Being interested in participating in training courses

Exclusion criteria:

Pulmonary resection Neurological disease Mental illness COPD disease A history of orthopedic and neurological disease that prevents exercise Uncontrolled blood pressure Cardiovascular disease Pregnancy and breastfeeding status

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on the table of random numbers, the patients included in the study will receive random numbers. By receiving codes 1, 2, 3, etc., they are placed in each of the three treatment groups. By receiving the number 1 (4, 7, 10, etc.), it enters group one. At first, he enters the pre-test stage and then begins the respiratory muscles training . By receiving code 2 (5, 8, 11, etc.), it is placed in the second group. They enter the pre-test stage. Then they participate in the peripheral muscles training . By receiving code 3 (6, 9, 12, etc.), it is placed in the third group (control). They enter the pre-test stage. They then continue to study. The treatment starts with the main therapist, but the results and interpretation are the responsibility of the people who are blind to the groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Baqiyatallah Hospital

Street address

Sheikh Bahai St., Mulla Sadra St., Vanak Square

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2023-02-27, 1401/12/08

Ethics committee reference number

IR.BMSU.BAQ.REC.1401.133

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

Respiratory volumes

Timepoint

Before and after the intervention

Method of measurement

Plethysmography system

2

Description

Maximal inspiratory mouth pressures

Timepoint

Before and after the intervention

Method of measurement

Plethysmography system

3

Description

Maximal expiratory mouth pressures

Timepoint

Before and after the intervention

Method of measurement

Plethysmography system

4

Description

Maximal Voluntary Ventilation

Timepoint

Before and after the intervention

Method of measurement

Plethysmography system

5

Description

Diffusing capacity for carbon monoxide

Timepoint

Before and after the intervention

Method of measurement

Plethysmography system

6

Description

Ratio diffusing capacity for carbon monoxide to Alveolar Volume (DLCO/VA)

Timepoint

Before and after the intervention

Method of measurement

Plethysmography system

Secondary outcomes

1

Description

Red Blood Cell Count or RBC

Timepoint

Before and after the intervention

Method of measurement

CBC blood test

2

Description

White Blood Cell Count or WBC

Timepoint

Before and after the intervention

Method of measurement

CBC blood test

3

Description

Percentage of red blood cells in a blood or Hematocrit (HCT)

Timepoint

Before and after the intervention

Method of measurement

CBC blood test

4

Description

White Blood Cell Count or WBC

Timepoint

Before and after the intervention

Method of measurement

CBC blood test

5

Description

Count measures the platelet level in blood or Plt

Timepoint

Before and after the intervention

Method of measurement

CBC blood test

Intervention groups

1

Description

Intervention group 1- Respiratory muscle training: They participate in a six-week training period. In addition to breathing training, these exercises include diaphragmatic breathing exercises, pursed lip breathing exercises, cough exercises, and stretching exercises. Exercises are done twice a week for one hour at home. Supervision of exercises is done through video and social networks.

Category

Rehabilitation

2

Description

Intervention group 2- Peripheral muscle training: They participate in a six-week training period. This course includes breathing, muscle, balance, aerobic and stretching exercises. Exercises are done twice a week for one hour at home. Exercises are done at home. Supervision of exercises is done through video and social networks.

Category

Rehabilitation

3

Description

Control group: The test group is asked not to participate in any exercise program during the research period and to continue their daily diet and to report any changes such as illness, stress, etc.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Mashhad Hospital

Full name of responsible person
Hossein Nabavinik

Street address
No. 43, Saadat 13, 23 Pyamber Azam Highway, Mashhad city

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Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Full name of responsible person
AbbasAli Imani Fooladi

Street address
Vanak Square, Mulla Sadra St., Sheikh Bahai St., Shahid Nusrati Alley., Baqiyatullah University.

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imanifouladi.a@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Vahid Sobhani

Position
Associate professor

Latest degree
Medical doctor

Other areas of specialty/work
Sport Medicine

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Vanak Square, Mulla Sadra St., Sheikh Bahai St., Baqiyatullah University, Sports Physiology Research Center

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Hossein Nabavinik

Position
Instructor

Latest degree
Ph.D.

Other areas of specialty/work
Sport Biomechanics

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Clinical trial data will be published as an article

When the data will become available and for how long

6 months after results are published, access begins

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Related scientific research

From where data/document is obtainable

Sports Physiology Research Center, Baqiyatullah University.

What processes are involved for a request to access data/document

Approved research plan documents

Comments