Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jul 2026

Comparing the effects of pulmonary rehabilitation interventions, whole body vibration and cognitive-behavioral therapy on fatigue, dyspnea, physical function and quality of life in people with post-COVID-19 syndrome. A randomized clinical controlled trial

Protocol summary

Study aim

The purpose of this study is to investigate the effects of breathing exercises, whole body vibration, and cognitive-behavioral therapy interventions on respiratory status, fatigue, physical performance, and quality of life in people with post-COVID-19 syndrome.

Design

This study will be a blinded clinical trial with a control group and two intervention groups on 51 patients with limited randomization method of block type.

Settings and conduct

Before and after the interventions, all evaluations are done by someone outside the research team in the Faculty of Rehabilitation of Iran University of Medical Sciences in order to comply with the blinding process. Then people will be randomly placed in one of the control or intervention groups, and the interventions will be conducted by a (blind) researcher.

Participants/Inclusion and exclusion criteria

People aged between 20 and 50 years who suffer from long-term fatigue and shortness of breath, after a period of infection with COVID-19 and at least 3 months have passed since they were infected. Also, there is no prohibition in carrying out the mentioned instructions.

Intervention groups

People will be randomly divided into three groups, which include the control group (pulmonary rehabilitation), the intervention group with whole body vibration training (pulmonary rehabilitation + Whole body exercise) and the intervention group with cognitive behavioral therapy (pulmonary rehabilitation + cognitive-behavioral therapy).

Main outcome variables

If the result of the present study shows the improvement of variables of fatigue, shortness of breath, functional capacity and quality of life, it is possible to use pulmonary rehabilitation, whole body vibration training or cognitive-behavioral therapy along with other interventions, in order to make the treatment more effective and as a result reduce The consequences of the complications of this disease.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231207060287N1**
Registration date: **2024-01-28, 1402/11/08**
Registration timing: **prospective**

Last update: **2024-01-28, 1402/11/08**
Update count: **0**

Registration date

2024-01-28, 1402/11/08

Registrant information

Name

Fatemeh Menatnia

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date
2025-02-19, 1403/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effects of pulmonary rehabilitation interventions, whole body vibration and cognitive-behavioral therapy on fatigue, dyspnea, physical function and quality of life in people with post-COVID-19 syndrome. A randomized clinical controlled trial

Public title
Investigating the effects of physiotherapy on the treatment of post-Covid-19 syndrome complications
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
People in the age range of 20 to 50 years People who have at least reading and writing literacy. (Having a primary degree) Patients who have been infected with Covid-19 for at least 3 months People with long-term covid diagnosis, according to C19-YRSm tool Patients who have not participated in any other intervention or training and rehabilitation program at the same time Individuals have no contraindications to exercise with a whole body vibration device (eg, vertigo, balance disorders, high blood pressure, severe osteoporosis, deep vein thrombosis, metal implants, pacemakers, epilepsy, tumors, arterial aneurysms, or arrhythmia)
Exclusion criteria:
Pregnant women Patients with previous psychological disorders or undergoing psychiatric treatment Cardiovascular, neuromuscular and other systemic diseases or other diseases affecting physical activity Any concurrent lung disease Patients who have suffered from other respiratory disease or other musculoskeletal disease during the last 12 months Hearing and vision impairment that may interfere with the implementation of procedures Heart rate at rest, more than 100 beats per minute If the patient's peripheral capillary oxygen saturation (SpO2) is less than 88% and does not resolve with rest, or if the patient has persistent symptoms such as heart palpitations, sweating, and shortness of breath, and the doctor determines that rehabilitation is inappropriate for him Other obstacles prohibiting the safety of sports Inability or unwillingness to continue cooperation in the study
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Investigator

Sample size
Target sample size: **51**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, we will use the restricted randomization method of the block balanced randomization type. In this method, the size of all the blocks is equal and we will have 6 blocks in this three-group experiment. The randomization tool is also used from random sequence generation software (Random allocation software), which in addition to simple randomization, these random sequence generation software are capable of generating random sequence by block method. For concealment, we use Concealment Allocation, which refers to the method used to perform a random sequence on the participants in the study, so that the allocated group is not known before the allocation of the individual. By using opaque, sealed, numbered sequentially envelopes, in this method, each random sequence created is recorded on a card, and the cards are inside the letter envelopes. They are placed in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of starting the registration of participants, based on the order in which eligible participants entered the study, one of the envelopes will be opened and the assigned group of that participant will be revealed. The process of random allocation will be done by someone outside the research team and before the start of the study, and since the therapist is not aware of the allocation of groups until the implementation of the intervention, the important feature of allocation concealment of RCT studies is observed in this study.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, the researcher who is in charge of treating patients is blind, and the process of dividing and placing each person in different groups will be done by someone other than the therapist.
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran University of Medical Sciences
Street address
Faculty of Rehabilitation Sciences, Iran University of

Medical Sciences, Maddkaran St., Shah Nazari St., Mader Square, Mirdamad, Tehran

City
Tehran

Province
Tehran

Postal code
۱۳۴۸۷ ۱۵۴۵۹

Approval date
2023-10-07, 1402/07/15

Ethics committee reference number
IR.IUMS.REC.1402.590

Health conditions studied

1

Description of health condition studied
Complications of post-COVID-19 syndrome including fatigue and shortness of breath

ICD-10 code
X, XIII, X

ICD-10 code description
Diseases of the respiratory system(X)، Diseases of the musculoskeletal system and connective tissue(XIII)، Factors influencing health status and contact with health services(XXI).

Primary outcomes

1

Description
Fatigue score in the Fatigue severity scale questionnaire

Timepoint
Measurements will be done once before the intervention, once immediately after the intervention and again 2 months after the last evaluation.

Method of measurement
Fatigue severity scale questionnaire

2

Description
Severity of shortness of breath in the Borg questionnaire

Timepoint
Measurements will be done once before the intervention, once immediately after the intervention and again 2 months after the last evaluation.

Method of measurement
Borg shortness of breath severity questionnaire

3

Description
Quality of life score through quality of life questionnaire

Timepoint
Measurements will be done once before the intervention, once immediately after the intervention and again 2 months after the last evaluation.

Method of measurement
The 12-Item Short Form Health Survey (SF-12)

Secondary outcomes

empty

Intervention groups

1

Description
Control group: pulmonary rehabilitation. In this study, for pulmonary rehabilitation, we will use breathing exercises, stretching exercises and resistance exercises with elastic band along with encouragement to carry out care recommendations at home, during 6 weeks and 3 sessions per week.

Category
Rehabilitation

2

Description
The first intervention group: pulmonary rehabilitation with whole body vibration. In this study, for lung rehabilitation, we will use breathing exercises, stretching exercises and resistance exercises with an elastic band along with encouragement to carry out care recommendations at home, during 6 weeks and 3 sessions per week, and in addition to exercise the total tremor. The body is made of lanaform brand, POWER FULLS model and model number LA 57665, made in Belgium. Each whole body vibration training session consists of ten sets of one minute, using the device with a frequency of 35 Hz, after each one minute of using the device, the person rests for one minute. The whole body vibration training is done in 12 sessions twice a week in the morning.

Category
Rehabilitation

3

Description
The second intervention group: pulmonary rehabilitation with cognitive-behavioral therapy. In this study, we will use breathing exercises, stretching exercises and resistance exercises with an elastic band for pulmonary rehabilitation, along with encouraging to carry out care recommendations at home, during 6 weeks and 3 sessions per week, and in addition to cognitive behavioral therapy. Stark and Beck et al.'s model will be used. The sessions will be held in 6 weeks with 8 sessions (the first week (2 sessions), the second to fifth weeks (one session per week) and the last week (2 sessions)) for a duration of 45 minutes to one hour.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram Hospital

Full name of responsible person
Sanaz shanbehzadeh

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Rasoul Akram Hospital, corner of Mansouri Street, Niayesh Street, Sattar Khan District, Tehran

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person
sanaz shanbehzadeh

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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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Fatemeh Menatnia

Position
Student

Latest degree
Master

Other areas of specialty/work
Physiotherapy

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Person responsible for updating data

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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
The individual data of the participants without mentioning their names and addresses, the protocols carried out in the study, the way of statistical analysis, statistical codes, data coding systems, consent forms, questionnaires and registered clinical reports are documents that can have sharing
When the data will become available and for how long
Since the publication of the article and the publication of the results, access to the data is possible.
To whom data/document is available
All people in scientific institutions, universities and research centers will be allowed to access the documents.
Under which criteria data/document could be used
If the documents are provided to qualified people, whose goal is to use the data for the development of scientific activities and treatment protocols.
From where data/document is obtainable
To access the documents, people can contact the researcher's email at Fatemeh.menatnia@gmail.com.
What processes are involved for a request to access data/document
After receiving the request from the qualified people and providing the identity and scientific documents, the data files will be available to the applicants within one working week.
Comments