

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Enhancing Symptom Management in Long-COVID 19 Patients: A Comparative Study of Pulmonary Rehabilitation and Progressive Muscle Relaxation Techniques

Protocol summary

Study aim

The objective of this study was to investigate the effects of pulmonary rehabilitation and additional progressive muscle relaxation techniques in patients with long-COVID 19 symptoms.

Design

We included 61 post-COVID-19 patients who came for pulmonary rehabilitation. The pulmonary rehabilitation program lasted for 21 days. In the order in which they came to admission, patients were randomly allocated into two groups: one group followed the PR program, while the other group underwent the PR program along with a PMR. The intervention group engaged in additional daily 20-minute PMR sessions.

Settings and conduct

The study was performed at a single pulmonary rehabilitation center in Timisoara, Romania. All the included patients received pulmonary rehabilitation. The intervention group received additional PMR.

Participants/Inclusion and exclusion criteria

The inclusion criteria were: previous infection with COVID-19, age over 18 years, primary symptom of dyspnea and fatigability lasting for over one month, motivation, and willingness to participate in the program. Exclusion criteria: severe heart disease, severe acute illness, other lung diseases, patient refusal, severe cognitive impairment.

Intervention groups

The intervention group engaged in additional daily 20-minute PMR sessions focusing on progressively tensing and then relaxing major muscle groups, starting from the hands and moving up through the body, while maintaining slow, deep breathing.

Main outcome variables

GAD-7 will improve, PSQI will improve

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231115060065N3**

Registration date: **2023-12-06, 1402/09/15**

Registration timing: **retrospective**

Last update: **2023-12-06, 1402/09/15**

Update count: **0**

Registration date

2023-12-06, 1402/09/15

Registrant information

Name

Alexandru Florian Crişan

Name of organization / entity

University of Medicine and Pharmacy Victor Babes
Timisoara

Country

Romania

Phone

+40 765 525 688

Email address

crisan@umft.ro

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-01, 1402/03/11

Expected recruitment end date

2023-11-01, 1402/08/10

Actual recruitment start date

2023-06-01, 1402/03/11

Actual recruitment end date

2023-06-01, 1402/03/11

Trial completion date

2023-11-01, 1402/08/10

Scientific title

Enhancing Symptom Management in Long-COVID 19 Patients: A Comparative Study of Pulmonary Rehabilitation and Progressive Muscle Relaxation Techniques

Public title

Progressive muscle relaxation techniques in patients with COVID-19 symptoms

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Previous infection with COVID-19
Age over 18 years
Primary symptom of dyspnea and fatigability lasting for over one month

Exclusion criteria:

Severe heart disease
Severe ischemic or hemorrhagic stroke
Severe cognitive impairment
Medication that could potentially affect their exercise responses

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **65**

Actual sample size reached: **61**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients were randomized to either an interventional group or a control group according to their moment of admission. The patients who were admitted to the study at the same time were assigned to different treatment groups. This method of randomization was used to ensure that the patients in the two groups were similar in terms of their time of admission, which could affect the outcome of the study.

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**

Comisia de Etică a Spitalului de Boli Infectioase si Pneumoftiziologie Victor Babes Timisoara

Street address

Gheorghe Adam nr. 13

City

Timisoara

Postal code

300310

Approval date

2023-05-30, 1402/03/09

Ethics committee reference number

4990

Health conditions studied**1****Description of health condition studied**

Post COVID-19 condition

ICD-10 code

U09.9

ICD-10 code description

Post COVID-19 condition, unspecified

Primary outcomes**1****Description**

Reduced general anxiety level

Timepoint

before intervention and 3 weeks after intervention

Method of measurement

GAD-7 questionnaire

Secondary outcomes**1****Description**

Improved sleep quality

Timepoint

before intervention and 3 weeks after intervention

Method of measurement

PSQI questionnaire

2**Description**

Improved overall health

Timepoint

before intervention and 3 weeks after intervention

Method of measurement

GHQ-12 questionnaire

Intervention groups

1

Description

Intervention group: pulmonary rehabilitation and additional progressive muscle relaxation techniques. The patients performed the pulmonary rehabilitation program for 21 days, twice a day. The pulmonary rehabilitation program included: gradual aerobic conditioning, strength training focusing on the major muscle groups, and breathing exercises with an emphasis on pursed lip breathing, double inhale breathing, and chest expansion exercises. The intervention group engaged in additional daily 20-minute PMR sessions focusing on progressively tensing and then relaxing major muscle groups, starting from the hands and moving up through the body, while maintaining slow, deep breathing. The program involved tensing the muscle group for 5 seconds and then releasing and relaxing for 20 seconds.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinical Hospital of Infectious Diseases and Pulmonology, Victor Babes Timisoara, Romania

Full name of responsible person

Crisan Alexandru Florian

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Eftimie Murgu

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Medicine and Pharmacy Victor Babes Timisoara

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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

University of Medicine and Pharmacy Victor Babes Timisoara

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

University of Medicine and Pharmacy Victor Babes Timisoara

Full name of responsible person

Crisan Alexandru Florian

Position

Lecturer

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data**Contact****Name of organization / entity**University of Medicine and Pharmacy Victor Babes
Timisoara**Full name of responsible person**

Crisan Alexandru Florian

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)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable