

# Improvement of the quality of life of people with Long COVID through a multimodal rehabilitation program

<b>Submission date</b> 28/12/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 15/03/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 17/06/2024	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Long COVID is defined as when patients who have been affected by COVID-19 have symptoms that persist over time, becoming chronic in some cases, resulting in a poor quality of life. It is not yet known how long these symptoms persist, and there is limited evidence to guide clinicians in treating people with persistent symptoms. This uncertainty adds to the concerns of patients. There is an urgent need to better understand the individual experience of long-term COVID and to help clinicians understand what is needed to support these patients in their recovery. For this reason, the aim of this study is to analyze the effectiveness of multimodal rehabilitation through therapeutic recommendations and those related to aspects that influence health (diet recommendations, sleep hygiene, physical activity, cognitive stimulation exercises, respiratory exercises, and use of community resources), in an online format, for improving the quality of life and symptoms of people with Long COVID.

### Who can participate?

People over the age of 18 years with long COVID who belong to scientific societies, associations or groups of Long COVID patients

### What does the study involve?

People who decide to enter the study must complete a data collection notebook on their quality of life, data on the COVID-19 episode and persistent symptoms, if they do physical exercise, their diet, sleep hygiene, and social support and variables that influence making this lifestyle modification. After this first evaluation, they will be randomly assigned, that is, by chance, as if a coin were tossed, to a treatment group or a control group.

The people assigned to the intervention group, in addition to continuing with the pharmacological regimen prescribed by their family doctor, will receive therapeutic recommendations related to physical exercise, diet, sleep hygiene, respiratory exercises, cognitive exercises, and use of community resources that can serve to carry out these recommendations, depending on their context and their persistent symptoms. To do this, they must connect to an online platform for 8 consecutive weeks where they will have access to the recommendations mentioned above through a PowerPoint presentation. On this platform

participants will also find content and recommendations that they can carry out in their home and other environments.

People assigned to the control group will not be provided with any recommendation other than that prescribed by their family doctor. They will be called a month and a half after starting to find out their health status.

Once the intervention is finished another evaluation will be carried out. The duration of these evaluations will be about half an hour and they will be carried out at the Arrabal health center if there is the possibility of attending in person, or online (by video call) if not.

What are the possible benefits and risks of participating?

As it is a study aimed at generating knowledge, it is likely that the participants will not obtain any benefit from their participation, although they will contribute to the advancement of knowledge and social benefit. Participants will not receive any financial compensation for their participation.

Both for the evaluation and for the intervention that is going to be developed in this study, there should be no risks or discomfort. The questionnaires that are going to be used do not involve any invasive or painful tests and are widely used in research and clinical practice. Both the evaluation and the intervention to be carried out will be directed by qualified personnel and are based on the scientific evidence available to date.

Where is the study run from?

Primary Care Research Unit Zaragoza (Spain)

When is the study starting and how long is it expected to run for?

September 2022 to June 2024

Who is funding the study?

Instituto de Salud Carlos III (Spain)

Who is the main contact?

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2. Bárbara Oliván Blázquez, [barbaraolivan@gmail.com](mailto:barbaraolivan@gmail.com)

## Contact information

### Type(s)

Scientific

### Contact name

Mrs Sandra León-Herrera

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Principal Investigator

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Public

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

PI21/01356

## Study information

**Scientific Title**

Multimodal rehabilitation to improve the quality of life and symptoms of people with Long COVID: a randomized clinical trial

**Acronym**

Cov-rehabqol

**Study objectives**

Multimodal rehabilitation through therapeutic recommendations and those related to aspects that influence health (physical activity, diet, sleep, community resources, cognitive stimulation and respiratory exercises) is an effective approach to improve the symptoms and quality of life of people with Long COVID.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 01/12/2022, Clinical Research Ethics Committee of Aragon (Avda. San Juan Bosco, 13., Zaragoza, 50009, Spain; +34 (0)976 716584 / +34 (0)976 715836; ceica@aragon.es), ref: PI22/482

**Study design**

Single-centre interventional blinded randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Internet/virtual

**Study type(s)**

Quality of life, Treatment

**Participant information sheet**

See trial outputs table

**Health condition(s) or problem(s) studied**

Long COVID

**Interventions**

Once baseline data have been collected, the participants will be randomised. An independent statistician will perform the individual randomisation using a computer-generated random number sequence (blinded sequence). The randomisation will be carried out using a list of patients. Given the nature of the interventions, participants will not be blind to their allocation. A researcher will call them to explain their assigned intervention and will request that participants do not inform other researchers of their allocation.

A researcher from outside the project will carry out randomization into two groups:

1. Intervention group: Online multimodal rehabilitation (for 8 consecutive weeks on a Moodle-type platform, PowerPoint presentations will be published on therapeutic recommendations and related to aspects that can influence health)
2. Control group: This group will not benefit from any type of intervention. They will continue with the treatment recommended and prescribed by their doctor.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

Current primary outcome measure as of 13/02/2024:

Quality of life assessed using the SF-36 Questionnaire at the beginning of the study and at the end of the intervention, that is, 3 months later.

Previous primary outcome measure:

Quality of life assessed using the SF-36 Questionnaire at the beginning of the study and at the end of the intervention, that is, approximately 2 or 3 months later

## **Secondary outcome measures**

1. Sociodemographic variables measured using a structured interview at the beginning of the study and at the end of the intervention, that is, approximately 2 or 3 months later
2. Clinical variables (time of evolution of Long COVID, number of residual symptoms and their intensity) measured using a structured interview at the beginning of the study and at the end of the intervention, that is, approximately 2 or 3 months later. The intensity of each symptom will be measured using a Visual Analog Scale
3. Self-efficacy measured using Sherer's General Self-Efficacy Scale (SGSES) at the beginning of the study and at the end of the intervention, that is, approximately 2 or 3 months later
4. Activation of the patient measured using Patient Activation Measure (PAM) at the beginning of the study and at the end of the intervention, that is, approximately 2 or 3 months later
5. Health literacy measured using the European Health Literacy Survey Questionnaire- short version (HLS-EU-Q16) at the beginning of the study and at the end of the intervention, that is, approximately 2 or 3 months later
6. Physical activity measured using the Physical Activity Questionnaire (IPAQ) at the beginning of the study and at the end of the intervention, that is, approximately 2 or 3 months later
7. Cognitive state measured using the Montreal Cognitive Assessment (MOCA) at the beginning of the study and at the end of the intervention, that is, approximately 2 or 3 months later
8. Emotional state measured using the Hospital Anxiety and Depression Scale (HADS) at the beginning of the study and at the end of the intervention, that is, approximately 2 or 3 months later
9. Sleep problems measured using the Insomnia Severity Index (ISI) at the beginning of the study and at the end of the intervention, that is, approximately 2 or 3 months later
10. Dyspnea and fatigue measured using the 30-second Sit and Stand up Test at the beginning of the study and at the end of the intervention, that is, approximately 2 or 3 months later

## **Overall study start date**

09/09/2022

## **Completion date**

30/06/2024

# Eligibility

## Key inclusion criteria

1. People with Long COVID
2. Over the age of 18 years
3. People cared for by Primary Care and belonged to scientific societies, associations or groups of Long COVID patients in Spain

## Participant type(s)

Patient

## Age group

Adult

## Lower age limit

18 Years

## Sex

Both

## Target number of participants

116 participants in total (58 in control group; 58 in intervention group)

## Total final enrolment

134

## Key exclusion criteria

1. Presence of a serious uncontrolled medical illness that may interfere with compliance with the recommendations
2. Significant suicide risk
3. Pregnancy or lactation
4. Participation in another clinical trial in the last 6 months
5. Being receiving structured physiotherapeutic or psychotherapeutic treatment by a mental health professional
6. Presence of any medical, psychological or social problems that could seriously interfere with the patient's participation in the study

## Date of first enrolment

01/12/2022

## Date of final enrolment

30/01/2023

# Locations

## Countries of recruitment

Spain

**Study participating centre****Unidad de investigación en Atención Primaria de Aragón**

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## Sponsor information

**Organisation**

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**Sponsor type**

Research organisation

**Website**

<https://www.isciii.es/Paginas/Inicio.aspx>

**ROR**

<https://ror.org/00ca2c886>

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**Sponsor type**

Research organisation

**Website**

<https://www.iisaragon.es/>

ROR

<https://ror.org/03njin4610>

## Funder(s)

### Funder type

Research organisation

### Funder Name

Instituto de Salud Carlos III

### Alternative Name(s)

SaludISCI, Instituto de Salud Carlos III, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, ISCI

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

Spain

## Results and Publications

### Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal

### Intention to publish date

30/06/2025

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Sandra León-Herrera ([tsandraocupacional@gmail.com](mailto:tsandraocupacional@gmail.com)).

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version 3	28/11/2022	29/12/2022	No	Yes
<a href="#">Protocol article</a>		07/09/2023	25/09/2023	Yes	No