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

Submission date
28/12/2022

Recruitment status
No longer recruiting

Registration date
15/03/2023

Overall study status
Completed

Last Edited
28/01/2026

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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?
1. Sandra León Herrera, tsandraocupacional@gmail.com
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Quality of life, Treatment

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(s)

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
110 years

Sex
All

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
Instituto de Salud Carlos III

ROR
https://ror.org/00ca2c886

Organisation
Instituto de Investigación Sanitaria Aragón

ROR
https://ror.org/03njn4610

Funder(s)

Funder type
Research organisation

Funder Name
Instituto de Salud Carlos III

Alternative Name(s)
SaludISCIII, InstitutodeSaludCarlosIII, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, La misión del Instituto de Salud Carlos III (ISCIII), ISCIII

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

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).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/09/2024	28/01/2026	Yes	No
Protocol article		07/09/2023	25/09/2023	Yes	No
Participant information sheet	version 3	28/11/2022	29/12/2022	No	Yes