

Analysis of the symptoms and quality of life of people with a diagnosis of long COVID-19, and the effectiveness of an intervention in primary care using ICTs

Submission date 25/01/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 10/02/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/06/2024	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Current plain English summary as of 11/03/2022:

Background and study aims

For some people, coronavirus (COVID-19) can cause symptoms that last weeks or months after the infection has gone. This is sometimes called post-COVID-19 syndrome or "long COVID". People with long COVID are suffering various symptoms that reduce their quality of life. After a qualitative study to analyze what these symptoms are and how they affect them in their daily lives, different strategies were proposed by these patients participating in this qualitative study to improve their quality of life.

For this reason, the objective of this study is to analyze the effectiveness of a multimodal intervention using an APP aimed at minimizing the persistent symptoms of long COVID.

Who can participate?

Adults who were infected with COVID-19 and have persistent symptomatology

What does the study involve?

Two groups will be considered in parallel, and the following interventions will be used:

1. Usual treatment by the general practitioner (treatment as usual).
2. Multimodal program through an APP and supported by three weekly 30-minute face-to-face sessions. The APP will contain the the following recommendations and exercices: cognitive exercises, physical activity, respiratory exercises, adherence to the Mediterranean diet pattern, sleep hygiene, social activation and utilization of community resources. During the three face-to-face sessions, a motivational interviewing and supervision of the recommendations will be performed.

The primary outcome will be the quality of life. Data will be collected before the intervention, with 3-months, 6-month, and 12-month follow-ups.

What are the possible benefits and risks of participating?

The possible benefits are the improvement of the quality of life of people diagnosed with long

COVID.

There are no risks expected.

Where is the study run from?

Aragón (Spain)

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

January 2022 to December 2024

Who is funding the study?

Carlos III Health Institute (Spain)

Who is the main contact?

Dr Bárbara Oliván Blázquez, bolivan@unizar.es

Previous plain English summary:

Background and study aims

For some people, coronavirus (COVID-19) can cause symptoms that last weeks or months after the infection has gone. This is sometimes called post-COVID-19 syndrome or "long COVID".

People with long COVID are suffering various symptoms that reduce their quality of life. After a qualitative study to analyze what these symptoms are and how they affect them in their daily lives, different strategies were proposed by these patients participating in this qualitative study to improve their quality of life.

For this reason, the objective of this study is to analyze the effectiveness of a multimodal intervention aimed at minimizing the persistent symptoms of long COVID.

Who can participate?

Adults who were infected with COVID-19 and have persistent symptomatology

What does the study involve?

Two groups will be considered in parallel, and the following interventions will be used:

1. Usual treatment by the general practitioner (treatment as usual).
2. Multimodal program of four weekly 30-minute individual sessions, intended to improve the following aspects: cognitive exercises+daily physical activity+respiratory exercises+adherence to the Mediterranean diet pattern+sleep hygiene.

The primary outcome will be the quality of life. Data will be collected before the intervention, with 3-months, 6-month, and 12-month follow-ups.

What are the possible benefits and risks of participating?

The possible benefits are the improvement of the quality of life of people diagnosed with long COVID.

No risks.

Where is the study run from?

Aragón (Spain)

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

January 2022 to December 2024

Who is funding the study?

Carlos III Health Institute (Spain)

Who is the main contact?

Dr Bárbara Oliván Blázquez, bolivan@unizar.es

Study website

<http://www.gaiap.es>

Contact information

Type(s)

Principal Investigator

Contact name

Dr Bárbara Oliván-Blázquez

ORCID ID

<http://orcid.org/0000-0001-6565-9699>

Contact details

Violante de Hungría 23.

Zaragoza

Spain

50430

+34 876554547

bolivan@unizar.es

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

PI21-01356

Study information

Scientific Title

Effectiveness and cost-effectiveness of a multimodal programme as coadjuvant treatment in people with a diagnosis of long COVID-19 from primary health care: a randomised clinical trial

Acronym

COV-RACAP

Study objectives

Current study hypothesis as of 11/03/2022:

The recommendation of a modification of lifestyles and certain physical, respiratory and cognitive exercises from Primary Health Care using a APP is effective in improving the quality of life of people with persistent symptoms of COVID-19, and in reducing pharmaceutical prescription and use of health services.

Previous study hypothesis:

The recommendation of a modification of lifestyles and certain physical, respiratory and cognitive exercises from Primary Health Care is effective in improving the quality of life of people with persistent symptoms of COVID-19, and in reducing pharmaceutical prescription and use of health services.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 12/01/2022, Clinical Research Ethics Committee of Aragon (Avda. San Juan Bosco 13, Zaragoza, 50009, Spain; +34 976 715836; ceica@aragon.es), ref: P21-454

Study design

Multicenter pragmatic randomized controlled trial in two parallel groups

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

See additional files (in Spanish)

Health condition(s) or problem(s) studied

Long COVID-19

Interventions

Current intervention as of 11/03/2022:

Patients allocated in the control group will follow the usual treatment provided by their GP (treatment as usual (TAU)).

Patients allocated in the intervention group will follow the TAU and a multimodal programme. This programme will consist of three sessions (one per week, and lasting 30 min each) led by an experienced psychologist and physiotherapist. The recommendations will be provided through an APP (reCOVerry) sessions and the contents will be the following: a) Respiratory exercises to improve the dyspnoea; b) Sleep hygiene habits to improve the quality of sleep; c) Physical activity (type of physical exercise may be practiced, the intensity, how and when to do them).; d)

Exercises of Cognitive stimulation to improve the cognitive deficits and e) Adherence to the Mediterranean diet to improve the intake of omega-3, B, and D vitamins; f) social activation and use of community resources.

As the symptomatology is very varied, during the face-to-face sessions, the recommendations will be personalized, especially directing the intervention to the symptomatology presented by the participant. Health assets will be sought that help in carrying out these exercises and recommendations in the area where the participant lives. These sessions are aimed at empowering the patient so that they carry out the recommendations autonomously. The patients will be telephoned to monitoring the adherence to the recommendations, and to find out about possible difficulties in the compliance one month after finishing the 3 sessions.

Once baseline data are collected, the participants will be randomised. An independent statistician will perform the individual randomisation using a computer-generated random number sequence. The randomisation will be carried out using a list of patients from Zaragoza health care centers. Given the nature of the interventions, participants will not be blinded to their allocation.

A research assistant will call them to explain their assigned intervention, where they should go and when. The assistant researcher will request that participants not inform other researchers (mainly the person who will perform the assessments) of their allocation.

Previous intervention:

Patients allocated in the control group will follow the usual treatment provided by their GP (treatment as usual (TAU)).

Patients allocated in the intervention group will follow the TAU and a multimodal programme. This programme will consist of four sessions (one per week, and lasting 30 min each) led by an experienced psychologist and physiotherapist. The sessions will consist of the following content: a) Respiratory exercises to improve the dyspnoea; b) Sleep hygiene habits to improve the quality of sleep; c) Physical activity based on personalised recommendations about what physical exercise may be practiced, how and when to do so.; d) Cognitive stimulation to improve the cognitive deficits and e) Adherence to the Mediterranean diet to improve the intake of omega-3, B, and D vitamins.

As the symptomatology is very varied, it will be personalized, especially directing the intervention to the symptomatology presented by the participant. Health assets will be sought that help in carrying out these exercises and recommendations in the area where the participant lives. These sessions are aimed at empowering the patient so that they carry out the recommendations autonomously. They will be telephoned to activate the patients and to find out about possible difficulties, adherence, and compliance one month after finishing the 4 sessions.

Once baseline data are collected, the participants will be randomised. An independent statistician will perform the individual randomisation using a computer-generated random number sequence. The randomisation will be carried out using a list of patients from Zaragoza health care centers. Given the nature of the interventions, participants will not be blinded to their allocation.

A research assistant will call them to explain their assigned intervention, where they should go and when. The assistant researcher will request that participants not inform other researchers (mainly the person who will perform the assessments) of their allocation.

Intervention Type

Behavioural

Primary outcome measure

Quality of life using SF-36 at baseline, 3 months, 6 months and 12 months.

Secondary outcome measures

Current secondary outcome measures as of 14/03/2022:

1. Cognitive status using Evaluación Cognitiva de Montreal (MoCA), Memory Impairment Screen (MIS), semantic fluency test and digits and symbols test. At baseline, 3 months, 6 months and 12 months.
2. Respiratory status will be evaluated using 6 minutes walking test, 30-second chair stand test, and Borg scale at baseline, 3 months, 6 months and 12 months.
3. Physical activity using IPAQ-SF at baseline, 3 months, 6 months and 12 months.
4. Adherence to mediterranean diet using MEDAS at baseline, 3 months, 6 months and 12 months.
5. Quality and patterns of sleep using Insomnia Severity Index at baseline, 3 months, 6 months and 12 months.
6. Depression and anxiety using HADS at baseline, 3 months, 6 months and 12 months.
7. Social support using MOS at baseline, 3 months, 6 months and 12 months.
8. Self-efficacy using self-efficacy scale at baseline, 3 months, 6 months and 12 months.
9. Patient activation in their own health using the PAM at baseline, 3 months, 6 months and 12 months.
10. Use of health and social services measured using the Client Service Receipt Inventory at baseline, 3 months, 6 months and 12 months.

Previous secondary outcome measures as of 11/03/2022:

1. Cognitive status using Evaluación Cognitiva de Montreal (MoCA), Memory Impairment Screen (MIS), semantic fluency test and digits and symbols test. At baseline, 3 months, 6 months and 12 months.
2. Respiratory status will be evaluated using 6 minutes walking test, 30-second chair stand test, and Borg scale at baseline, 3 months, 6 months and 12 months.
3. Physical activity using IPAQ-SF at baseline, 3 months, 6 months and 12 months.
4. Adherence to mediterranean diet using MEDAS at baseline, 3 months, 6 months and 12 months.
5. Quality and patterns of sleep using Insomnia Severity Index at baseline, 3 months, 6 months and 12 months.
6. Depression and anxiety using HADS at baseline, 3 months, 6 months and 12 months.
7. Self-efficacy using self-efficacy scale at baseline, 3 months, 6 months and 12 months.
8. Patient activation in their own health using the PAM at baseline, 3 months, 6 months and 12 months.
9. Use of health and social services measured using the Client Service Receipt Inventory at baseline, 3 months, 6 months and 12 months.

Previous secondary outcome measures:

1. Cognitive status using Mini-Mental State Examination (MEC-35), Memory Impairment Screen (MIS), semantic fluency test and digits and symbols test. At baseline, 3 months, 6 months and 12 months.
2. Respiratory status will be evaluated using 6 minutes walking test and 30-second chair stand test, at baseline, 3 months, 6 months and 12 months.
3. Physical activity using IPAQ-SF at baseline, 3 months, 6 months and 12 months.

4. Adherence to mediterranean diet using MEDAS at baseline, 3 months, 6 months and 12 months.
5. Quality and patterns of sleep using Insomnia Severity Index at baseline, 3 months, 6 months and 12 months.
6. Depression and anxiety using HADS at baseline, 3 months, 6 months and 12 months.
7. Self-efficacy using self-efficacy scale at baseline, 3 months, 6 months and 12 months.
8. Patient activation in their own health using the PAM at baseline, 3 months, 6 months and 12 months.
9. Use of health and social services measured using the Client Service Receipt Inventory at baseline, 3 months, 6 months and 12 months.

Overall study start date

12/01/2022

Completion date

31/12/2024

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 11/03/2022:

1. Individuals over the age of 18 years
2. Suffering from long COVID-19
3. From Primary Health Centers of Aragón (Spain)
4. Understand written and spoken Spanish
5. Have provided their informed consent
6. Who are not undergoing training or rehabilitation through respiratory physiotherapy, physical activity, or cognitive stimulation

Previous participant inclusion criteria:

1. Individuals over the age of 18 years
2. Suffering from long COVID-19
3. From Primary Health Centers of Aragón (Spain)
4. Understand written and spoken Spanish
5. Have provided their informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

78

Total final enrolment

100

Key exclusion criteria

1. Presence of serious uncontrolled medical illness, which may interfere with compliance with the activities and recommendations
2. Risk of suicide
3. Pregnancy or lactation
4. Patients who have participated in another clinical trial over the past 6 months
5. Are currently receiving structured psychotherapeutic treatment by a mental health professional over the past 6 months
6. The presence of any medical, psychological or social problem that could seriously interfere with the patient's participation in the study

Date of first enrolment

01/03/2022

Date of final enrolment

01/06/2022

Locations**Countries of recruitment**

Spain

Study participating centre**Arrabal Primary Health Center**

Andador Aragues Puerto, 26

Zaragoza

Spain

50015

Study participating centre**Parque Goya Primary Health Center**

Eugenio Lucas 31

Zaragoza

Spain

50018

Sponsor information**Organisation**

Instituto de Salud Carlos III

Sponsor details

C/ Sinesio Delgado, 4
Madrid
Spain
28029
+34 91 822 21 00
oficina.informacion@isciii.es

Sponsor type

Government

Website

<http://www.isciii.es/>

ROR

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

Funder(s)**Funder type**

Government

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, ISCIII

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.
Also planned dissemination in long covid patients associations and general population using social networks and mass media.

Intention to publish date

30/06/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request (Bárbara Oliván, barbaraolivan@gmail.com)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 4.0	11/03/2022	11/03/2022	No	Yes
Protocol article		27/12/2022	02/03/2023	Yes	No
Results article	results	17/05/2023	17/05/2023	Yes	No