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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

Registration date
10/02/2022

Overall study status
Completed

Last Edited
17/06/2024

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Contact information

Type(s)
Principal investigator

Contact name
Dr Bárbara Oliván-Blázquez

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Contact details
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Zaragoza
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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 (reCOVery) 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) Exercices 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 recomendations, 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(s)
Quality of life using SF-36 at baseline, 3 months, 6 moths and 12 months.

Key secondary outcome(s))
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 moths 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 moths 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 moths 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 moths 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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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

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, 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 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?
Results article	results	17/05/2023	17/05/2023	Yes	No
Protocol article		27/12/2022	02/03/2023	Yes	No
Participant information sheet	version 4.0	11/03/2022	11/03/2022	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes