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SPACO+: a mixed methods protocol to assessing the effectiveness of an educative intervention in patients with Long Covid

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Abstract

Background The management of many chronic diseases requires a multidisciplinary and holistic approach. Long Covid is a recent, poorly understood disease with several symptoms. Most recommendations suggest a multidisciplinary approach. While there are a few programs aimed to the management of Long Covid, to our knowledge very few were assessed. The SPACO + study therefore aims to evaluate an innovative program which combines the methods used in therapeutic education and in personalized multifactorial intervention for management of Long Covid. Here, we present the protocol of our study, which aims to evaluate the effectiveness of an educational intervention in terms of changes in quality of life at 6 months in comparison with standard clinical practice in patients suffering from Long Covid.

Methods To achieve our objectives, we have planned to carry out a prospective, multicentre, two-arm randomized controlled trial with a convergent parallel mixed methods design. Two countries are involved in this study: France and Cameroon. The study concerns patients aged 18 and over, who have been infected with Covid-19. They must also be diagnosed as having Long Covid in accordance with the WHO definition. The number of subjects required for the study is 400 individuals. Participants will be randomly assigned to either the intervention or control group using a dynamic randomization process to ensure balanced group characteristics. The SPACO + program is an educative intervention with individual follow-up by a nurse dedicated to the program. The SPACO + program offers five workshops, two of which are compulsories. Patients take part in the other workshops according to their needs. The program includes an 8 – 10 weeks intervention period. Each session lasts two hours and includes breaks (pacing). The main outcome measure will be quality of life, evaluated through the SF-36. Primary and secondary

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outcomes, with few exceptions, are assessed before the intervention ("T0"), at 8 weeks ("T1" corresponding to the end of SPACO + program's session period) and then 3 months later ("T2").

Discussion If the SPACO + program is effective and accepted by professionals and patients, it could be disseminated in other regions to assess its transferability. The medico-economic evaluation will also make it possible to assess the benefits provided.

Trial registration This trial is registered under the number NCT05787366 (March 24, 2023).

Protocol Version N°3.0 (May 31, 2024)

Keywords Long Covid, Health pathway, Quality of life, Educative intervention, Randomized controlled trial, Mixed methods

Background

Although Covid-19 is no longer front-page news, it continues to pose a major public health problem. The emergence of Long Covid symptoms was observed as early as spring 2020. Physicians were quick to recognise the different clinical conditions, leading to more or less severe forms.

The high incidence of Long Covid has ensured that this pathology has become an epidemic within the Covid-19 pandemic [1]. In a recent review of the literature, Chou et al. [2] discussed the different definitions of Long Covid and concluded that it would be judicious to find a consensual definition. However, one of the most widely accepted definitions is that of the WHO defining Long Covid as the continuation or development of new symptoms 3 months after the initial SARS-CoV-2 infection; with these symptoms lasting for at least 2 months with no other explanation [3].

Long Covid is a worldwide epidemy [4, 5]. According to WHO criteria, 10–20% of patients infected with Covid-19 develop Long Covid syndrome [6, 7]. The period between 4 and 12 weeks is then classified as subacute or ongoing symptomatic infection [8, 9].

Long Covid has multiple symptoms and therefore, the management of this type of pathology requires a multidisciplinary and holistic approach [10, 11]. Long Covid is an important public health issue that has been highlighted as a clinical, policy, and research priority worldwide [12]. Different strategies for managing this condition are suggested [13, 14]. However, there seems to be a consensus on the multidisciplinary approach, which is the most frequently described in the literature [15–18].

Therapeutic education is one of the strategies that provides a multi-factorial response for the management of a chronic condition. It allows for the combination of drug and non-drug therapies. In a recent review, it was shown that for pathologies similar to Long Covid such as fibromyalgia (FM), health education may be beneficial, particularly for mitigating symptom severity [19].

Although there is a consensus on the multidisciplinary approach and therapeutic education of patients, there still a debate on some aspects of the care provided and the content of the programmes provided. Patients suffering from Long Covid are likely to experience symptoms such as fatigue, shortness of breath, pain, cough, and cognitive impairment, anxiety, and sleep disorders [20].

In France, several programs focusing on management of Long Covid are implemented. One of the most described programs is Occitania [south-west France] region which brings together 24 hospital centres [21].

While there are a few programs aimed to the management of Long Covid, to our knowledge very few were assessed. The SPACO + study therefore aims to evaluate an innovative program which combines the methods used in therapeutic education and in personalized multifactorial intervention for management of Long Covid.

Research hypothesis

Long Covid symptoms differ from one patient to another. In the literature, more than 100 symptoms have been reported [22]. Patients with Long Covid have increased needs for management for their overall health (physical, psychological, and social). Long Covid negatively impact quality of life.

Therefore, we hypothesized that the implementation of a therapeutic educative program including workshops based on multiple component items such as the management of pain, fatigue, psychological aspects, and cognitive disorders improves the quality of life of patients suffering from Long Covid. Secondary, that in identifying barriers and levers to adherence to our educative program and evaluating her cost/utility ratio through a medico-economic analysis would assess the efficiency of our program.

Objectives

Primary objective

The primary objective of the present study is to evaluate the effectiveness of an educative intervention in terms of

changes in quality of life at 6 months in comparison with standard clinical practice in patients suffering from Long Covid.

Secondary objective(s)

The secondary objectives of the research are as follows:

- Evaluate the program's impact on: Frailty, Comorbidities, and various symptoms such as dyspnea, hyperventilation, fatigue, cognitive decline, pain and neuropathic pain, musculoskeletal disorders, post-exertional malaise, anxiety and depression.
- Assess barriers and levers to participation and adherence to educative program, as well as patient and professional satisfaction (qualitative analysis).
- Evaluate the cost/utility ratio of educative program through a medico-economic analysis.

Methods

This study protocol is developed based on the SPIRIT (Standard Protocol Items: Recommendation for Interventional Trials) guidelines [23] (supplementary data).

Study design and setting

This is a prospective, multicenter, two-arm randomized controlled trial with a convergent parallel mixed methods design [24]. The multicenter, observational study involves a comparison of two management strategies for people suffering from Long Covid. Thus, we assess an "intervention" versus "control" group that will compare the effectiveness of an educative intervention in improving the quality of life at 6 months post-intervention in comparison with standard of care (Fig. 1).

Two countries are involved in this study: France and Cameroon. The design will use a parallel (QUANT + QUAL) mixed-methods study because, in the first phase, quantitative data (Fatigue [25], Quality of life [26], Cognitive performance [27], Pain [28]…) assessed by questionnaires) and qualitative data (interviews on the reasons for continuing or dropping out of the SPACO + program) will be collected at the same time and combined when the data are analyzed (convergent).

In other words, the quantitative data will provide information on changes in quality of life and the efficacy of the program through a cost-utility analysis, while the qualitative data will assess the barriers and levers to participation and adherence to the program, as well as the satisfaction of patients and professionals via semi-directive interviews conducted by sociologists.

The qualitative study will consist of individual semi-directive interviews and observation during workshops. The interviews, in the form of discussions, will focus on themes established in advance using an interview guide. The themes examined encompass participants' experiences with Long Covid, their assessments of the program, their motivations for participation, and the factors that facilitated or hindered their engagement. The qualitative method will be based on a protocol developed by Riquier et al. [29]. The Fig. 2 presents the scheme of qualitative study.

Longitudinal follow-up in parallel with the collection of quantitative data (questionnaires).

- Interview at T0: to explore the reasons for entering the program,
- Interview at T1: to explore the reasons for dropping out or continuing with the program (intra-program factors, external factors, etc.),
- Interview at T2: interest/satisfaction with the program, areas for improvement
- Observation of workshops.

Target population

The target population of the study includes participants and professionals. We will rely on local structures and institutions interested in the study and ready to invite patients to take part to the study:

- In France, patients will be recruited from the Infectiology and exercise Physiology departments of Saint-Etienne University Hospital, as well as via the Regional Union of Health Professionals (URPS AURA) and the Coordination Support System (DAC Loire). During a follow-up consultation, the investigator will propose the study to the patient, and give him or her the information and consent leaflet.
- In Cameroon, two hospital centres: Douala Laquintinie Hospital and Yaoundé Central Hospital will involve. Inclusion criteria and follow-up of participants will be the same as described concerning France. Whatever the centre of investigation, the patient will have one week to agree to participate in the study.

A cohort letter will also be distributed to the media (radio-TV-local newspapers-social networks), as well as to departments of University Hospital and health facilities (pharmacies and private nursing practices). Those interested in participating will fill in a "reply coupon". An investigator will contact the patient to explain the study, check the inclusion criteria and make an appointment with the clinical research assistant of the SPACO + study.

When a patient is interested in participating in the study, and meet the inclusion criteria, he /she will receive the information leaflet/consent form.

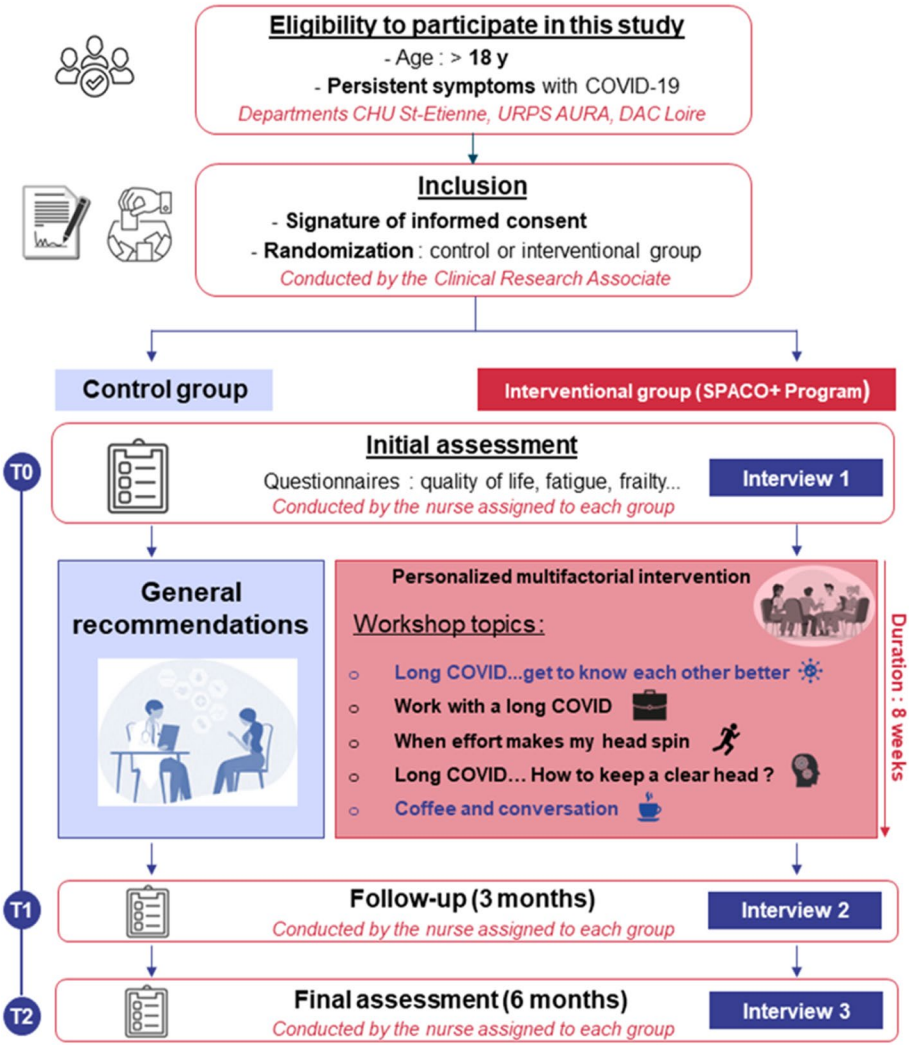

Fig. 1 Schematic overview of SPACO + Study

Eligibility criteria

Inclusion criteria

The study concerns patients aged 18 and over, who have been infected with Covid-19 (based on a positive PCR test). They must also be diagnosed as having Long Covid in accordance with the WHO definition (persistence of Covid-19 symptoms more than 12 weeks after the primo infection) [3] and who have agreed to take part to the study. Persistent signs of Covid19 include fatigue, which can be severe, neurological disorders (cognitive, sensory, headache), cardio-thoracic disorders (chest pain and tightness, tachycardia, dyspnea, cough), smell and taste disorders, Pains, digestive and skin disorders.

Furthermore, participants must not (i) have a diagnosed cardiovascular, pulmonary or any other physical condition that can prevent them from being physically active; (ii) participate simultaneously in another Long-Covid care pathway; (iii) have severe cognitive impairment.

Before inclusion, to ensure that participants who may have exhibited some of the similar symptoms associated with Long COVID prior to contracting COVID-19 are excluded from the study, a physician realizes a differential diagnosis to eliminate all other conditions that could be confused with Long Covid. Thus, the physician delivers a certificate (Supplementary data 1).

Allocation

Patients who agree to take part and who meet the inclusion criteria co-sign the consent form with the investigator and will be randomly assigned to either the intervention or control group using a dynamic randomization process to ensure balanced group characteristics.

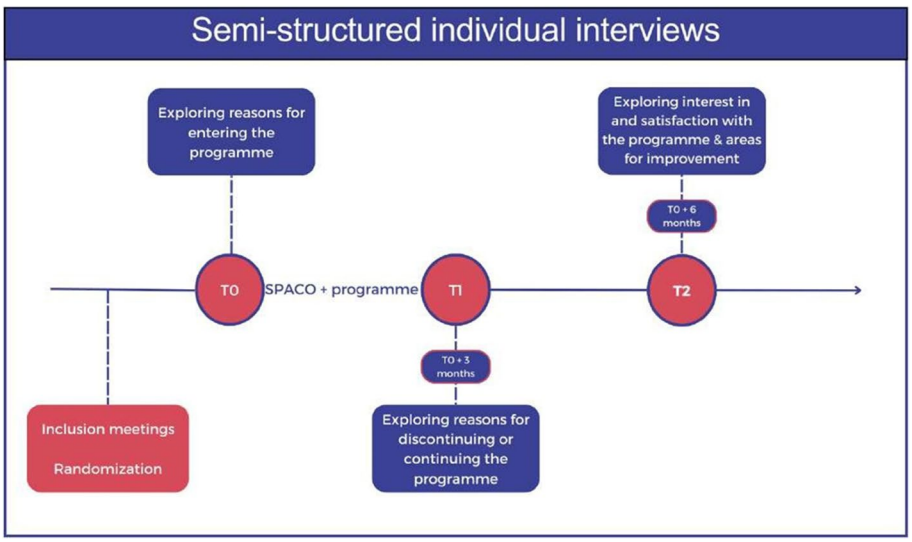

Fig. 2 Overall design of the qualitative study

Randomisation by minimisation is a dynamic randomisation that considers the characteristics of individuals as they are included. It will be carried out in each country separately. In practice, the computer algorithm calculates the group allocation in real time, thus guaranteeing the best possible balance between the groups. The steps are as follows:

- 1st: patients' random allocation
- For each additional subject: allocation of the group in such a way as to minimise the imbalance between the groups, considering the values of the subject's stratification criteria (sex, age, precariousness) and subjects already randomised. This process is repeated for each new subject included. To minimise contamination bias, each participating nurse will be assigned to a specific group.

Interventional Group: coordinated by a nurse. Patients included in the intervention group will participate to workshops for a period of 8 to 10 weeks.

Control Group: coordinated by another nurse. Patients included in the control group receiving conventional treatment, i.e. referral to one or more specialists depending on symptoms.

Intervention

Intervention group

The SPACO + program is an educative intervention based on French [30] and WHO recommendations [3] for the management of Long Covid. The program was co-constructed by a group of researchers, practitioners and a Long Covid patient association. This co-construction made it possible to optimize the content and the acceptability of the workshops.

The SPACO + program offers five workshops (see Table 1), two of which are compulsories. Patients take part in the other workshops according to their needs. Workshops are coordinated by a nurse dedicated to each group.

The various workshops are as follows: "*Long Covid… get to know each other better*", "*Work with a long Covid*"; "*When effort makes my head spin*"; "*Long Covid… How to keep a clear head*"; "*Coffee and conversation*" (experiences exchanges between patients).

The program includes an 8- 10 weeks intervention period with group sessions supervised by a nurse. However, a qualified adapted physical activity professional or a doctor can co-supervise the workshop with the nurse if necessary. Each session lasts two hours and includes breaks (pacing). The animation tools and technics are adapted according to the theme of the session. The sessions bring together 6 to 8 participants. The content of the intervention is defined according to the results of the initial assessment, in line with the patient's needs and their nature. The pace and methods of follow-up and support for this intervention will be defined on a case-by-case basis.

For patients needing several actions at once, a strategy based on the educational approach will enable priorities and the order of interventions to be defined with the patient. The aim is to strike the right balance between enough interventions without being too ambitious, so as not to set the patient up for failure.

Table 1 Overview of the SPACO + program workshops (details of the content in supplementary data)

Short title	Content of Workshops	Primary objectives	Secondary objectives	Supervisor	
W1: Long Covid…. get to know each other better	Get to know each other better between patients and understanding the disease	Bring out everyone's perceptions of everyday life with a long Covid + questions	Getting to know each other, creating a friendly atmosphere	Nurse + Physician	Mandatory
W2: Working with a long covid	Social and professional impact	Identify the main difficulties encountered in the course of professional activity	- Identify the different people to contact and their role (Occupational physician, consultant physician, treating physician, etc.) - The different options for maintaining employment or returning to work	Nurse + occupational health physician	
W3: When effort makes my head spin	Fatigue, Physical Activity and Post-Exertional Malaise	Discussing the difficulties associated with fatigue and post-exertion malaise: - Identifying "triggering" factors - Identifying "soothing" factors Drawing up a joint summary to be sent to patients	Knowledge update Presentation of the various recommendations and resources	Nurse + APA	
W4: cognitive and sensory disorders	"Long Covid and Cognitive Impairment"	Description and identification of symptoms related to cognitive and sensory disorders	theoretical contribution on the subject exchange and sharing of strategies to combat the various symptoms	Nurse + Neuropsychology physician	
W5: Coffee and conversation	SPACO + course assessment	Presentation of various resources + final summary Evaluation of the workshops and/or the course Time for socialising + satisfaction Questionnaires	enable patients to project themselves with new resources to improve their daily lives	Nurse	Mandatory

W1 Workshop 1, *W2* Workshop 2, *W3* Workshop 3, *W4* Workshop 4, *W5* Workshop 5

Control group

Participants in the control group will not receive any intervention. They will receive a summary of the SPACO + program workshops at the end of the study.

To encourage patients of this group, the inclusion visit explains to them the benefits of the study, the possibility of seeing a specialist medical doctor if they really need to, and the documents they will receive at the end of the study.

Outcomes and measures

Main outcome measure

The main variable will be quality of life, evaluated through the SF-36 [28]. This questionnaire measures eight dimensions of health: physical function, physical role, aches and pains, general health, vitality, social function, emotional role, and mental health; it also includes a declared health evolution item. The eight dimensions define two main components of health: a physical summary component and a mental summary component. The French validated version of the questionnaire will be used.

Secondary outcomes

Primary and secondary outcomes, with few exceptions, are assessed before the intervention ("T0"), at 8 weeks ("T1" corresponding to the end of SPACO+ program's session period) and then 3 months later ("T2") (see Table 2 for data collection and measurements of variables).

Participant timeline

Follow-up will be carried out by state-registered nurses following patients, corresponding to the group (intervention or control). The information collected during follow-up will be identical to that collected during the first evaluation. Participants will be contacted by telephone at 3 and 6 months after inclusion.

Data collection methods

Quantitative data collection

Quantitative data will be collected at different times during the study: at inclusion at T0, 3 months (T1) and 6 months (T2) afterwards.

Table 2 Data collection and measurements of variables

Inclusion		**T0:**		**T1: 3-month visit**	**T2: 6-month visit**
Centre of investigation	Quantitative data		Control group Or Intervention Group		
Inclusion criteria	Physical Test - Walking speed over 4 meters(m/s) [31] - Handgrip (kg)	x		x	x
Exclusion criteria	Health statuts	x			
Randomisation	- SF-36 [26]	x			
Socio-demographics Epices scale [32], Age, Sex	- FRIED [33]				
History of COVID-19	- Charlson [34]	x		x	x
-	- mMRC [35]	x		x	x
-	- Nijmegen [36]	x		x	x
-	- Chadler [25]	x		x	x
-	- MoCA [27]	x		x	x
-	- VAS [28]	x		x	x
-	- DN4 [37]	x		x	x
-	- Nordique [38]	x		x	x
	Medico-economics assessments	x			x
	-Healthcare expenditure	x		x	x
-	- EQ-5D-5L [39]	x			x
-	- Mini-Zarit [40]	x			x
	Qualitative data :	x		x	x
-	- Exploration of the reasons for entering the program	x			
-	- Exploration of the reasons for dropping out or remaining in the program			x	
-	- Exploration of interest in and satisfaction with the program and areas for improvement				x

Inclusions will be carried out at the different investigation sites (Saint-Etienne University Hospital in France, Central Hospital in Yaoundé, Cameroon, and Laquintinie Hospital in Douala, Cameroon). Firstly, the patient will fill in a questionnaire on a tablet. They can ask a clinical research associate for help if necessary. Then, the T0 evaluation will be carried out by the nurse, who will record the data in specific software designed for the purposes of the study. The data at T1 and T2 will also be collected by the nurse.

Qualitative data collection

The qualitative data will be collected by experienced sociologist. The interviews will last between 30 and 90 min, depending on the availability and pace of the participants. They will take place in a dedicated room, face-to-face, following a guide designed for the purposes of the study. To guarantee the rigour and accuracy of the data, all interviews will be recorded with the prior consent of the participants. The recordings will then be anonymised to ensure the confidentiality of the information collected. A full transcript of each interview will be made to enable a detailed and comprehensive analysis of the data.

A thematic analysis will be carried out to identify the main categories and occurrences in the data. According to the inductive approach of the interactionist sociology, the data will be processed iteratively, with constant comparison of the information collected to allow the concepts to emerge [41]. Dedoose software version 10 will be used to organise and facilitate this analysis, allowing the information to be structured and a rigorous and systematic analysis of the interviews and observations to be carried out. The themes will be identified from the analysis of qualitative data, carried out using a systematic process including initial coding, recoding and interpretation of the data. The lead sociologist responsible for the survey and an experienced researcher in health sociology will both code the data.

Data analysis

Statistical analysis

The analyses carried out will first be descriptive analyses of the study population and the variables collected, as well as comparisons between control and intervention groups (parametric or non-parametric tests depending on the distribution of variables: *t*-test for quantitative variables, chi^2 test for qualitative variables, significance of tests at 5%). We will then describe in greater detail the quality of life and frailty scores, as well as the frequency of suggested preventive recommendations. A sub-analysis will be performed by country. Finally, we will analyze the evolution of quality of life and frailty (mixed and multi-state models on repeated data), as well as the implementation of recommendations. Statistical analyses will be performed using SPSS version 15 and SAS version 9.4.

Medico-economic evaluation

- Cost evaluation: direct medical and non-medical costs (hospitalization, general and specialist medical consultations, costs of biological analyses, treatment costs, transport costs, out-of-pocket expenses for patients). These costs will be collected by means of specific medico-6 economic questionnaires. And indirect costs (sick pay, sick leave), intangible costs (psychological impact).
- Utility assessment: Based on the answers to the EQ5D questionnaire, QALYs will be calculated. These are the life expectancy gained by the health intervention, weighted by quality of life, during these years of life gained.
- A cost-utility ratio will be calculated in each group to see whether the intervention is cost-effective.

A sensitivity analysis will be performed to test the robustness of the model.

Qualitative analysis

Qualitative monitoring of patients The qualitative interviews will be anonymized and analysed. This analysis will make possible to identify the drivers of people's acceptance or refusal of the participation to the program. The qualitative analysis will also make possible to identify typologies of participants (profiles).

Qualitative monitoring of professionals A sociologist expert will interview the professionals involved in the SPACO + program. Analysis of the interviews with the professionals who took part in the project will enable us to assess the obstacles to and incentives for participation in the program. The course of the qualitative study is presented in Fig. 2.

Sample

Quantitative The primary outcome measure in this study is the change in quality of life during the follow-up period. In an article on the effect of peer education on quality of life in patients with type 2 diabetes [42], the authors show a 20% improvement in the percentage of change between 6-month follow-up and baseline for individuals included in the peer education group, compared with less than 5% for the group receiving "more

traditional" health education. According to the study of Burholt V. and Nash P., [43] with a mean value of 77.8 (+—30.0) for the SF-36 PF (Physical Functioning) at inclusion and an expected difference of 15% between the intervention group and the control group, the number of subjects needed to have a significant change is 164 individuals, for a risk of 5% and a power of 0.9 [44]. In the case of the SF-36 MH (Mental health), with an average of 74.0 (+−18.9), the number of subjects needed is 100. For physical pain, with an average of 70.1 (+−32.3), the number of subjects required is 324 and for general health, with an average of 66.2 (+—24.0), the number is 202. Considering that 10% of individuals will be lost during follow-up and that 10% of individuals are likely not to complete the SF36, the number of subjects required for the study is therefore 400 individuals, i.e. 200 per group. This number of subjects will give us significant power overall.

Qualitative The sample and the sampling process will be established in accordance with the epistemological, theoretical, and methodological positions of the research. Patients and professionals will be recruited to form a sample of the population. This sample will not be representative in the statistical sense, but its composition will seek to represent the variety of attitudes and contexts (age-sex-SDC-date of Covid-19 infection, etc.). In an empirical or qualitative approach, the appropriate sample size is that which reaches theoretical saturation. The latter is reached when the sociologist is no longer able to find additional information to improve the theory.

Data management

The participants are each given a unique identification code (without any personal information that could allow for their identification). During the procedure, all of the collected data is stored in a locked cabinet at the local organizations, according to a procedure compliant with GCP guidelines. When the study is complete, the collected data will be securely transmitted to the research team's logistic department, who will create the databases. The collected data will be stored according to standards for archiving research materials.

Dissemination

Investigators will communicate the trials results to participants, healthcare professionals, patients' association, and the public by newsletters and on the website of the study (https://spacoplus.fr). Our results will also be communicated by publishing scientific articles and during congress.

Trial statuts

The recruitment for the SPACO + study started in October 2023 and still ongoing at the time of this manuscript submission.

Discussion

While there are several projects on the care of Long Covid, to our knowledge very few focus on the effectiveness of multifactorial personalized intervention. Furthermore, there is no common basis for international comparisons. The type and intensity of symptoms vary from one patient to another and may differ by geographical region, given the genetic, ethnic, dietary, and climatic background of the population. The SPACO + project therefore aims to offer an innovative way to alleviate Long Covid symptoms with the advantage of comparing data from two countries. Due to the heterogeneity of each case, the rehabilitation program must be personalised [45].

The SPACO + program is an educational intervention for patients with Long Covid which is part of a multidisciplinary pathway. This type of intervention seems more appropriate for complex pathologies with symptoms that vary greatly from one person to another. It provides an individualised response tailored to each patient. The SPACO + program is based on the educational approach. This approach is regularly used in therapeutic education. The content of the intervention is co-constructed with the patient. In addition to the fact that the SPACO + programme is a personalised multifactorial intervention, the last workshop is an innovation because it allows patients to take stock of their journey during a friendly exchange over a coffee with other patients to share their experiences. This workshop is co-led by the intervention group nurse and an expert patient who is a member of the Long Covid patients' association.

There is no standard strategy for the management of long Covid, it is a heterogeneous clinical syndrome. Its clinical management is differed worldwide [46]. Programs are being designed with the aim of improving the physical health and mental well-being of patients. However, some key points such as the content of these programs, the method of delivering them and their duration, among other factors, are still discussed.

Some authors have tried to summarise the different strategies for managing Long Covid in literature reviews [2, 47]. In a recent scoping review of strategies for managing Long Covid Chou et al. [2], show that most models were specialty-based (most often physiatry or pulmonology). Those models followed published guidelines on management of Long covid and used a multidisciplinary approach. The place of physical activity is still a matter of

debate. Humphreys et al., [48] suggest that physical activity is beneficial for patients suffering from Long Covid. Some studies showed that when physical activity was adapted to symptoms, the reduction in perceived fatigue levels was significant [49, 50]. It is important to consider the balance benefits risks between fatigue, physical activity, and post-exertional malaise [51]. Thus, studies highlight the need to systematically check for the presence of post-exertional malaise (PEM) [51, 52] before and during any exercise rehabilitation.

Our study is based on a mixed method. This type of method not only provides the answers of a quantitative evaluation of the effects of a programme, but also makes it possible to assess the obstacles, levers, and conditions for the success of a programme. In our project, the patient's place was considered from the design of the intervention. Thus, a patient association is part of the steering committee. This inclusion of patients in the design has made it possible to highlight the perception and fears of adapted physical activity in the programmes of patients with Long Covid.

The SPACO + study is an international multicentre study conducted in France and Cameroon, i.e. in two very different environments. To limit bias, the same protocol is used in both countries. In addition, joint training sessions were organised for all the investigators involved in the project. Best practices exchanges are periodically organised for facilitate joint activity. Adaptations have been made to the SPACO workshops in Cameroon to take account of the local environment. Comprehension tests have been carried out to ensure the suitability of the workshops. Furthermore, we will use mixed and multi-levels models on repeated data during statistical analyses. The variables such as socioeconomic conditions, healthcare access, lifestyle differences, the center of investigation, the country will be included in the model as covariates. This holistic framework will make it possible to obtain valid results that consider the cultural and environmental differences that exist between the populations studied.

Our study has limitations. The first limitation may be the selection bias, as patients with mild long Covid symptoms who are able to return to work do not all enrol in the SPACO + program. The second limitation could be the barriers due to the distance and the hospital university access for SPACO + workshops. Another limitation may be the dropout of study participants, which might happen due to reinfections that cause their health status to worsen, or to the search for other healthcare solutions.

In conclusion, our project aims to assess the effectiveness of the SPACO + program. Thus, if this program is effective and accepted by professionals and patients, it could be disseminated in other regions to assess its transferability. Our study is international in scope, and as such it will produce data from sub-Saharan Africa, an area where data on the management of Covid Long is still very limited. The medico-economic evaluation will also make it possible to assess the benefits provided.

Abbreviations

SPACO+	Monitoring and Adapted Pathways for People Suffering from Persistent Symptoms of Covid-19 (Suivi et Parcours Adapté des personnes souffrant de symptômes persistants à la COvid-19)
SF-36	Short Form 36
mMRC	Modified medical research council
MoCA	Montréal cognitive assessment
VAS	Visual analogue scale
DN4	Neuropathic pain diagnostic questionnaire (Douleur neuropathique en 4 questions)
EQ-5D-5L	EuroQol 5- Dimension 5- Level 5

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Authors' contributions

OLK, JG, BB, SHM, wrote the research proposal that was sent to the funding organisation and design the study with CNN, CEEM, DH, FR, EBN and drafted the first version of the manuscript with CD, EE, LR, NB, TC, CAA. OLK, VH, EE, MN, NG, AB, MD, FS, VR, WBN, FNS, MSNE, RFM implemented the pilot study - MF, MPV, PO, SB, DH, CB, JLN designed and experimented the workshops. CD, CB, BB, OT, YMB managed the statistics aspects and randomisation. ESL, BB, MB managed the cost effectiveness of the project. PAN, DH, VN managed the physical activity Workshops design. JG, NG, JM, NB managed the qualitative aspects of the project. OLK, CD, SHM, CNN, BB coordinated the writing of the manuscript at all stages. EE, PAN, CAA, VN, MSNE, CNN, FR, BB, VR, SHM, EBN, CEEM, DH supervised the study at all stages. All authors contributed to the design of the manuscript, read, and approved final version of the manuscript before submission.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

This protocol proposal received the approval of the following institutions:
i- The French ethics committee (Comité de Protection des Personnes Ouest II—CHU Angers, France) under the respective reference numbers SI: 22.04823.000128 and national: 2022-A02766-37
ii- Institutional Ethics Committee for Research on Human Health of the University of Douala, Cameroon under n° 3468/CEI-UDo/08/2022/P
iii- Cameroon Ministry of Health under n° 631–2923 of Nov 20, 2023
All participants sign an informed before entering the study.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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