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Teleconsultation for patients with postviral symptoms

Submission date
04/03/2025

Recruitment status
Not yet recruiting

Registration date
28/04/2025

Overall study status
Ongoing

Last Edited
28/04/2025

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Long- and post-COVID stands for various health complaints that patients suffer from after they have survived a SARS-CoV-2 primary infection. The most common long-term symptoms include persistent fatigue, dyspnoea, but also cardiovascular and neurological complaints. The symptoms can persist, reappear or fluctuate after the initial recovery from an acute SARS-CoV-2 infection. Long- and post-COVID is therefore a complex disease with long-lasting, heterogeneous symptoms. The disease can be a major challenge, especially for those in employment, making it considerably more difficult to return to work. Comprehensive treatment of those affected requires interprofessional structures and networks, which only exist to a limited extent in Germany to date. This is particularly true for rural and structurally weak regions. Patients experience care bottlenecks in diagnosis, further treatment and outpatient follow-up care after rehabilitation stays. This trial is being conducted to investigate the extent to which an interprofessional, patient-centred teleconsultation, initiated and accompanied by the general practitioner (GP), helps to reduce the symptoms of patients with long-COVID and other post-viral symptom complexes. At the centre of this intervention is the interprofessional exchange between GPs and long-COVID specialists at Rostock University Medical Center (Long-COVID Board) and the direct involvement of patients via teleconsultation. On the one hand, this approach enables patients to receive care close to home in familiar structures. On the other hand, the specific experience and expertise of the specialists in the treatment of long-COVID and other post-viral complaints enriches the diagnosis and treatment of the patients included. The aim is a focussed and efficient evidence-based differential diagnosis and, depending on the participatory decision-making process, the application of elaborated therapeutic approaches.

Who can participate?
Patients from participating GP practices in Mecklenburg-Vorpommern (Germany) who are at least 18 years old and suffer from a post-viral symptom complex can take part in the study.

What does the study involve?
At the beginning of the study and four months later, all included patients visit their GP practice for data collection (physical performance, health-related quality of life, cognitive impairment, lung performance and fatigue symptoms). For patients in the intervention group, a teleconsultation takes place between the two appointments at the GP practice, during which

they and their GP discuss the diagnosis and treatment options with a representative of the Long-COVID Board. Patients in the control group receive care as usual.

What are the possible benefits and risks of participation?
Prompt interprofessional dialogue between specialists, GPs and patients can help to improve diagnosis and access to treatment. As diagnosis and treatment are carried out according to current guidelines and procedures, no harm to the patient is to be expected.

Where is the study run from?
Institute for General Practice, Rostock University Medical Center (Germany)

When is the study starting and how long is it expected to run for?
November 2024 to December 2028

Who is funding the study?
German Federal Ministry of Health

Who is the main contact?
Dr Christin Löffler, christin.loeffler@med.uni-rostock.de

Study website
https://allgemeinmedizin.med.uni-rostock.de/forschung/forschungsprojekte/aktuelle-projekte

Contact information

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Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil knows

Secondary identifying numbers
ZMII2-2524FSB031

Study information

Scientific Title
Patient-centred interprofessional teleconsultation for patients with postviral symptom complexes (Subproject of, "Coordinated LongCOVID care system for integrated supply and capacity expansion in Mecklenburg-Western Pomerania (COVI-Care M-V)")

Acronym
COVI-Care M-V

Study objectives
The trial tests whether the COVI-Care M-V intervention (interprofessional, patient-centred teleconsultation, initiated and accompanied by the general practitioner (GP) with long-COVID specialists from Rostock University Medical Center (Long-COVID Board) is more effective in improving physical performance among patients than care as usual.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/02/2025, Ethics Committee at Rostock University Medical Center (St.-Georg Str. 108, Rostock, 18055, Germany; +49 381 494 9900; ethik@med.uni-rostock.de), ref: A2025-0033

Study design
Interventional cluster-randomized controlled

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice, Hospital, Medical and other records, Telephone

Study type(s)
Diagnostic, Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a participant information sheet

Health condition(s) or problem(s) studied
Long- and post-COVID and other post-viral symptom complexs

Interventions
Interprofessional, patient-centred teleconsultation initiated and supervised by the GP with the patient and GP at one end (GP practice) and Long-COVID specialists from Rostock University Medical Center (Long-COVID board) at the other end.

Intervention Type
Other

Primary outcome measure
Physical performance measured using the target and actual value of the walking distance of the 6-minute walk test between patient inclusion (T0) and 4 months later (T1)

Secondary outcome measures
The following secondary outcome measures are assessed before the intervention (T0) and four months later (T1):
1. Health-related quality of life measured using the Post Acute COVID-19 Quality of Life (PAC-19QoL) tool
2. Cognitive impairment measured using the DemTect screening test
3. Lung performance measured using a peak flow meter
4. Symptoms of fatigue measured using the Fatigue Assessment Scale (FAS)

Overall study start date
01/11/2024

Completion date
31/12/2028

Eligibility

Key inclusion criteria
Patients:
1. Presence of a post-viral symptom complex
2. Age from at least 18 years

Physicians:
1. General practitioners based in Mecklenburg-Western Pomerania (Germany)

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex
Both

Target number of participants
A total of 240 patients from 42 GP practices in Mecklenburg-Vorpommern (Germany) will be recruited. The practices will be cluster-randomised so that approximately half of the patients will be assigned to the intervention group and the other half to the control group.

Key exclusion criteria
Patient exclusion criteria:
1. Presence of an acute underlying malignant disease
2. Remaining life expectancy of less than 12 months as assessed by a GP
3. Language barriers (e.g. hearing impairment, lack of language skills)
4. Dementia and lack of capacity to give consent

Date of first enrolment
01/04/2026

Date of final enrolment
31/12/2027

Locations

Countries of recruitment
Germany

Study participating centre
Rostock University Medical Center, Institute of General Practice
Doberaner Str.142
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Sponsor information

Organisation
Bundesverwaltungsamt

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Sponsor type
Government

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Funder(s)

Funder type
Not defined

Funder Name
German Federal Ministry of Health

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
01/09/2029

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Christin Löffler, christin.loeffler@med.uni-rostock.de. Raw data will be available on request following publication of results in 2029. Informed consent will be obtained during patient enrolment. Data will be anonymised. An inter-institutional data sharing agreement will be required.

IPD sharing plan summary
Available on request