# Teleconsultation for patients with postviral symptoms

Submission date	Recruitment status	[X] Prospectively registered
04/03/2025	Not yet recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
28/04/2025	Ongoing	Results
Last Edited	Condition category	Individual participant data
28/04/2025	Infections and Infestations	[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**

### Type(s)

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 Rostock Germany 18057

# Sponsor information

### Organisation

Bundesverwaltungsamt

### Sponsor details

Eupener Str. 125 Köln Germany 50933 +49 228 99358-24124 tobias.kujath@bva.bund.de

### Sponsor type

Government

### Website

www.bundesverwaltungsamt.de

# 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