COVID-19 Follow-up care paths and Long-term Outcomes Within the Dutch health care system: a combined rehabilitation, pulmonary, and intensive care perspective

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Viral infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON54173

Source
ToetsingOnline

Brief title
CO-FLOW

Condition

- Viral infectious disorders

Synonym
COVID-19; CORONA

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,ZON MW,Rijndam Revalidatie en Laurens zorginstellingen

Intervention

Keyword: COVID-19, health care paths, long-term consequences, predictors

Outcome measures

Primary outcome

Primary study parameters include physical, cognitive, and psychological

functioning in the long term.

Secondary outcome

Secundary outcomes include health-related quality of life, social

participation, health care paths, and patient satisfaction.

Study description

Background summary

The world is overwhelmed by COVID-19, a new respiratory infectious disease. This new disease and surreal situation are expected to cause severe and long-lasting physical, cognitive and psychological consequences, affecting participation and health-related quality of life. After hospitalization, many patients may need inpatient treatment in a rehabilitation or geriatric center, while others may be able to go home with outpatient rehabilitation. Health care paths and long-term functional outcomes after COVID-19 are not known yet. Knowledge on the extent and predictors of recovery after hospitalization in patients with COVID-19 is urgently needed, and will facilitate optimization of triage and rehabilitation of COVID-19 patients and comparable (future) infectious diseases.

Study objective

The aim of this study is to set up a registry and to systematically study the long-term out-comes of patients with COVID-19 who survived hospitalization in

the Rotterdam Rijnmond area, by recording data from usual care and collecting additional data over a 2 years period.
Specific aims are to study:
1] trajectories and predictors of physical, cognitive and psychological recovery (primary);
2] effects of physical, cognitive and psychological outcomes on social participation and health-related quality of life;
3] patient flows, health care utilization, and patient satisfaction with care paths;
4] effects of diversity (age, sex, socio-economic status, cultural background) on recovery, health care utilization, and patient satisfaction.

Study design

Multicenter prospective cohort study with a 2-year follow-up period. Data registration as part of regular care takes place in rehabilitation centers and nursing homes (at admission and discharge) and during regular out-patient visits. Additional measurements predominantly concern long-term measurements after 6, 12, and 24 months post-hospital-discharge. If complaints persist, follow-up will be extended by means of questionnaires at 36, 48 and 60 months after hospital discharge.

Study burden and risks

The registry is set up for patients with COVID-19 and is therefore group-related. Data are copied from patient records and additional measurements are non-invasive and minimally physically demanding. Completion of questionnaires and additional measurements require a certain time investment from patients and might lead to temporary fatigue. Yet, by providing frequent breaks and a maximum duration of 60-85 minutes per session for the online questionnaires and a maximum duration of 40-45 minutes for the clinical tests, we aim to minimize the burden for patients. Participants will gain more insight in their recovery.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80
Rotterdam 3015CN
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80
Rotterdam 3015CN
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• COVID-19; based on positive PCR or multidisciplinary team decision based on symptoms and CT or positive serology
• requiring and surviving hospitalization;
• within 6 months post hospital discharge;
• patient or relative has sufficient knowledge of Dutch or English language.

Exclusion criteria

• age< 18 years;
• incapacitated subjects.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2020
Enrollment:	650
Type:	Actual

Ethics review

Approved WMO Date:	23-06-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-08-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-08-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-09-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-10-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	

Date:	06-12-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-05-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL74252.078.20
Other	NL8710