The Neurobiological basis of persisting fatigue and cognitive complaints as a consequence from COVID-19

Published: 22-04-2022
Last updated: 05-04-2024

Primary Objectives: 1. To investigate the nature and extent of persistent fatigue and cognitive complaints 2. To investigate the impact of persistent complaints on health-related quality of life and health care consumption3. To identify risk factors...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON51404

Source
ToetsingOnline

Brief title
VeCosCO

Condition

- Other condition
- Viral infectious disorders
- Psychiatric disorders NEC

Synonym
long COVID-19: chronic fatigue syndrome

Health condition

long COVID-19 (>3 maanden na acute infectie)

Research involving

Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: cognition, COVID, fatigue, psychosocial

Outcome measures

Primary outcome

Persistent fatigue and cognitive complaints

Secondary outcome

2. Impact of persistent complaints on health-related quality of life, health

care consumption

3. Risk factors for persistent fatigue and cognitive problems: cognitive

behavioural factors (coping, illness perceptions) , cognitive

neuropsychological functioning sociodemographic factors (eg. age, gender),

medical factors (severity of initial covid19 infection, ICU admission,

vaccination status, comorbidity, covid19 virus variant)

4. Post-exertional malaise

Study description

Background summary

The magnitude of the current COVID-19 pandemic is unprecedented with >500,000 infections so far in the Netherlands and >54 million worldwide. A large number of post-COVID-19 patients have already developed "chronic" complaints, such as fatigue and cognitive complaints, which persist > 3 months after infection (36-53%). Post-infectious fatigue and cognitive

complaints are characterized by chronic, debilitating and unexplained fatigue and difficulty concentrating and remembering months after an infection. The exact severity of persistent fatigue and cognitive complaints, maintaining factors of these complaints and their risk factors are unknown. This study hopes to shed more light on this.

Study objective

Primary Objectives:
1. To investigate the nature and extent of persistent fatigue and cognitive complaints
2. To investigate the impact of persistent complaints on health-related quality of life and health care consumption
3. To identify risk factors for persistent fatigue and cognitive problems: cognitive behavioural factors (coping, illness perceptions) , cognitive neuropsychological functioning, sociodemographic factors (eg. age, gender), medical factors (severity of initial covid19 infection, ICU admission, vaccination status, comorbidity, covid19 virus variant)
4. To investigate the presence of post-exertional malaise (PEM)

Study design

Cross-sectionele observationele case-control studie

Study burden and risks

A maximum of two study visits will be required, depending on the moment of inclusion (compared to time of infection). Participants will be asked to complete an online battery of standardized validated questionnaires at inclusion (baseline), after 9 months to assess fatigue, cognitive symptoms, health related quality of life, coping, illness perceptions and health care consumption. Completion of the battery of questionnaires will take approximately take a maximum of 45 minutes. Neuropsychological assessment (approximately 50 minutes) will be performed at baseline. During the first study visit blood sampling for biomarkers and genotyping is done, of which the risk is considered minimal. There is no direct benefit of participation in the study for the patient.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- At least 3 months after diagnosis of COVID-19 (hospitalized or non-hospitalized) confirmed by a positive PCR for SARS-CoV-2, positive SARS-CoV-2 serology or CO-RADS (COVID-19 Reporting and Data System) >=4 on CT-scan, or antigen quicktest.
For post COVID-19 participants with long-term fatigue and cognitive complaints
- Experience severe fatigue after going through COVID-19 (>40 on the fatigue scale of the Checklist Individual Strength (CIS)(Worm-Smeitink et al., 2017))
- A score of >=18 on the concentration subscale of the CIS, at least 3 months after COVID-19
For post-COVID-19 participants without persisting fatigue and/or cognitive complaints
- No severe fatigue on the Checklist Individual Strength (CIS)(Worm-Smeitink et al., 2017)) (score <=34 on the fatigue scale)
- No substantial cognitive complaints <=18 on the concentration subscale of the CIS) at least 3 months after COVID-19.

Exclusion criteria

Subject who meets any of the following criteria will be excluded from participation in this study:
- Known psychiatric or somatic conditions prior to COVID-19 that could explain the fatigue or cognitive symptoms.
- Disabling fatigue and/or cognitive complaints prior to COVID-19.
- Re-infection with SARS-CoV-2 within the last 3 months

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-05-2022
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	22-04-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-07-2022

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-08-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL79575.018.21