ReCOVer: A Randomised Controlled Trial testing the efficacy of Cognitive Behavioural Therapy for preventing chronic postinfectious fatigue among patients diagnosed with COVID-19.

Published: 14-09-2020
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Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50042

Source
ToetsingOnline

Brief title
ReCOVer

Condition

- Other condition
- Ancillary infectious topics

Synonym
fatigue, Postinfectious chronic fatigue

Health condition

Vermoeidheid

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Cognitive Behavioral Therapy, COVID-19, fatigue, Randomized Controlled Trial

Outcome measures

Primary outcome

To investigate whether timely delivery of iCBT, i.e. 3 to 6 months after COVID-19 diagnosis or hospital discharge, will lead to a significant reduction in fatigue severity (CIS-fatigue) between baseline (T0) and the post-assessment (T1, T2) as compared to care as usual.

Secondary outcome

To investigate whether timely delivery of iCBT will lead to a clinically relevant reduction in fatigue, reduce the proportion of patients who progress to chronic fatigue (i.e. caseness) and will foster patients* work ability, physical and social functioning and will reduce other somatic symptoms as compared to care as usual.

Study description

Background summary

The COVID-19 pandemic is a serious health crisis that will likely result in debilitating long-term symptoms in a large group of patients. As acute fatigue is among the most common symptoms in patients with COVID-19, postinfectious chronic fatigue, a debilitating long-term symptom with severe adverse impacts

on patients* health and functioning, is a major concern. Timely delivery of Cognitive Behavioural Therapy [CBT], an evidence-based treatment for chronic fatigue, is promising to prevent that patients progress from acute to chronic fatigue.

Study objective

To investigate whether timely delivery of CBT, i.e. 3 to 6 months after COVID-19 diagnosis or hospital discharge, will lead to a significant relevant reduction in fatigue severity (primary outcome), will lead to a clinically relevant reduction in fatigue, will reduce the proportion of patients who progress to chronic fatigue, will foster patients* work ability, physical and social functioning and will reduce other somatic symptoms (secondary outcomes) as compared to care as usual.

Study design

This is a multicentre 2-arm Randomised Controlled Trial. Patients will be randomised to internet-based CBT [iCBT] or care as usual (ratio 1:1).
Self-report assessments will take place at three to four time points: before randomisation (T0, baseline), after iCBT or the care as usual period (T1, 4 months after randomisation), 6 months (T2, follow-up) and 12 months later (T3, CBT-arm only).

Intervention

iCBT will be delivered by trained cognitive-behavioural therapists on a secured webportal (Minddistrict) during 17 weeks and entails up to 8 modules (e.g. sleep-wake pattern, helpful thinking, graded activity). A detailed description of the modules can be found elsewhere (document 'C1. Onderzoekprotocol ReCOVer').
Patients randomised to care as usual will self-report their care use.

Study burden and risks

Study participation is estimated to take 16 months (incl. T3 for the CBT-arm), which includes iCBT delivery (or care as usual) and three to four questionnaire assessments. Patients in the iCBT arm will receive therapy for their fatigue, which is expected to be effective. Their potential benefit will be decreased fatigue severity and related benefits (see secondary outcomes). Patients will have to invest time for responding to questionnaires (± 45 min. at T0, ± 30 min. at T1 to T3) and, if randomised to the iCBT arm, to follow the intervention. There are no health risks. As CBT can be delivered in its internet-based format and surveys can be completed online, the travel required is limited to T0 (collecting the actigraph) and the study can proceed despite

preventive measures due to the COVID-19 pandemic.

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:
1. The patient was diagnosed with symptomatic COVID-19, confirmed by a positive PCR for SARS-CoV-2, positive SARS-CoV-2 serology or CORADS 5 on CT-scan, or had typical symptoms and was part of a household in which another person was tested positive by PCR 2 weeks before or after the first day of illness;
2. The patient is 3 to 6 months after being diagnosed with COVID-19 or after hospital discharge in case the patient was admitted. If the number of new COVID-19 cases is very small and not enough patients can be recruited 3-6

months post COVID-19, we will extent the period in which patients can be recruited first to 9 months post COVID-19 and, in the unlikely case this still would not suffice, up to 12 months;
3. The patient experiences severe levels of fatigue (>= 35 on the fatigue severity subscale of the Checklist Individual Strength [CIS-fatigue]). The severe fatigue started with or increased substantially directly after the onset of symptoms of COVID-19;
4. The patient reports physical/social disability (<= 65 on the Rand36 physical functioning subscale or a score of >= 10 on the Work and Social Adjustment Scale [WSAS]);
5. The patient is 18 years of age or older;
6. The patient has sufficient command of the Dutch language.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
1. The patient has an already known psychiatric or somatic condition that can explain the presence of fatigue. We will also screen for the presence of Post-Traumatic Stress Disorder [PTSD] which prevalence may be high in this patient group because of traumatic experiences during the acute phase of COVID-19. These patients will be referred for PTSD treatment;
2. The patient currently participates in a multi-disciplinary rehabilitation programme aimed to ameliorate the consequences of COVID-19;
3. The patient has objectified hypoxemia in rest for which oxygen therapy at home is indicated.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	12-11-2020
Enrollment:	114
Type:	Actual

Ethics review

Approved WMO Date:	14-09-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-09-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-10-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-05-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-01-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-07-2022
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

ID: 28363
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL74828.018.20

Study results

Date completed: 22-02-2023

Results posted: 17-11-2023

First publication
01-01-1900