ReCOVer: Cognitive Behavioural Therapy for post-COVID-19 fatigue

Published: 04-10-2020
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Primary Objective: To investigate whether timely delivery of iCBT will lead to a significantly lower mean fatigue severity score (CIS-fatigue) across follow-up visits (T1 and T2) as compared to care as usual. Secondary Objectives: To investigate...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON28363

Source
Nationaal Trial Register

Brief title
ReCOVer

Condition

- Viral infectious disorders

Health condition

COVID-19; fatigue

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam University Medical Centers
Source(s) of monetary or material Support: ZonMW

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

Mean fatigue severity score (CIS-fatigue) across follow-up visits (T1 and T2)

Secondary outcome

(a) proportion of patients no longer meeting the cutoff score for severe fatigue (i.e. caseness as defined by a CIS-fatigue score of >= 35) at follow-up visits; (b) proportion of patients no longer meeting the cut-off score (as defined in a)) and additionally reporting a clinical significant change (i.e. Reliable Change Index) in fatigue severity at follow-up visits; (c) proportion of patients with chronic fatigue (i.e. caseness as defined in a) and self-reported 6 months duration of fatigue; (d) mean physical functioning as assessed with the RAND-36 across follow-up visits (T1 and T2); (e) mean level on the work and social adjustments scale (WSAS) across follow-up visits (T1 and T2); (f) mean level of somatic symptoms as assessed with the PHQ-15 across follow-up visits (T1 and T2). (g) mean level of cognitive symptoms as assessed with the subscale concentration problems of the CIS across follow-up assessments (T1 and T2). The primary and secondairy outcomes will be tested in an interim analysis at T1 only.

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, post-infectious chronic fatigue, a debilitating long-term symptom with severe adverse impact on patients' health and functioning, is a major concern. Cognitive Behavioural Therapy [CBT] is an evidence-based treatment for severe fatigue among various populations, but it has not been tested in COVID-19 patients. Until now, CBT has generally been tested in populations with a long symptom duration. As there is evidence that a long symptom duration is associated with a less favourable outcome of CBT, we expect timely delivery to help prevent the severe fatigue to become chronic. The aim of this study is to test the efficacy of timely delivered internet-based Cognitive Behavioural Therapy [iCBT] for severe fatigue compared to care as usual.

Study objective

Primary Objective: To investigate whether timely delivery of iCBT will lead to a significantly lower mean fatigue severity score (CIS-fatigue) across follow-up visits (T1 and T2) as compared to care as usual. Secondary Objectives: To investigate whether timely delivery of iCBT as compared to care as usual will result in: (a) a higher proportion of patients no longer meeting the cutoff score for severe fatigue (i.e. caseness as defined by a CIS-fatigue score of >= 35) at follow-up visits; (b) a higher proportion of patients no longer meeting the cut-off score (as defined in a)) and additionally reporting a clinical significant change (i.e. Reliable Change Index) in fatigue severity at follow-up visits; (c) a lower proportion of patients with chronic fatigue (i.e. caseness as defined in a) and self-reported 6 months duration of fatigue; (d) a significantly higher mean physical functioning as assessed with the RAND-36 across follow-up visits (T1 and T2); (e) a significantly lower mean level on the work and social adjustments scale (WSAS) across follow-up visits (T1 and T2); (f) a significantly lower mean level of somatic symptoms as assessed with the PHQ-15 across follow-up visits (T1 and T2). (g) a significantly lower mean level of cognitive symptoms as assessed with the subscale concentration problems of the CIS across follow-up assessments (T1 and T2). All the aboves will be tested in an iterim analysis at T1 only.

Study design

Screening for eligibility T0 – Baseline assessment. Randomisation: Stratified by (1) illness severity (no admission, admission non-ICU, admission ICU) and (2) MRC dyspnoea score (<3 vs ≥ 3). T1 – 19 weeks after randomization After T1: interim analysis T2 – 6 months after T1

Intervention

Patients will be randomised to either iCBT or care as usual (ratio 1:1). iCBT The intervention to be delivered is internet-based Cognitive Behavioural Therapy [iCBT]. This intervention is based on the cognitive-behavioural model of fatigue, stating that disease and/or its treatment initially triggers fatigue while cognitive-behavioural variables perpetuate fatigue. Patients randomised to iCBT will receive 17 weeks of individual iCBT, based on an existing treatment manual for chronic fatigue which has been adapted to COVID-19. iCBT will be delivered by trained cognitive-behavioural therapists on a secured webportal and entails up to 9 modules. Of these modules, 7 target the perpetuating factors of fatigue. Patients only receive modules that are indicated for them, based on baseline scores (T0) and intake. Patients who are not able or willing to follow iCBT will be offered face-to-face CBT at a treatment facility or via video consults using the same treatment manual. Care as usual Currently, care as usual for patients who passed the acute phase of COVID-19 can entail different forms of care. Participants will have no access to the study intervention during the study period, but are not restrained from using any care for their fatigue or a related symptoms/health complaints (e.g. through referral by their practitioner).

Contacts

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Eligibility criteria

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

Inclusion criteria

- The patient was diagnosed with symptomatic COVID-19, confirmed by a positive PCR for SARS-CoV-2, another positive NAAT test (RT-PCR, LAMP, TMA or mPOCT), positive SARS-CoV-2 serology, a positive Antigen test or CORADS 4 or 5 on CT-scan; - The patient is 3 up to and including 12 months after being diagnosed with COVID-19 or after hospital discharge in case the patient was admitted; - The patient experiences severe levels of fatigue (≥ 35 on the fatigue 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; - The patient reports physical disability (≤ 65 on the Rand36 physical functioning subscale) and/or social disability (≥ 10 on the Work and Social Adjustment Scale [WSAS]); - The patient is 18 years of age or older; - The patient has sufficient command of the Dutch language.

Exclusion criteria

- The patient has an already known psychiatric or somatic condition that can explain his/her fatigue. We will also screen for the presence of Post-Traumatic Stress Disorder ([PTSD], (PCL-5) which prevalence may be high in this patient group because of traumatic experiences during the acute phase of COVID-19. We will also screen for the presence of depressive disorder (Mini- International Neuropsychiatric Interview); - The patient currently participates in a multi-disciplinary rehabilitation programme aimed to ameliorate the consequences of

COVID-19; - The patient has objectified hypoxemia in rest for which oxygen therapy at home is indicated.

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

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

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Approved WMO

Date:	14-09-2020
Application type:	First submission
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214

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Study registrations

Followed up by the following (possibly more current) registration

ID: 50042
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8947
CCMO	NL74828
CCMO	NL74828.018.20
OMON	NL-OMON50042

Study results

Results posted: 15-11-2023

Summary results
"Patients who received CBT were significantly less severely fatigued across follow-up assessments compared to patients receiving CAU (-8.8, (95% confidence interval (CI)) -11.9 to -5.8); P<0.001), representing a medium Cohen’s d effect size (0.69). The between-group difference in fatigue severity was present at T1 -9.3 (95% CI -13.3 to -5.3) and T2 -8.4 (95% CI -13.1 to -3.7). All secondary outcomes favored CBT. Eight adverse events were reported during CBT, and 20 during CAU. No serious adverse events were recorded. There was no indication that patients following CBT deteriorated with respect to fatigue severity.

A uncontrolled long-term follow-up study revealed that favorable outcomes of CBT targeting severe fatigue following COVID-19 are maintained at least up to one year post-intervention.

Publications:
Kuut, T.A., Müller, F., Aldenkamp, A. et al. A randomised controlled trial testing the efficacy of Fit after COVID, a cognitive behavioural therapy targeting severe post-infectious fatigue following COVID-19 (ReCOVer): study protocol. Trials 22, 867 (2021). https://doi.org/10.1186/s13063-021-05569-y

Efficacy of Cognitive-Behavioral Therapy Targeting Severe Fatigue Following Coronavirus Disease 2019: Results of a Randomized Controlled Trial, Clinical Infectious Diseases, Volume 77, Issue 5, 2023; Pages 687–695, https://doi.org/10.1093/cid/ciad257

Letter to the editor: Positive effects of cognitive-behavioral therapy targeting severe fatigue following COVID-19 are sustained up to one year after treatment, Clinical Infectious Diseases, 2023; ciad661,
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First publication
27-10-2023

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