The psychological well-being and health-related quality of life of patients admitted to the hospital with COVID-19.

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Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23092

Bron
Nationaal Trial Register

Verkorte titel
Psychological outcomes after COVID-19

Aandoening

COVID-19

Ondersteuning

Primaire sponsor: Franciscus Gasthuis & Vlietland Group
Overige ondersteuning: BeterKeten, Stichting Coolsingel, Franciscus Vriendenfonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The occurrence and severity of psychological distress, defined as either one or a combination of PTSD, depression and/or anxiety, at 1, 3 and 12 months after hospital discharge in patients admitted with symptoms suitable with COVID-19 during the COVID-19 pandemic.

Toelichting onderzoek

Achtergrond van het onderzoek

A novel coronavirus, SARS-CoV-2, was identified in Wuhan China in December 2019. The virus spread quickly around the globe and was officially declared a pandemic by the World Health Organization on March 11th 2020. This SARS-CoV2 pandemic has resulted in an exponential growth in diseased patients, causing a tremendous increase in both hospital and ICU admissions. In non-pandemic circumstances, illnesses requiring hospitalization already significantly impact patient's post-discharge psychological well-being as observed in various cohort studies. Moreover, survivors of critical illness and especially those requiring intensive care unit (ICU) treatment are known to be at particular risk for psychological impairments, with a prevalence up to 68%. This post-hospitalization psychological burden further impairs their health-related quality of life (HRQoL) and the ability to return to work.
During the COVID-19 pandemic peak in the Netherlands between March and May 2020, extensive measures were taken to reduce the further spread of the virus and to safeguard optimal standard of medical care. In general citizens were advised to work from home, minimize social contacts, keep distance in public places, and to remain in self-quarantine when experiencing possible COVID-19 symptoms. Within hospitals, patients with symptoms suggestive for COVID-19 were isolated upon hospitalization, visitation was restricted, contact with healthcare workers was limited to strictly necessary and included the use of personal protection measures. Due to its mayor effects on the whole society, socially as well as economically, the COVID-19 crisis was a constant factor on the news and on social media. Collectively, the uncertainties surrounding the pandemic and altered in-hospital circumstances raised concern of increased psychological distress in the general population, but especially in hospitalized patients and those with COVID-19. We hypothesized that patients admitted to the hospital during this pandemic period with a suspected or confirmed SARS-CoV2 infection, have a high risk to develop long-term or persistent symptoms of PTSD, anxiety and depression, that are associated with a decreased health related quality of life and a delayed work resumption. In addition, we hypothesize that psychological burden may vary between patients diagnosed with COVID-19 and those who were not, and that ICU patients would be more prone compared to non-ICU patients. In this study we examined the psychological burden, HRQoL and resumption of work in patients hospitalized with COVID-19 related symptoms, up to 12 months after discharge.

Doel van het onderzoek

We hypothesized that patients admitted to the hospital during this pandemic period with a suspected or confirmed SARS-CoV2 infection, have a high risk to develop long-term or persistent symptoms of PTSD, anxiety and depression, which are associated with a poor

health-related quality of life and a delayed work resumption. In addition, we hypothesize that psychological burden may vary between patients diagnosed with COVID-19 and those who were not, and that ICU patients would be more prone compared to non-ICU patients.

Onderzoeksopzet

T1: 1 months after hospital discharge
T2: 3 months after hospital discharge
T3: 12 months after hospital discharge

Contactpersonen

Publiek

Erasmus MC
Johan Vlake

+31641545743

Wetenschappelijk

Erasmus MC
Johan Vlake

+31641545743

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Above 18 years of age
- Admitted with symptoms suitable with COVID-19 (respiratory (dyspnea, coughing, sore throat, rhinorhea, saturation <94%, respiratory rate >24/minute) or gastro-intestinal (diarrhea, vomiting) for a duration >24 hours) and eventually tested for SARS-CoV-2 using PCR.
- Able to understand the Dutch language

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patients who participate in interventional trials of which the outcomes interfere with the outcomes in the current study
- Patients without a formal home adress and without an e-mail address.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	28-05-2020
Aantal proefpersonen:	250
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8882
Ander register	Institutional Ethics Committee of the Franciscus Gasthuis & Vlietland hospital : 2020-042

Resultaten