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

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23092

Source
NTR

Brief title
Psychological outcomes after COVID-19

Health condition

COVID-19

Sponsors and support

Primary sponsor: Franciscus Gasthuis & Vlietland Group
Source(s) of monetary or material Support: BeterKeten, Stichting Coolsingel, Franciscus Vriendenfonds

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

The health-related quality of life (HRQoL) at 1, 3 and 12 months after hospital discharge in patients admitted with symptoms suitable with COVID-19 during the COVID-19 pandemic.

Study description

Background summary

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.

Study objective

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.

Study design

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

Contacts

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

- 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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-05-2020
Enrollment:	250
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL8882
Other	Institutional Ethics Committee of the Franciscus Gasthuis & Vlietland hospital : 2020-042

Study results