Intensive Care specific Virtual Reality (ICU-VR) to improve psychological impairments in survivors of COVID-19

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50036

Source
ToetsingOnline

Brief title
ICU-VR after COVID-19

Condition

- Other condition
- Anxiety disorders and symptoms

Synonym
post-intensive care syndrome (PICS), PTSD

Health condition

psychische klachten na IC opname, kwaliteit van leven

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Subsidie van Stichting Coolsingel;subsidie van Stichting BeterKeten

Intervention

Keyword: COVID-19, Intensive Care Unit, post-intensive care syndrome (PICS), Virtual Reality

Outcome measures

Primary outcome

The primary endpoint is the effect of ICU-VR after three months on the severity

and occurrence of psychological sequelae and the HRQoL in ICU patients treated

for COVID-19 up to 6 months after discharge.

Secondary outcome

The secondary endpoint is the effect of ICU-VR after six months on the severity

and occurrence of psychological sequelae and the HRQoL in ICU patients treated

for COVID-19 up to 12 months after discharge.

Study description

Background summary

The SARS-CoV-2 outbreak has resulted in a tremendous increase of Intensive Care Unit (ICU) admissions all over the world. Due to the long ICU stay and amount of mechanical ventilation, these patients are at risk for developing several psychological impairments, such as posttraumatic stress disorder (PTSD), anxiety and depression. These sequelae are part of the post-intensive care syndrome (PICS) and will adversely impact their health-related quality of life (HRQoL). An effective treatment strategy for these psychological PICS-related sequelae is still lacking.
In a recent ICU specific Virtual Reality (ICU-VR) study in sepsis patients we demonstrated that ICU-VR is safe, easy applicable and decreased PTSD and depression in sepsis survivors. We therefore want to study if ICU-VR has

similar effects in COVID-19 patients.

Study objective

The primary objective is to determine the effect of ICU-VR at three months after discharge on psychological sequelae and HRQoL up to 6 months after discharge in patients treated for COVID-19 on the ICU. The secondary objective is to determine the effect of ICU-VR at six months after discharge on psychological sequelae and HRQoL up to 12 months after discharge.

Study design

A multicentre randomized controlled trial in four hospitals in Rotterdam. The study will be conducted in the Erasmus MC (an academic hospital), the Franciscus Gasthuis & Vlietland (teaching hospital), the Ikazia Hospital (teaching hospital) and the Maasstad hospital (teaching hospital).

Intervention

All patients will be invited to a post-COVID outpatient clinic at six weeks, three months and six months after discharge as part of care as usual. During the first visitation at six weeks of prior to the second visitation at three months after discharge, patients will be informed about the study. During the second visitation patients will be included and thereafter randomized into two study groups:
1) Group A: Patients in this group will receive ICU-VR once during the 3-month visitation to the post-COVID outpatient clinic.
2) Group B: Patients in this group will receive ICU-VR once during the 6-month visitation to the post-COVID outpatient clinic.
Additionally, patients receive questionnaires prior to the post-COVID outpatient clinic visitations, 1 month after receiving ICU-VR and 12 months after discharge.

Study burden and risks

No additional burden is expected. ICU-VR is proven safe and feasible. No safety issues or adverse events have been reported using ICU specific VR nor in other studies using VR. In addition the questionnaire that is used is already validated and used in multiple clinical studies.

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

* * 18 years old
* A positive SARS-CoV-2 PCR with clinical signs of COVID-19 necessitating ICU care
* Able to understand the Dutch language
* Signed informed-consent

Exclusion criteria

* Documented active, established psychiatric disease (for instance personality disorders or schizophrenia)
* Admitted with or a history of a primary neurological impairment necessitating ICU admission to or discharge of the ICU (patients admitted with traumatic brain injury, CVA, stroke, meningitis). Patients with a medical history of delirium are eligible, if symptoms of delirium are not present at the time of inclusion.
* Lack of formal home address

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2020
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO Date:	10-06-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-08-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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: 20934
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL73667.078.20
OMON	NL-OMON20934