Intensive Care Unit specific Virtual Reality (ICU-VR) to improve psychological impairments in survivors of COVID-19; a multicentre, randomised controlled trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20934

Source
NTR

Brief title
ICU-VR after COVID-19

Health condition

COVID-19, anxiety, depression, post-traumatic stress disorder (PTSD)

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: BeterKeten, Stichting Coolsingel, Foundation Friends of Franciscus Gasthuis & Vlietland

Intervention

Outcome measures

Primary outcome

The effect of ICU-VR, given 3 months after hospital discharge, on the severity and prevalence of psychological sequelae, such as PTSD, anxiety and depression, and the health-related quality of life in ICU patients treated for COVID-19 up to 6 months after discharge, assessed using a between-group analysis.

Secondary outcome

Satisfactions with and rating of ICU care and aftercare, and perspectives on ICU-VR. Additionally, we explored the effect of ICU-VR, given 6 months after hospital discharge, on the severity and prevalence of psychological sequelae, such as PTSD, anxiety and depression, and the health-related quality of life in ICU patients treated for COVID-19 up to 12 months after discharge, assessed using a within-group analysis.

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 long ICU stay and duration of mechanical ventilation, these patients are at risk for developing psychological impairments, such as post-traumatic stress disorder, anxiety and depression. These sequelae are part of the post-intensive care syndrome (PICS) and adversely impacts the 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, decreased PTSD and depression and improved mental health. We therefore want to study is ICU-VR has similar effects in COVID-19 patients treated on the ICU.
All post-COVID patients will be invited to a post-COVID outpatient clinic at 3 months after discharge, where participants will be randomised between two groups; the early intervention group, receiving ICU-VR during the outpatient clinic visitation three months after discharge, and the late intervention group, receiving ICU-VR during an additional outpatient clinic visitation six months after discharge.
The primary outcome is the effect of ICU-VR after three months on the severity and occurrence of psychological impairments and the HRQoL in ICU patients treated for COVID-19 up to 6 months after discharge. The secondary outcomes are the effect of ICU-VR after six months on the severity and occurrence of psychological impairments and the HRQoL up to 12 months after ICU discharge. Psychological impairments are expressed as symptoms of PTSD as assessed with the Impact of Event Scale – Revised (IES-R) and symptoms or anxiety and depression as assessed using the Hospital Anxiety and Depression Scale (HADS). The health-related quality of life (HRQoL) was assessed using the RAND-36 and the EuroQol 5 dimensions (EQ-5D).

Study objective

We hypothesized that ICU-VR improves psychological impairments and subsequently results in an improved health-related quality of life.

Study design

T1: 3 months after hospital discharge, the early group will receive ICU-VR
T2: 4 months after hospital discharge
T3: 6 months after hospital discharge; the late group will be offered ICU-VR
T4: 7 months after hospital discharge
T5: 12 months after hospital discharge

Intervention

Intensive Care Unit Specific Virtual Reality:
An interdisciplinary team of three intensivists, a psychologist, a psychiatrist, two ICU nurses, a post-ICU patients, a VR/film director and a researcher designed the Intensive Care specific Virtual Reality (ICU-VR) module based on previous studies. The content available for other VR exposure therapy-based treatments are often based on or preselected out of standardized material. For different illnesses, specific VR content must be developed to improve response and specific traumatic experiences or fears. For the COVID-19 patients we therefore developed a specific COVID-19 module. Real ICU nurses and ICU physicians were used to re-enact a typical day/treatment for a mock patients undergoing COVID related ICU treatment. The module will be watched via HMD-VR glasses (Oculus Go, Irvine, CA, CE: R-CMM-OC8-MH-A). Participants will be allowed to move their head freely so that they can experience all aspects of the virtual environment.
This way of ICU-VR is safe and feasible, as determined in previous research, and has been already approved for use in sepsis patients in our hospital (https://www.trialregister.nl/trial/6611). The only difference of the concurrent module is that this will be a COVID-19 specific ICU-VR module (with extra explanation about COVID-19, prone position and isolation measures).

Contacts

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Eligibility criteria

Inclusion criteria

- Above 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 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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-06-2020
Enrollment:	80
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Plan description
The datasets created during the study are available upon reasonable request by the corresponding investigator.

Ethics review

Positive opinion
Date: 14-08-2020

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50036
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8835
CCMO	NL73667.078.20
OMON	NL-OMON50036

Study results