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

Gepubliceerd: 14-08-2020 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20934

Bron
NTR

Verkorte titel
ICU-VR after COVID-19

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus Medical Center
Overige ondersteuning: BeterKeten, Stichting Coolsingel, Foundation Friends of Franciscus Gasthuis & Vlietland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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).

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 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	29-06-2020
Aantal proefpersonen:	80

Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

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

Ethische beoordeling

Positief advies

Datum:	14-08-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50036
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten