The HORIZON-IC study: The effect of Intensive Care Unit-specific Virtual Reality (ICU-VR) on mental health and health-related quality of life in critical illness survivors.

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We hypothesized that truthfully reconstructing memories about ICU treatment in order to replace and adjust the delusional memories may reduce psychological symptoms and offer additional treatment-related information using an Intensive Care Unit-...

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

Samenvatting

ID

NL-OMON28097

Bron
Nationaal Trial Register

Verkorte titel
HORIZON-IC study

Aandoening

Post-Intensive Care Syndrome, Post-Traumatic Stress Disorder, Anxiety, Depression

Ondersteuning

Primaire sponsor: Erasmus MC, Rotterdam, the Netherlands & Franciscus Gasthuis & Vlietland, Rotterdam, the Netherlands
Overige ondersteuning: BeterKeten, DSW, Stichting Theira, Stichting SGS

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is the difference in the severity of PTSD-related symptoms six months after ICU discharge between patients in the control group and 1) patients in the early ICU-VR group, and 2) patients in the late ICU-VR group.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
Due to advances in critical care medicine, more patients survive their critical illness. Up to 60% of these Intensive Care Unit (ICU) survivors experience long-term physical, cognitive and psychological impairments, collectively referred to as the Post-Intensive Care Syndrome (PICS), adversely impacting the health-related quality of life (HRQoL). The psychological component of PICS comprises anxiety-, depression- and posttraumatic stress disorder- (PTSD-) related complaints and is known to be an important determinant for a decreased HRQoL. An effective preventive or therapeutic strategy to improve these impairments is still lacking. We recently demonstrated that ICU-VR is safe and immersive in healthy volunteers. We confirmed these findings in a pilot study in ICU sepsis survivors and our results suggested that ICU-VR decreased depression and PTSD-related sequelae after ICU compared to controls. In the current multicenter randomized study, we aim to confirm the beneficial effect of ICU-VR on psychological sequelae and HRQoL in a multicenter setting. We secondly aim to examine whether ICU-VR can better be offered shortly (within 2 weeks) after ICU discharge, or later, during an ICU follow-up clinic three months after ICU discharge.

Objectives:
The primary objective is to assess the effect of ICU-VR, offered early (within two weeks after ICU discharge) or late (three months after ICU discharge during an ICU follow-up clinic), on the severity of PTSD-related symptoms six months after ICU discharge. Secondary objectives are to assess the effect of ICU-VR, offered early of late, on the prevalence of severity of psychological distress, i.e., symptoms of PTSD, anxiety and depression, at each follow-up time-point and during follow-up, to determine whether ICU-VR is most effective when offered early of later after ICU discharge, and to asses patients' satisfaction with ICU aftercare and patients' perspectives on the ICU-VR intervention.

Study design:
A multicenter, three-armed randomized controlled trial.

Study population:

All adult (≥18 years) patients admitted to ICU with an ICU length of stay ≥72 hours and mechanically ventilated for ≥24 hours. Exclusion criteria are 1) known, active psychiatric, cognitive or neurologic impairments, 2) active delirium or a decreased cognitive function during inclusion, 3) being moribund at the ICU with a life expectancy of <48 hours or receiving palliative care, 4) absence of a formal home address or unable to understand the Dutch language.

Intervention:
An Intensive Care Unit-specific Virtual Reality (ICU-VR) intervention, designed by an interdisciplinary team of intensivists, ICU nurses, a psychiatrist, a psychologist, and a former ICU patient, to expose patients to the ICU environment while offering treatment- and department-related information and reframing delusional memories. During the 12-minute lasting intervention, patients re-experience different facets of ICU treatment and receive information on the ICU environment, treatment and workflow.

Primary endpoints:
The primary endpoint is the difference in the severity of PTSD-related symptoms six months after ICU discharge between patients in the control group and 1) patients in the early ICU-VR group, and 2) patients in the late ICU-VR group.

Doel van het onderzoek

We hypothesized that truthfully reconstructing memories about ICU treatment in order to replace and adjust the delusional memories may reduce psychological symptoms and offer additional treatment-related information using an Intensive Care Unit-specific Virtual Reality intervention could improve psychological recovery and thereby health-related quality of life in critical illness survivors treated in the ICU.

Onderzoeksopzet

T0: Baseline
T1: 1 month after ICU discharge
T2: 3 months after ICU discharge
T3: 6 months after ICU discharge
T4: 12 months after ICU discharge

Onderzoeksproduct en/of interventie

Intensive Care Unit-specific Virtual Reality (ICU-VR)

An interdisciplinary team of three intensivists, a psychologist, a psychiatrist, two ICU nurses, post-ICU patients, a VR/film director and a researcher designed the Intensive Care specific Virtual Reality (ICU-VR) film, so that patients received relevant and truthful information regarding their ICU treatment with the aim to reduce stress and anxiety. The final film lasts approximately 12 minutes. Real ICU nurses and ICU physicians re-enacting a typical day/treatment for a mock patient undergoing ICU treatment. Based on the focus group meetings and previous studies, we determined to include the following information in the

video module: 1) an introduction by an intensivist and a ICU nurse to welcome the patient to the ICU VR environment, 2) route to the ICU room accompanied by a voice-over explaining daily movement in ICU, 3) explanation of monitors and sounds in an ICU room, 4) information on intubation, invasive mechanical ventilation and tracheal tube suction 5) necessity of central/peripheral lines and IV/drips, and 6) information and necessity of the treatment team and ICU workflow (24). The module will be watched via HMD-VR glasses (PICO G2 VR; Pico Technology, Beijing, China) with the SyncVR Relax & Distract application (SyncVR, Utrecht, the Netherlands). This application allows patients to see different pre-recorded films with the aim to reduce stress and anxiety and the ICU-VR film are implemented within the application. Only the ICU-VR films will be used during this study. Participants are allowed to move their head freely so that they could experience all aspects of the virtual space.
As part of regular care, all patients will be invited to an ICU follow-up clinic 3 months after ICU discharge. Patients will be invited approximately 2.5 months after ICU discharge. Before the ICU follow-up clinic visit, patients will have a consult with a dedicated ICU-nurse under supervision of an intensivist. If needed, patient will be referred to a healthcare professional, such as a psychologist, a revalidation physician, or a physiotherapist.

Patients will be randomized into three groups:
- The control group: Patients randomized to this group will receive care as usual including a visit to an ICU follow-up clinic three months after discharge, but will not receive ICU-VR.
- The early ICU-VR group: Patients randomized to this group will receive care as usual including a visit to an ICU follow-up clinic three months after discharge and will receive ICU-VR for a maximum of three times within two weeks after hospital discharge during recovery in the hospital ward.
- The late ICU-VR group: Patients randomized to this group will receive care as usual including a visit to an ICU follow-up clinic three months after discharge and will receive ICU-VR once during this visit.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- ≥18 years old
- ICU-Length of stay ≥72 hours
- Mechanical ventilation ≥24 hours
- Able to read and speak in the Dutch language
- Signed informed-consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Documented active, established psychiatric disease (for instance personality disorders, posttraumatic stress disorder, schizophrenia, severe depression). Patients who have suffered from psychiatric diseases in the past can participate.
- A history or a primary neurological impairment necessitating ICU treatment (patients admitted with traumatic brain injury, CVA, stroke, meningitis).
- Decreased cognitive functioning during inclusion, as defined by a Telephone Interview for Cognitive Status (TICS) score less than 27. The Telephone Interview for Cognitive Status (TICS) will be used directly after signing informed consent and is a brief, standardized test for cognitive functioning that was developed for use in situations where in-person cognitive screening is impractical of inefficient (25, 26).
- Active delirium during inclusion
- Lack of formal home address
- Moribund patients at the ICU or hospital ward with a life expectancy <48 hours of receiving palliative care

Onderzoeksopzet

Opzet

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

Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2021
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
The final, deidentified individual clinical trial participant-level data will be shared upon publication of the results of this study.

Ethische beoordeling

Positief advies

Datum:	21-10-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54059
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9812

Register	ID
CCMO	NL78555.100.21
OMON	NL-OMON54059

Resultaten

Samenvatting resultaten
Safety in healthy volunteers:
https://journals.lww.com/ccejournal/Fulltext/2021/05000/Virtual_Reality_Tailored_to_the_Needs_of_Post_ICU.7.aspx

ICU-VR in sepsis survivors:
https://journals.lww.com/ccejournal/Fulltext/2021/09000/Virtual_Reality_to_Improve_Sequelae_of_the.20.aspx

ICU-VR in COVID-19 survivors:
Protocol:
https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-021-05271-z

Case-report:
https://www.frontiersin.org/articles/10.3389/fmed.2020.629086/full