

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.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28097

Source

Nationaal Trial Register

Brief title

HORIZON-IC study

Health condition

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

Sponsors and support

Primary sponsor: Erasmus MC, Rotterdam, the Netherlands & Franciscus Gasthuis & Vlietland, Rotterdam, the Netherlands

Source(s) of monetary or material Support: BeterKeten, DSW, Stichting Theira, Stichting SGS

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary outcomes are:

- 1) The difference in the severity of PTSD-, anxiety- and depression-related symptoms and the prevalence of probable PTSD throughout follow-up at each follow-up time-point and throughout follow-up.
- 2) The difference in Health-Related Quality of Life at each follow-up time-point and throughout follow-up.
- 3) Patients' satisfaction with ICU aftercare

Study description

Background summary

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 or 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 or later after ICU discharge, and to assess 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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

Public

Erasmus MC
Johan Vlake

+31641545743

Scientific

Erasmus MC

Johan Vlake

+31641545743

Eligibility criteria

Inclusion criteria

- ≥ 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

Exclusion criteria

- 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 or 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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-11-2021
Enrollment:	300
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description

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

Ethics review

Positive opinion	
Date:	21-10-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 54059
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register

NTR-new

CCMO

OMON

ID

NL9812

NL78555.100.21

NL-OMON54059

Study results

Summary results

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>