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

Summary

ID

NL-OMON54059

Source
ToetsingOnline

Brief title
The HORIZON-IC study

Condition

- Other condition
- Anxiety disorders and symptoms

Synonym
anxiety, depression, post-traumatic stress disoder

Health condition

post-intensive care syndroom (angst/post-traumatische stress/depressie)

Research involving
Human

Sponsors and support

Primary sponsor: Franciscus Gasthuis & Vlietland
Source(s) of monetary or material Support: Ministerie van OC&W,Stichting BeterKeten

Intervention

Keyword: Intensive Care Unit, Post-Intensive Care Syndrome, Post-Traumatic Stress Disorder, Virtual Reality

Outcome measures

Primary outcome

The primary endpoint is the difference in the severity of PTSD-related symptoms

six months after ICU discharge between patients in the control group, patients

in the early ICU-VR group, and patients in the late ICU-VR group.

Secondary outcome

The secondart study endpoints are the severity of PTSD-, anxiety, and

depression-related symptoms and the prevlaence of probable PTSD, anxiety and

depression up to 12 months after hospital discharge and the overall, mental,

and physical health-related quality of life up to 12 months after hospital

discharge.

Study description

Background summary

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 an ICU-specific Virtual Reality (ICU-VR) intervention is safe, feasible, and immersive. Also, ICU-VR appears to improve psychological recovery, mental HRQoL, and satisfaction with ICU aftercare in a two-center pilot study.

Study objective

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 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.

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.

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-VR nor in other studies using VR. VR is a non*invasive technique and participants do not have to undergo extra procedures. In addition, the questionnaire that is being used is 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
• 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.
• 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)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-12-2021
Enrollment:	270
Type:	Actual

Medical products/devices used

Generic name:	Intensive Care Unit-specific Virtual Reality within the SyncVR Relax & Distract application.
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	20-10-2021

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-12-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-03-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-01-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-06-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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: 28097
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL78555.100.21
Other	NL9812
OMON	NL-OMON28097