# 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)

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### **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

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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

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ed)

Primary purpose: Prevention

## Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	14-12-2021
Enrollment:	270
Туре:	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
ССМО	NL78555.100.21
Other	NL9812
OMON	NL-OMON28097