# Virtual reality for relatives of ICU patients (ICU-VR-F) to improve psychological sequelae.

No registrations found.

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

## Summary

### ID

NL-OMON23834

**Source**
Nationaal Trial Register

**Brief title**
ICU-VR for relatives (ICU-VR-F)

**Health condition**

Post-Intensive Care Syndrome Family (PICS-F), post-traumatic stress disorder, anxiety, depression

### Sponsors and support

**Primary sponsor:** Erasmus Medical Center, Rotterdam, the Netherlands
**Source(s) of monetary or material Support:** BeterKeten, DSW, Stichting Theia, Stichting SGS

### Intervention

### Outcome measures

**Primary outcome**

The primary endpoint is the effect of ICU-VR-F on PTSD, anxiety, depression, and quality of

life in relatives of ICU patients up to six months after ICU discharge. PTSD will be assessed using the impact of event scale-revised (IES-R), anxiety and depression using the hospital anxiety and depression scale (HADS), and quality of life using the RAND-36.

### Secondary outcome

The secondary endpoint is the participants' understanding of ICU procedures, i.e., monitors, sounds, and daily work practice. Participants' understanding of ICU procedures will be assessed using a subset of the Consumer Quality Index – Relatives in the ICU (CQI-Relatives in the ICU).

Additional outcomes are the perceived stress factors of ICU treatment in relatives of ICU patients and the perspectives of relatives on the ICU-VR-F intervention, assessed using the Caregivers Strain Index (CSI), a self-composed 'perceived stress factors' questionnaire, and a self-composed 'perspectives on the ICU-VR intervention' questionnaire.

## Study description

### Background summary

An Intensive Care Unit (ICU) admission of a relative can lead to psychological distress and complicated grief in relatives due to the unknown and often unexpected situation and worries about their kin (post–intensive care syndrome–family; PICS-F). Evidence suggests that increased distress during ICU stay increases risk of PICS-F, resulting in difficulty returning to their normal lives after their ICU experience. To date, effective interventions to improve PICS-F-related sequelae are lacking. In the current trial, we hypothesized that information provision using Intensive Care Unit-specific Virtual Reality for Family members/relatives (ICU-VR-F) can improve understanding of ICU treatment and surrounding and subsequently improve psychological well-being and quality of life in relatives of patients admitted to the ICU.
This multicentre, clustered randomized controlled trial will be conducted from January to December 2021 in the mixed medical-surgical ICUs of four hospitals in Rotterdam, the Netherlands. We aim to include adult relatives (or close friends) of 160 ICU patients, with an expected ICU length-of-stay (ICU-LOS) over 72 hours. Participants will be randomized per patient in a 1:1 ratio to either the intervention or control group. Participants allocated to the intervention group will receive ICU-VR-F, a 10-minute lasting information module that can be watched in VR, while participants in the control group will receive usual care. Initiation of ICU-VR-F will be during their initial hospital visit, unless participants cannot visit the hospital due to COVID-19 regulations, than VR can be watched digitally. The primary objective is the effect of ICU-VR-F on psychological well-being and quality of life up to 6 months after ICU discharge of the patient. The secondary outcome is the degree of understanding of ICU treatment and ICU modalities.

### Study objective

We hypothesize that offering treatment- and environment-related information about the ICU through VR increases relatives' understanding of ICU treatment and environment, and subsequently improves psychological well-being and mental quality of life.

### Study design

T0: ICU admission (within 48 hours); retrospective assessment of psychological distress (HADS) and health-related quality of life (RAND-36) prior to the ICU admission.

T1: At ICU discharge; Subset of the CQI-relatives in the ICU (understanding of the ICU), the perspectives on the ICU-VR-F intervention questionnaire (only the interventional group), the perceived stress factors questionnaire and the IES-R (PTSD).

T2/3/4: At 1, 3, and 6 months after ICU discharge; the perspectives on the ICU-VR-F intervention questionnaire (only the interventional group), RAND-36 (HRQoL), IES-R (PTSD), HADS (anxiety and depression) and the CSI (caregivers strain)

### Intervention

The ICU-VR-F module was adapted to a prior designed patient VR module to match the need of relatives. The current VR module was designed with the aim to show relatives relevant and truthful information regarding their ICU treatment. The point of view for the camera was the field of vision of the mock patient lying in a hospital bed. Based on focus group meetings and previous studies, the following information was included in the module: 1) an introduction by an intensivist and an ICU nurse to welcome the patient to the ICU and VR environment explaining daily movements at an ICU, 2) explanation of monitors and noises in an ICU room, 3) information regarding mechanical ventilation, intubation and tracheal tube suction, 4) necessity of central/peripheral lines and IV/drips, 5) information and necessity of the treatment team and ICU workflow.
After randomization, participants in the intervention group will receive ICU-VR using head-mounted display VR (Oculus Go, Irvine, CA, CE: R-CMM-OC8-MH-A), followed by the possibility to watch the ICU-VR-F module again whenever desirable via cardboard VR glasses through an access link. The number of sessions via the cardboard VR glasses will be noted. Participants who are not allowed to visit the hospital due to COVID-19 regulations, i.e., mandatory self-quarantine, inability to visit the ICU, or a limited number of visitors, will only receive ICU-VR-R using cardboard VR glasses.

## Contacts

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# Eligibility criteria

## Inclusion criteria

• ≥18 years old
• First/second degree relatives (spouses, sibling, parent, children), responsible for decision making, sharing the same household (in absence of next of kin), or close friend (in absence of other relatives)
• Able to understand the Dutch language
• In possession of a smartphone/tablet compatible to watch ICU-VR-F at home
• Signed informed-consent

## Exclusion criteria

• Lack of a formal home address
• Family members of patients with an ICU-LOS <72 hours
• Relatives of patients who decease during ICU treatment will retrospectively be excluded from the main analysis

# Study design

## Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 25-01-2021 |
| Enrollment: | 160 |
| Type: | Anticipated |

## IPD sharing statement

**Plan to share IPD:** Yes

**Plan description**
The de-identified individual clinical trial participant-level data will be shared as supplemental material when publishing about the findings of the study.

# Ethics review

Positive opinion

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|---|---|
| Date: | 25-01-2021 |
| Application type: | First submission |

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 52583
Bron: ToetsingOnline
Titel:

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

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL9220 |
| CCMO | NL73670.078.20 |
| OMON | NL-OMON52583 |

# Study results