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

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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.

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

Samenvatting

ID

NL-OMON23834

Bron
Nationaal Trial Register

Verkorte titel
ICU-VR for relatives (ICU-VR-F)

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus Medical Center, Rotterdam, the Netherlands
Overige ondersteuning: BeterKeten, DSW, Stichting Theia, Stichting SGS

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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)

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• ≥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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	25-01-2021
Aantal proefpersonen:	160

Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

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

Ethische beoordeling

Positief advies

Datum:	25-01-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52583
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten