Intensive Care Unit specific Virtual Reality for family members (ICU-VR-F) of patients in the ICU.

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

Summary

ID

NL-OMON52583

Source
ToetsingOnline

Brief title
ICU-VR for family members

Condition

- Other condition
- Anxiety disorders and symptoms

Synonym
post-intensive care syndrome family (PICS-F), PTSD

Health condition

psychische klachten na IC opname van naaste, kwaliteit van leven

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Subsidie van Stichting Coolsingel;subsidie van Stichting BeterKeten;subsidie van Franciscus Vriendenfonds

Intervention

Keyword: Intensive Care, Post-intensive care syndrome family (PICS-F), Virtual Reality

Outcome measures

Primary outcome

The primary endpoint is the effect of ICU-VR-F on the psychological distress (depression, anxiety and PTSD) and HRQoL in family members of ICU patients up to 6 months after ICU discharge.

Secondary outcome

The secondary endpoint is the understanding of the ICU in family members of ICU patients. Other, explorative endpoints are the perceived stress factors of ICU treatment in family members of ICU patients, and the perspective of family members on the ICU-VR-F intervention.

Study description

Background summary

An Intensive Care Unit (ICU) admission of a family member can lead to anxiety, depression, and induce post-traumatic stress disorder (PTSD) and complicated grief in family members due to the unknown and often unexpected situation and worries about the critically ill patient. The inability to visit patients in the ICU during the COVID-19 pandemic is expected to further increase this risk. These impairments are part of the so-called Post-Intensive Care Syndrome Family (PICS-F). To date, there is a lack of effective interventions to ameliorate PICS-F, although provision of information may be of added value. In the current trial, we hypothesized that information provision using an Intensive Care Unit specific Virtual Reality intervention for Family members (ICU-VR-F) can improve

understanding of the ICU and subsequently reduces psychological distress and improves health-related quality of life (HRQoL) in family members of patients admitted to the ICU.

Study objective

Our primary objective is to determine the effect of ICU-VR-F on symptoms of depression, anxiety and PTSD, and the health-related quality of life (HRQoL) in family members of ICU patients. The secondary objective is to determine the effect of ICU-VR-F on the understanding of and satisfaction with ICU care.

Study design

A multicentre, clustered randomized trial conducted in one academic and three teaching hospitals in Rotterdam, the Netherlands.

Intervention

Family members will be randomized, based on the patient that is admitted, into two study groups, multiple family members per patient can be included and will be allocated clustered to the same randomization group. Family members in the intervention group who are allowed to visit the hospital will receive ICU-VR-F the first time in the hospital. Furthermore, the intervention group will receive Intensive Care Unit specific Virtual Reality for Family (ICU-VR-F), a 15-minute lasting information video that can be watched using Virtual Reality or 2D, using an access link and cardboard VR glasses. The control group will receive care as usual.

Study burden and risks

No additional burden is expected. ICU-VR, the patient version of ICU-VR-F, was previously tested safe in healthy volunteers and sepsis survivors and is currently used in a trial in survivors of COVID-19. No safety issues or adverse events have been reported using ICU specific VR content nor in other studies using VR of an informational video. Patients are asked to fill out questionnaire for a total of four times.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• >= 18 years old
• First degree family member (sibling, parent, children), responsible for decision making, or sharing the same household (in absence of next of kin)
• Able to understand the Dutch language
• In possession of a smartphone/tablet which is compatible to watch the ICU-VR module at home
• Signed informed consent

Exclusion criteria

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

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):	27-01-2021
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	14-12-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-02-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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: 23834
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL73670.078.20
OMON	NL-OMON23834