Intensive Care Unit-specific Virtual Reality as preparation for ICU admission in lung transplant patients

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To evaluate the contribution in terms of information provision and patients* perspectives of ICU-VR to prepare lung transplant patients for their future ICU admission

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

Summary

ID

NL-OMON57322

Source
ToetsingOnline

Brief title
ICU-VR LOTX PREP study

Condition

- Other condition

Synonym
Posttrauamtic stress disorder

Health condition

PTSS

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

Intervention

Keyword: ICU-VR, Lung transplant patients, Preparation

Outcome measures

Primary outcome

The primary endpoint will be the difference in information provision of the ICU

care of lung transplant patients on the waiting list.

Secondary outcome

Patients' perspectives about the ICU-VR intervention and the lung transplant

preparation process. We also measure PTSD symptoms 2 weeks after ICU admission.

Study description

Background summary

A substantial proportion of the Intensive Care Unit (ICU) survivors develop psychological impairments due to their ICU admission. Several interventions to mitigate these impairments have been explored but lack a proper effect. Intensive Care Unit-specific Virtual Reality has proven to be potentially effective in treating PTSD and depression-related sequelae in ICU-survivors.

Study objective

To evaluate the contribution in terms of information provision and patients* perspectives of ICU-VR to prepare lung transplant patients for their future ICU admission

Study design

A monocentre randomized controlled study.

Intervention

The ICU-VR intervention is 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. During the 12-minute lasting intervention, patients experience different facets of ICU treatment and receive information on the ICU environment, treatment and workflow. The intervention group will receive this treatment as many times as desired, as part of the study outcomes, during the appointment with the lung transplantation nurse. The placebo group will receive standard care and no additional intervention.

Study burden and risks

The safety and immersiveness of the ICU-VR module was previously examined in healthy volunteers. ICU-VR did not lead to clinically relevant symptoms of cybersickness or to changes in vital signs and VR resulted in high immersion scores. The feasibility, safety, and effect were tested in a pilot study in sepsis survivors. There were no safety concerns, the intervention was feasible, and may improve psychological impairments following critical illness. The questionnaires will take approximately 15-20 minutes to fill in. No risks are expected for participating patients. Participants in the intervention group will have to visit the hospital once to undergo the VR session, this will be combined with other hospital appointments as much as possible to minimize the time burden for participants.
Potential benefits of the study are a better understanding of the ICU environment, workflow, and treatment, a reduction in PTSD after ICU discharge, and an increased satisfaction with the preparation and aftercare of the ICU.

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

On the waiting list for lung transplantation
Able to understand en read the Dutch language

Exclusion criteria

Epilepsy

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2025

Enrollment:	24
Type:	Anticipated

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:	27-02-2025
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT06642636
CCMO	NL87675.078.24