VRET in sepsis survivors

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27123

Source
NTR

Brief title
VRET-ICU

Health condition

ENGLISH/DUTCH

Virtual Reality Exposure Therapy; Sepsis; ICU; PTSD; depression

Sponsors and support

Primary sponsor: Franciscus Gasthuis & Vlietland hospital
Source(s) of monetary or material Support: Stichting Coolsingel; Foundation Friends of Franciscus Gasthuis & Vlietland

Intervention

Outcome measures

Primary outcome

Feasibility of VRET with measures of cybersickness, presence, practicability and the number of patient’s needed/desired sessions among ICU sepsis survivors.

Secondary outcome

- Measure the effect of ICU-specific VRET on psychological PICS related symptomatology, such as PTSD, depression, and anxiety among ICU sepsis survivors.

Other outcomes:

- Tolerability

- other post-ICU syndrome symptomatology using the questionnaire

- quality of life

- health care use

- Treatment related information

Study description

Background summary

Critically ill patients admitted to the ICU often experience long term ICU related physical complications, psychological complications such as post-traumatic stress disorders and depression, and cognitive complications such as memory and attention deficit. These impairments are part of the 'post-ICU syndrome' (PICS). Of these patients, sepsis patients demonstrate a sharp decline of quality of life during ICU stay, which slightly improves at the ward but may persist until 6 months after discharge. Until now there is hardly any treatment to improve psychological recovery and quality of life after discharge from the ICU.

VRET (virtual reality exposure therapy) effectively circumvents the natural tendency to avoid traumatic memories by directly delivering multisensory and contextual cues that help the patient retrieve, confront, and process these experiences. Several recent studies showed beneficial effects of VRET for patients with several mental health disorders such as panic disorders, social anxiety, fear of public speaking, for the management of psychological stress, and in patients with post-traumatic stress disorder. From a psychological point of view VRET may help to modify behaviors, thoughts, and emotions through virtual experiences designed for and adapted to the person's needs, in order to facilitate and enhance a process of change. VRET can provide patients with detailed/visual information about their ICU admission and illness. We therefore hypothesized that VRET in sepsis survivors is feasible and safe and might be able to reduce psychological post-ICU syndrome-related impairments.

COUNTRY OF RECRUITMENT: The Netherlands

Study objective

We hypothesized that a Virtual Reality Exposure Therapy in sepsis survivors is feasible and safe and might be able to reduce psychological post-ICU syndrome symptomatology such as PTSD, depression, and anxiety.

Study design

There are different moments of assessment:

1 - Four days after ICU discharge we will start with the specific designed questionnaire (before the intervention) for the concurrent assessment.

2 - Hereafter we will start with the VRET

3- After the VRET symptomatology will be assessed and;

4- 1 week after VRET (follow-up)

5- 1 month after VRET (follow-up)

6- 6 months after VRET (follow-up)

Intervention

The VRET-ICU module encompasses a 1:1 real virtual, three dimensional (3D) environment that shows the current ICU of the Franciscus Gasthuis Hospital. This is a 16-bed ICU in Rotterdam, the Netherlands. In this virtual environment, patients will see the ICU and will re-experience an ICU admission. During this structered tour different aspects of the ICU will be explained. Such as; explaining space design (i.e. ICU environment), modified procedures (i.e. ward rounds) and stressing several stressful experiences (such as intubation).

The control/placebo group will have a control experience. It exists of the VR Head-mounted-display without actual VR treatment, it consist of a freezed frame of a surrounding by choice.

Contacts

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Eligibility criteria

Inclusion criteria

Consecutively admitted patients to the ICU:

- Patients with prolonged mechanical ventilation (>24 hours)

- Understanding of the Dutch language

- Admitted to the ICU with sepsis or septic shock according to the recent guidelines

- Patients between 18-75 years of age.

- Maximal Glasgow Coma Score at start of the VRET

- No clinical suspicion for active delirium at start of the VRET. Delirium is defined as a positive CAM-ICU >1, or if a screening tool is not used, pragmatically defined as 1) new administration of haloperidol >1mg/day or other antipsychotic drug; or 2) delirium reported by a physician or ICU nurse in the patient record, as confirmed by a designated research nurse on site.

- Mentally competent. As judged by the attending ICU physician, nurse or dedicated researcher

- Signed informed consent

- Patients must be mentally competent (TICS score)

Exclusion criteria

The key exclusion criterion is cognitive impairment, as determined by the Telephone Interview of Cognitive Status (score ≤27).

- Patients who are pregnant

- Patients with established schizophrenia.

- Patients known with epilepsy

- Patients with documented epileptic seizures the year prior to ICU admission

- Known participation in another randomized controlled biomedical study

- Patients admitted after stroke, cerebral vascular accident or traumatic brain injury

- Patients admitted after drowning or drug overdose

- No signed informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2017
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-11-2017

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47028
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6611
NTR-old	NTR6795
CCMO	NL57641.101.16
OMON	NL-OMON47028

Study results