# Feasibility and clinical relevance of Virtual Reality Exposure Therapy in sepsis survivors

Published: 22-02-2017
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To evaluate the feasibility and clinical application of Virtual Reality (headmounted display and software) among sepsis survivors.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON47028

**Source**
ToetsingOnline

**Brief title**
Virtual Reality among sepsis survivors

### Condition

- Other condition

**Synonym**
PTSD, Virtual Reality

**Health condition**

psychischische ervaring /onduidelijkheid na IC opname

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Sint Franciscus Gasthuis
**Source(s) of monetary or material Support:** Ministerie van OC&W,Subsidie van Stichting Coolsingel

## Intervention

**Keyword:** Intensive Care, PTSD, sepsis., Virtual Reality

## Outcome measures

### Primary outcome

To evaluate the feasibility and clinical relevance of Virtual Reality Exposure

Therapy among survivors of sepsis

### Secondary outcome

1. To determine if adaptation (pre-exposure) is accompanied with a reduction of

cybersickness during the VR-ICU application

Treatment related information for healthy volunteers and patients

- Age

- Sex

- BMI

- Race

- Heart rate

- Saturation

- Respiratory rate

Treatment related information only in patients.

- Biochemical data

- Source of infection, No. (%) (Community acquired vs nosocomial)

- Recent surgical history, No. (%)

- Sputum cultures

- Blood cultures

- Wound cultures

- ICU stay (days)

- Hospital stay (days)

- APACHE II / APACHE IV / SOFA score.

- Days of mechanical ventilation (endotracheal vs tracheotomy)

- Noninvasive ventilation

- Renal replacement therapy

- Use of vasopressors

- Use of (analgo)-sedatives (remifentanil/ propofol etc)

- Use of analgetics (morfine / paracetamol / sufentanyl / fentanyl)

- Scoring of delirium

- Use of Haldol

- RASS score

- VAS score

- CAM ICU score

- TICS score

# Study description

**Background summary**

Therapy with VR is based on exposure-based therapy (VR-EBT or VRET: virtual reality exposure therapy). VRET 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. VR also provides the therapist with an objective and consistent format for documenting the sensory stimuli to which a patient is exposed and the resulting reactions; if this is not possible then the therapy operates exclusively within the unseen world of the patient*s imagination
VR typically refers to computer technologies that use software to generate realistic images, sounds and other sensations that replicate a real environment (or create an imaginary setting), and simulate a user's physical presence in this environment, by enabling the user to interact with this space and any objects depicted therein using specialized display projectors. Most 2016-era virtual realities are displayed with a virtual reality headset (also called head-mounted display or HMD). Virtual realities artificially create sensory experiences, which can include sight, touch, and hearing.

Medical therapies might benefit from becoming integrated in future exciting technical innovations, such as VR. VR is still far from mainstream in the medical world, but its tri-dimensional environment has potential to influence multiple areas that can immediately impact both patients and physicians. VR-training has already been shown to improve operating room performance in surgeons6 and in ophthalmologists , and helps training of general practitioners in prescribing antibiotics.
In addition, 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. Besides improving cognitive and psychological performance, recent research demonstrated that VRET may also have a beneficial effect on physical function. For instance VR has a positive impact in alleviating pain after burn injury, improves motor function in older patients, and improves balance and gait after stroke. Moreover, a recent trial demonstrated that VR is a non-invasive, non-pharmacological, and engaging treatment with no identified side-effects after critical illness.
In conclusion, VR is a highly potential technique which concurrently may have beneficial value in different aspects of treating mental disorders and might improve rehabilitation.

Critically ill patients admitted to the ICU often experience long term ICU related physical and psychological complications, such as post-traumatic stress disorders, depression, memory and attention deficit and pulmonary and neuromusculair impairments. These impairments are part of the *post-ICU syndrome* (PICS) which is associated with a decreased quality of life and a significant socioeconomic burden.
All of these problems are prominently present in survivors of sepsis who are mechanically ventilated >48 hours. Sepsis is de*ned as a powerful in*ammatory

response to severe infection. The annual total cost of sepsis syndromes in the USA is $16.7 billion nationally. As the incidence is projected to increase by 1.5% per year, sepsis possess a major public health concern. The risk of dying from sepsis has decreased in recent decades, owing to earlier detection and more effective treatment. 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. Because more patients survive sepsis and are increasingly discharged from the hospital, it is to expect that more patients have sequelae of the post-ICU syndrome and have declined of quality of life. Several interventions to ameliorate post-ICU syndrome have been implemented in the ICU, and in the hospital ward.
The effect of timing on different aspects of the post-ICU syndrome are however still undetermined

Until now there is hardly any treatment to improve psychological recovery after discharge from the ICU. VRET can provide patients with detailed/visual information about their ICU admission and illness, we hypothesized that a VRET in sepsis survivors is able to reduce post-ICU syndrome related impairments irrespective of implementation at the ICU or at the ward.
The primary aim of the present pilot study is to determine whether VRET among sepsis survivors on is feasible and could influence sequelea of the post-ICU syndrome. A part of this VRET is pre-exposure, we will incorporate this as part of the study

## Study objective

To evaluate the feasibility and clinical application of Virtual Reality (headmounted display and software) among sepsis survivors.

## Study design

A multi center, randomized, placebo-controlled pilot study

## Intervention

Therapy with VR is based on exposure-based therapy (VR-EBT or VRET: virtual reality exposure therapy). VRET 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. VR also provides the therapist with an objective and consistent format for documenting the sensory stimuli to which a patient is exposed and the resulting reactions; if this is not possible then the therapy operates exclusively within the unseen world of the patient*s imagination. VRET is extensively used in the psychology for treatment.

## Study burden and risks

No additional burden for the patient is expected. The VR technique is non* invasive and the patient does not have to undergo extra invasive interventions. No risks of VRET are currently known. Moreover several future studies showed that VRET can be easily applied in elderly patients and does no harm nor had side-effects.

## 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

1. Healthy volunteers
- 18-75 years
- no previous history of ICU admission
- no previous VR experience
- no pregnant woman will be included

- no history of mental illness
- signed informed consent;2. Survivors of sepsis staying at the ICU
Patients with prolonged mechanical ventilation (>24 hours) and understanding of the Dutch language are eligible for study participation if they are fulfilling the following criteria:
- Sepsis or septic shock according to the recent guidelines
- Patients between 18-75 years of age.
- Patients must be awake during VR-application
- Maximal Glasgow coma score.
- No clinical suspicion for an untreatable delirium. 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.
- Signed informed consent;3. Survivors of sepsis admitted to the hospital ward after ICU discharge
Patients with prolonged mechanical ventilation (>24 hours) and understanding of the Dutch language are eligible for study participation if they are fulfilling the following criteria:
- Sepsis or septic shock according to the recent guidelines
- Patients between 18-75 years of age.
- Patients must be awake during VR-application
- Maximal Glasgow coma score.
- No clinical suspicion for an untreatable delirium. 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.
- Signed informed consent

## Exclusion criteria

1. Healthy volunteers
- Volunteers with established schizophrenia.
- Volunteers known with epilepsy;2. Survivors of sepsis staying at the ICU / 3. Survivors of sepsis admitted to the hospital ward after ICU discharge
The key exclusion criterion was cognitive impairment, as determined by the Telephone Interview of Cognitive Status (score <=27). The TICS is a brief, standardized test of cognitive functioning that was developed for use in situations where in-person cognitive screening is impractical or inefficient, i.e. an ICU ward in which there is high turnover of critically ill patients. Moreover TICS can be used in participants with visual or motor impairments and is proven to be useful in older patients. Although the TICS is designed to be administered using the telephone, it also may be administered face-to-face. We therefore will use the TICS in the current study.
Furthermore the following patients will be excluded:
- Patients who are pregnant
- Patients with established schizophrenia.
- Patients admitted for status epilepticus
- Patients known with epilepsy

- Patients with documented epileptic seizures the year prior to ICU admission
- Patients admitted after stroke, cerebral vascular accident, known hemiplegia or traumatic brain injury
- Patients admitted after drowning or drug overdose
- No signed informed consent

# Study design

## Design

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-11-2017 |
| Enrollment: | 70 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 22-02-2017 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 20-06-2018 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

# 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: 27123
Source: NTR
Title:

## In other registers

| Register | ID |
|---|---|
| CCMO | NL57641.101.16 |
| OMON | NL-OMON27123 |