Reducing Pain and Anxiety with Virtual Reality at the Emergency department, in children

Published: 19-02-2024
Last updated: 27-12-2024

Primary- Does the application of Virtual Reality (VR) reduce anxiety in patients undergoing treatment for traumatic injury in the emergency department compared to patients not using VR headset? Secondary- Does the use of Virtual Reality (VR) lead to...

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

Summary

ID

NL-OMON56622

Source
ToetsingOnline

Brief title
REPAVE-C

Condition

- Fractures
- Skin and subcutaneous tissue therapeutic procedures

Synonym
traumatic injury

Research involving
Human

Sponsors and support

Primary sponsor: OLVG
Source(s) of monetary or material Support: SGO fonds en wetenschappelijk

subsidiefonds OLVG

Intervention

Keyword: anxiety, children, pain, virtual reality

Outcome measures

Primary outcome

Anxiety reduction (Δ anxiety = preprocedural STAI-C - postprocedural STAI-C).

The anxiety score is measured with STAI-C (State-Trait Anxiety Inventory - Children, abbreviated version). The STAI-C score is measured before and after the procedure. The questionnaire consists of 6 items with 3 options:

1) I feel: very calm, calm or not calm

2) I am: very tense, tense or not tense

3) I am: very confused, confused or not confused

4) I feel: very relaxed, relaxed or not relaxed

5) I feel: very satisfied, satisfied or not satisfied

6) I am: very worried, worried or not worried

Secondary outcome

- Postprocedural anxiety score (STAI-C)

- Painreduction (postprocedural painscore - preprocedural pain score)

- Pain score after treatment, using WONG-Baker Faces Scale Indicator for Pain

- Procedural distress (distress) and coping of a child periprocedural, measured with the CAMPIS-SF score (Child Adult Medical Procedure Interaction Scale - Short Form).

- Coping and distress promoting factors by parents and healthcare provider measured with the CAMPIS-SF

- VRMS (virtual reality motion sickness) during the procedure

- Treatment satisfaction, both child and parents

- VR headset use satisfaction, by child, parents and healthcare provider

- Duration of treatment in minutes (start treatment to discharge)

- Future perspective of using a VR headset for a medical intervention

Study description

Background summary

Children often undergo painful and stressful procedures in the emergency department. There has been much focus on providing trauma-free care in hospitalised children, as inadequate pain management can lead to traumatic experiences, increased anxiety and stress, decreased patient satisfaction and, in the long term, even risk of care avoidance. Moreover, exposure to the procedure contributes to increasing levels of procedural distress and, consequently, the intensity of pain.

A pain-free procedure using 'procedural sedation and analgesia' (PSA) is not feasible for every patient in the emergency department. This is partly due to the time burden of one to two hours and the presence of trained staff. Furthermore, PSA is not strictly pain-free: intravenous access must be created. Also, PSA is not desirable in every patient because of the risks of complications (cardiopulmonary, anaphylaxis or aspiration). Careful consideration must be made per patient.

Recent studies have shown that Virtual Reality (VR) is an effective and non-invasive distraction method to reduce pain and anxiety perception in children during various medical procedures such as blood sampling, dressing change in burns and obtaining intravenous access in chemotherapy. The advantage of a VR headset is that a virtual 3D environment is created and thus the child is not exposed to the medical procedure. This has also led to higher patient satisfaction in previous studies. Given these experiences, VR headsets could provide a solution for anxious and painful patients who are not eligible for PSA in the emergency department.

To date, no studies have been conducted on the use of a VR headset in the treatment of traumatic injuries in children. It is hypothesised that the use of a VR headset will reduce the anxiety, pain and procedural distress levels in

children undergoing trauma-related treatment in the emergency department.

Study objective

Primary
- Does the application of Virtual Reality (VR) reduce anxiety in patients undergoing treatment for traumatic injury in the emergency department compared to patients not using VR headset?

Secondary
- Does the use of Virtual Reality (VR) lead to pain reduction in children undergoing treatment for traumatic injury in the emergency department compared to the non-VR group
- Is there a difference in post-procedural anxiety and painscore in children undergoing treatment for traumatic injury (between the groups)?
- Does the use of VR headset lead to less procedural distress and better coping in contrast to the non-VR group?
- Is there a difference in duration of treatment and amount of pain relief between the two groups?
- Investigating patient satisfaction and satisfaction of children, parents and caregivers regarding the use of VR headset

Study design

* A single-centre prospective randomised trial (n=112)
* This study is conducted at the emergency department in Onze Lieve Vrouwe Gasthuis (OLVG)

Intervention

VR versus non-VR group (care as usual)

Study burden and risks

Wearing a VR headset is not associated with any risks. Desorientation and balance disturbance is avoided by having the patient sit or lie down during the procedure. The included patients answer some questions before and after treatment of the traumatic injury. Completing this questionnaire takes about 15 minutes per patient. The patients won't receive compensation for participating in this study.

Contacts

Public

OLVG

Oosterpark *
Amsterdam 1091 AC
NL
Scientific
OLVG

Oosterpark *
Amsterdam 1091 AC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Aged 8-18 years
Medical treatment required after traumatic injury (e.g. wound closure, closed reduction of a fracture / luxation)

Exclusion criteria

o Contact isolation
o Resistance
o PSA (Procedural Sedation and Analgesia) with propofol, ketamin and/or midazolam
o Language barrier
o Intellectual disability
o History of epilepsy
o Hearing impairment

o Visual impairment
o High energy injury

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-11-2024
Enrollment:	112
Type:	Actual

Medical products/devices used

Generic name:	SyncVR Relax & Distract
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	19-02-2024
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL83738.100.23