Virtual Reality for Pain Relief in the Emergency Room for Reduction of Fractures and Joint Dislocations

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Primary Objective: Can VR reduce periprocedural and postprocedural pain during reduction of fractures and joint dislocations in the ED? Secondary Objectives: What are the effects of VR on peri-procedural anxiety?Does the level of peri-procedural...

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

Summary

ID

NL-OMON51717

Source
ToetsingOnline

Brief title
VR4ER Reduction

Condition

- Other condition

Synonym
fracture, Joint dislocation

Health condition

Botten en gewrichten

Research involving
Human

Sponsors and support

Primary sponsor: Elisabeth-Tweesteden ziekenhuis
Source(s) of monetary or material Support: WeCare fonds

Intervention

Keyword: Emergency Room, Fracture Reduction, Pain, Virtual Reality

Outcome measures

Primary outcome

Pain intensity will be assessed using a standard numerical rating scale (NRS) ranging from 0 (no pain) to 10 (worst pain ever experienced), before, during and after the intervention.

Secondary outcome

The GAD-7 will be used to assess anxiety in adults.

Pain related fear in children will be assessed using the Children*s Fear Scale (CFS).

Success of VR is defined as the ability to perform the procedure without the need for escape medication.

All adverse events will be recorded.

We will be assessing for cyber sickness using the 9-item Virtual Reality Sickness Questionnaire (VRSQ) [27].

We will measure satisfaction by using a standard numerical rating scale for both the patient and the physician, ranging from 0 (totally unsatisfied) to 10 (totally satisfied).

Additionally, we will ask physicians to score the observed discomfort of patients on a NRS as well, ranging from 0 (no visible pain) to 10 (worst pain ever experienced).

Finally, we will be investigating exploratory eye tracking data in response to procedural pain. We will measure pain by looking at the number of eye blinks, analyzing eye movement (saccades and fixation) as well as gaze direction shifts towards the hemifield of the operational site. Moreover, we will be recording heart rate variability as an additional biomarker to evaluate nociceptive response to the procedurally induced pain via the built in photoplethysmogram sensor of the VR headset.

Study description

Background summary

Pain control is a common challenge in the Emergency Department(ED). Effective pain management influences both patient and physician outcomes and experience. Many ED patients endure significant pain during procedures. Current pain control approaches still rely heavily on pharmacologic agents. Pharmacological agents have the risk of adverse reactions, and are not always satisfactory to achieve sufficient periprocedural analgesia. `
Drawing on the gate control theory, a non-pharmacological alternative for procedural pain management could be Virtual Reality(VR). VR offers the potential to divert patients* attention into an alternative reality, which reduces the focus on pain. Such an intervention could reduce the use of pharmacological agents and improve efficiencies in staff deployment, as well as improving the patient*s experience. Several studies have shown that VR is an effective tool in reducing acute pain experienced during various medical procedures such as labour contractions, episiotomy repair, periodontal procedures or burn-related pain, but did not yet demonstrate any feasability in the ED besides the use on children getting intravascular access. Previous studies have typically focussed on small sample sizes and/or homogenous patient populations. These studies have also often relied heavily on self-report

measures as a primary outcome, which is particularly problematic in VR studies wherein patients cannot be blinded to the intervention. To date, there is little evidence on the usability and performance of VR for pain control during medical procedures performed in the ED. The purpose of this study is to further investigate the use of VR for procedural pain management in the ED.

Study objective

Primary Objective:
Can VR reduce periprocedural and postprocedural pain during reduction of fractures and joint dislocations in the ED?

Secondary Objectives:
What are the effects of VR on peri-procedural anxiety?
Does the level of peri-procedural anxiety influence the success of VR?
What are the differences in adverse events between the intervention and control group?
What effect does the use of VR in ED procedures have on patient, parent (if applicable) and physician satisfaction?
What effect does the use of VR in ED procedures have on the duration of treatment in the ED?
How often was the use of antiemetics necessary in those receiving VR?
Was the procedure performed succesfully?

Study design

A prospective unblinded randomised controlled trial will be conducted in the ED of the Elisabeth TweeSteden hospital in Tilburg, the Netherlands. Patients will be randomised to the intervention group (VR) or the control group (standard of care).

Intervention

A Virtual Reality(VR) Head Mounted Display(HMD) with an additional wristband photoplethysmography sensor will be applied in the intervention group, in addition to the administration of paracetamol and a NSAID.
In the control group, a standard of care approach will be used.

Study burden and risks

a. Level of knowledge about mechanism of action
Drawing on the gate control theory, VR will achieve its pain and anxiety relief by distracting the patient. In daily practice, distraction in children is often accomplished by viewing a movie or listening to music. Recent literature suggests the same applies to adults. VR will achieve this distraction by starting an application that will display a computer generated environment in

front of the patient's eyes. The eyes and ears will be covered up by the device in order to achieve full immersion while the patient is visually and auditory isolated from the real environment., thereby creating a full immersion experience. This immersion will accomplish the feeling of presence in virtual reality. It is suggested that a higher feeling of presence will attain a higher degree of relief of pain and anxiety because less attention is available for the perception of pain.

b. Previous exposure of human beings with the test product(s) and/or products with a similar biological mechanism
As described in chapter 6, the Pico Neo is a relatively new product and so there are not yet any clinical studies reported using this device. It is comparable to HMD*s already in clinical use such as the HTC Vive or Oculus Rift, with the added benefit of being lighter in weight and untethered (wireless). Previous studies have reported VR HMD*s to be well-tolerated by patients .

e. Analysis of potential effect
Meta-analyses have been performed to review the potential benefits and side effects of VR.
Cybersickness is one of the most commonly described potential side effects. While this may be unpleasant, it will not have any long term effects. Weech et al. suggest that presence and cybersickness are negatively correlated though presence is necessary for adequate immersion and thus pain relief and relief of anxiety.
The incidence of cybersickness has been significantly reduced with the advancements of technology but some physical complaints may still occur.

g. Study population
For both the adult patients and the young adolescents, whom will be included in our study, there has been a decent amount of research regarding the effectiveness of VR on acute and the chronic pain, including systematic reviews. These suggest positive effects on pain and anxiety. Though these studies point towards a favourable outcome, they do not particularly highlight effectiveness in an acute ED setting.
Some studies have been performed in the acute setting of the ED and suggest a positive effect on pain, anxiety and even anger. We propose this study to enlighten us further concerning the effectiveness in acute periprocedural pain in the ED.

h. Interaction with other products
None. To avoid dizziness we will exclude patients that received opioids.

i. Predictability of effect
Mallari et al.l reviewed the literature in 2019 and included 20 articles, 10 of which addressed acute pain or procedural pain, nearly all of which showed a favourable outcome on pain.

As described by Eijlers et al. age might be a predictor in the effectiveness of VR. They showed the effect size of VR on pain decreased with 0.26 when age increased by 1 year, suggesting a favourable effect in younger children. Age was a significant predictor of the effect of VR on pain ($P < .001$). They found similar results for anxiety.

j. Can effects be managed?
Relief of pain and anxiety is the main goal of the intervention and is desirable. As described above, negative side effects in the form of cybersickness are possible, but with newer equipment the incidence of these symptoms will most likely be minimised. These effects might be alleviated with the removal of the VR headset and the use of antiemetics if necessary. In the case of insufficient pain relief, patients will be treated by the physician with additional analgesic agents and/or procedural sedation if necessary.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)

Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients aged >= 13 years in the ED undergoing fracture or joint reduction and do not require procedural sedation and analgesia.

Exclusion criteria

- Preprocedural use of opioids or sedatives.
- Patients with epilepsy
- Patients with migraine
- Patient with dementia
- Patients who are intoxicated (alcohol, drugs or other)
- Patients with cognitive impairment
- Patients with injuries to the eyes, face, neck that prevent comfortable use of VR headset
- Patients with a language barrier where it is not possible to get informed consent and/or provide proper instruction.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-10-2023
Enrollment:	40

Type:	Actual

Ethics review

Approved WMO Date:	09-11-2022
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL81388.028.22