Virtual Reality to Reduce Pain and Anxiety During Acute Pain Episodes in Patients with Sickle Cell Disease

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

Summary

ID

NL-OMON56508

Source
ToetsingOnline

Brief title
Fly me to the Moon

Condition

- Haemoglobinopathies

Synonym
Sickle cell disease; Sickle cell anemia

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Stichting Steun Emma Kinderziekenhuis and Sikkelcelfonds

Intervention

Keyword: Pain reduction, Sickle cell disease, Vaso-occlusive crisis, Virtual Reality

Outcome measures

Primary outcome

Study parameter:

• Level of pain reported via NRS.

Endpoint:

• The main endpoint of this study is the pain intensity in SCD patients hospitalized because of a VOC directly before and after the use of intervention and the pattern of pain intensity during hospitalization in both groups.

Secondary outcome

Anxiety of patients:

Study parameter:

• Level of general anxiety reported via PROMIS Anxiety Short-form 8a/PROMIS Anxiety Pediatric Custom Short-form 8, measured in the first 24h of admission and at discharge; and via 1 item from PROMIS Anxiety Pediatric Custom Short-form 8 questionnaire (*I felt scared**), measured directly before and after the use of intervention

Endpoint:

• Statistical difference between groups in the general anxiety level in SCD patients hospitalized because of a VOC.

Pain medication:

Study parameter:

• Total opioid medication dosage during hospitalization (continuous use - data from patient*s electronic record - and PCA pump).

Endpoint:

• Statistical difference between groups in the total opioid medication used by patients during hospitalization because of a VOC.

Length of stay (LOS):

Study parameter:

• Total LOS (data from patient*s electronic record).

Endpoint:

• Statistical difference between groups in the total LOS for a VOC management.

Complications:

Study parameter:

• Presence of ACS, need for blood transfusion and admission to (P)ICU (data from patient*s electronic record).

Endpoint:

• Statistical difference between groups in the total incidence of complications during hospitalization because of a VOC.

VR experience:

Study parameter:

• VR experience interview.

Endpoints:

• Qualitative assessment of VR sessions* feasibility, acceptability,

tolerability and satisfaction.

Tablet experience:

Study parameter:

• Tablet experience interview.

Endpoints:

• Qualitative assessment of the feasibility, acceptability and satisfaction of

tablet sessions

Cost-effectiveness:

Study parameter:

• Health Technology Assessment based, among others, on health-related quality

of life reported via EQ-5D questionnaire and on how many days are the

parents/companion absent from work because of the hospitalization

Endpoints:

• Assessment of cost-effectiveness of VR technology.

Study description

Background summary

Sickle cell disease (SCD) patients can suffer from vaso-occlusive crises (VOC), extremely painful acute episodes that can occur frequently (3x/year), unexpectedly, and last from hours until days . Periodic episodes of painful crises negatively impact the quality of life and may cause negative long-term

effects such as chronic pain syndrome, anxiety and psychological distress that can last into adulthood. Early interventions in children may influence pain perception positively throughout life and may help individuals with SCD to manage their pain and enhance their confidence and resilience.
Adequate management of acute pain in SCD patients is difficult because of its complex nature as a result of its biological, psychological and social components. As pharmacological therapy is insufficient to manage all the aspects of pain, a comprehensive pain management plan is required. Virtual Reality (VR) technology, via distraction, can produce an analgesic effect in patients with pain. This effect has been long studied and also implemented into clinical care, however not within the SCD population. VR has the potential to more effectively reduce sickle cell-related pain and anxiety during a vaso-occlusive crisis. If successful, VR technology can be easily implemented into clinical practice and will contribute to the urgent clinical need to optimize treatment of painful crisis in individuals with SCD.

Study objective

The primary objective is to investigate the efficacy of VR, complementary to standard care, in reducing intensity of pain in SCD patients hospitalized with VOC compared to the efficacy of another distraction method (tablet use) next to standard care. As secondary objectives we will investigate anxiety, total opioid use, length of stay, incidence of complications (including intensive care unit admission, need for blood transfusion, and acute chest syndrome), and the cost-effectiveness of this therapy. The VR sessions* feasibility, acceptability, tolerability and satisfaction will be investigated and compared with control group.

Study design

The study concerns a single centre, randomised controlled trial (RCT).

Intervention

Control group (standard care + tablet): 3 tablet-session per day, lasting 15 minutes. Before and after every session they will answer about their pain and anxiety level. Every day they will answer about their health-related quality of life using (less than 2 minutes). They will also answer, at admission and discharge, to an anxiety questionnaire. At admission, a short socio-demographic list will also be answered by patient/parents. At discharge they will be briefly interviewed about their hospitalization experience and the use of the tablet.
Intervention group (standard care + VR): 3 VR-sessions per day, lasting 15 minutes. Before and after every session they will answer about their pain and anxiety level. Every day they will answer about their health-related quality of life using (less than 2 minutes). They will also answer, at admission and

discharge, to an anxiety questionnaire. At admission, a short socio-demographic list will also be answered by patient/parents. At discharge they will be briefly interviewed about their hospitalization experience and the use of the VR.

Study burden and risks

The risk of participation in this study is expected to be negligibly low. VR technology does not impose any life-threatening or other major risks. The user of the VR glasses can possibly experience complaints of nausea and dizziness. This is called motion sickness, and the side-effects of VR are comparable to the symptoms of carsickness or seasickness. Motion sickness refers to symptoms that can occur during the experience of a virtual environment. The main cause is the conflict of the visual feeling and the physical feeling that you can experience of the virtual environment. When those complaints occur, the intervention can be stopped immediately. The chance of injury by falling of the hospital bed is very small as patients will use the VR glasses while seated or in bed (while using hospital bed side rails), and we will not use intense movement-requiring software. Possible skin and/or eye contamination while using the device will be prevented by the use of hairnets and proper disinfection. Age appropriate software will be downloaded and made available in accordance with advice from SyncVR. With the least risk of a possible harmful effect of the glasses, the VR intervention will be stopped. Even though both pain and anxiety levels will be investigated daily, we have designed this study to be as less of a burden to the patient as possible. Pain level will be measured each time using a NRS that is estimated to take around 30 seconds to be answered. The anxiety questionnaires, PROMIS Anxiety Pediatric Custom Short-form 8/PROMIS Anxiety Short-form 8a, are estimated to take around 2 minutes to be answered, and will only be fully answered in the first 24h of admission and at discharge. One item from the questionnaire PROMIS Anxiety Pediatric Custom Short-form 8 questionnaire (*I felt scared**) will be asked before and after intervention, but it also supposed to be answered in less than 30 seconds. Every day, participants will answer about health-related quality of life by answering the EQ-5D questionnaire, taking less than 2 minutes. At admission, both groups will answer to a short socio-demographic questionnaire, containing only 4 questions. The VR/tablet interview is also supposed to be answered without taking much time from the patient, during less than 15 minutes. The parents/companions of the participants will also be quickly asked, at discharge, how many days were they absent from work because of the hospitalization. Benefits of participating in this study can occur in short- and long-term . The use of VR technology during hospitalization for VOC pain management, if our hypothesis is correct, can lead to reduction of pain, reduction of anxiety, total dosage of opioids, LOS, and incidence of complications. In long-term, participating of this study can help the future development of non-invasive technologies and the implementation of a better pain management plan for SCD patients.
In this way, the possible risks and burdens are outweighed by the benefits

reached.

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)
Children (2-11 years)

Inclusion criteria

• Medical diagnosis of SCD;
• Age between 8 and 25 years old;
• Diagnosed with a current VOC;
• With moderate or severe pain reported (4 points or more in NRS);
• Capable to read in English or Dutch;
• Written informed consent

Exclusion criteria

• Refused informed consent;
• Pregnant women;
• Admission for other reason than VOC;
• Patients with history of opiate addiction;
• Blindness or significantly impaired vision.

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:	Recruiting
Start date (anticipated):	04-01-2024
Enrollment:	54
Type:	Actual

Medical products/devices used

Generic name:	Virtual Reality glasses
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	23-11-2023
Application type:	First submission

Review commission: METC Amsterdam UMC

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	NL84118.018.23