Virtual reality (VR) to reduce anxiety in children in the plaster room

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Primary Objective: The primary objective of this study is to evaluate the difference in anxiety levels in children in the plaster room with or without distraction with VR goggles.Primary outcome parameter:Child*s anxiety score right after the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Anxiety disorders and symptoms
Study type	Observational non invasive

Summary

ID

NL-OMON54162

Source
ToetsingOnline

Brief title
VR study

Condition

- Anxiety disorders and symptoms

Synonym
anxiety, distress., fear

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: Wetenschapsfonds Amphia

Intervention

Keyword: anxiety, children, plastertreatment, VirtualReality

Outcome measures

Primary outcome

The main study outcome parameter is the difference in anxiety scores between the two groups, given by the children using the Child Fear scale (CFS) after the procedure.

Secondary outcome

The secondary study parameters are the differences between the two groups in:

• Anxiety reduction measured by the difference in CFS scores before and after the plaster intervention

• NRS Pain score and painreduction, given by the scores before and after the procedure

• NRS Satisfaction score given by the child and parent(s) after the procedure

• Child*s heart rate measured during the procedure

Study description

Background summary

Fractures occur frequently in children in the Netherlands. In our hospital we see about 2000 fractures in children each year. Most fractures are treated with plaster, sometimes in combination with Kirschner wires. Kirschner wires or k-wires are used to fixate some displaced fractures. The k-wires are often removed in the plaster room, right after the plaster is removed. The application or removal of plaster (and k-wires) is often an anxious experience for children, particularly under the age of 13. In order to improve the quality of the healthcare for children with fractures who have to undergo plaster treatment, a method to effectively reduce this anxiety in children has yet to be found.

Different methods have been researched to reduce anxiety in children in clinical situations. Many of these have proven to be ineffective, such as using midazolam and showing an instructional video ahead of the procedure. However, a few methods were found to have a positive effect on the anxiety: watching videos on a smartphone or tablet during the procedure and using hearing protectors during the removal of a cast. Since both visual distraction and noise reduction seem to have a positive effect on the anxiety levels in children, researching the effect of Virtual Reality goggles connected to a pair of headphones is a logical next step.
Virtual Reality (VR) goggles are used in clinical settings to distract patients from anxious situations. A positive effect of VR goggles on anxiety and pain perception - and therefore on the quality of healthcare - is shown in children in several other situations, such as blood draw, dental procedures, vaccinations and treatment of burns. The use of VR goggles has shown to be more effective in reducing anxiety and pain perception than watching a video on a tablet. However, the effect of VR goggles during plastering specifically, has not yet been researched. Our hypothesis is that the use of VR goggles will lower the anxiety of children in the plaster room.

Study objective

Primary Objective:
The primary objective of this study is to evaluate the difference in anxiety levels in children in the plaster room with or without distraction with VR goggles.

Primary outcome parameter:
Child*s anxiety score right after the plaster intervention, using the Child Fear Scale (CFS).

Secondary Objective(s):
The secondary objectives of this study are evaluating the difference in anxiety and pain levels in children, the difference in amount of satisfaction from the child and the parent(s), and the difference in heart rates of the children in the plaster room, with or without distraction with VR goggles.

Secondary outcome measures:
- Anxiety reduction (child) (difference between the CFS score before and after the plaster intervention)
- NRS Pain (child) (right before and after the plaster intervention)
- NRS Satisfaction (child and parent) (right after the plaster intervention)
- Heart rate (child) (during the plaster intervention)

Study design

The study design is a randomised controlled study. The randomisation will have

a build-in stratification, to make sure that the two groups are equal when it comes to the different ages and whether k-wires are removed. The control group will include the 150 children who will receive standard treatment for a fracture in the plaster room. The intervention group will include the 150 children who will get VR goggles and headphones during the procedure on top of the standard treatment.
Before and after the plaster intervention, we conduct a short questionnaire with the patients and parents. During the plaster intervention, all patients will get a finger pulse oximeter to measure their pulse during the procedure.
Both age groups (5-11 and 12-17 years old) will have a choice between two videos of about 20 minutes long. The video length is based on the maximum length of the plaster intervention. The videos the children can choose between are single episodes of different series on Netflix. The content of the video is chosen based on Netflix recommendations and is screened to make sure the content is appropriate for the hospital setting and the age group. The age groups have different choices of videos and the video that is chosen will be recorded. The following videos are selected for the age groups:
- Age 5-11: Masha and the Bear season 1 episode 2, The Thundermans season 1 episode 2.
- Age 12-17: Modern Family season 1 episode 2, Brooklyn Nine-Nine season 1 episode 2.

Study burden and risks

The burden associated with participation is having to fill out short surveys and the addition of the finger pulse oximeter and for the intervention group also the VR goggles and headphones. The treatment itself and the follow up are unchanged.
The benefit of the study is to provide an answer to the question if Virtual Reality has a positive effect on the anxiety level of children in the plaster room.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age: 5-17 years old
At least one fractured bone in arm or leg
Needs treatment with, replacement or removal of plaster, with or without k-wires
Children can only participate once in this study

Exclusion criteria

Children who have already participated in this study at a previous cast treatment.
Children with known mental retardation, anxiety disorder, psychosis or epilepsy.
Children with an extreme visual impairment (i.e., myopia > 8 dioptres or presbyopia > 5 dioptres).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-01-2021
Enrollment:	364
Type:	Actual

Ethics review

Approved WMO Date:	08-12-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-03-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-02-2024
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: 28930
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL75353.100.20
OMON	NL-OMON28930