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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28930

Source
Nationaal Trial Register

Brief title
VR study

Health condition

Fracture

Sponsors and support

Primary sponsor: N/A
Source(s) of monetary or material Support: Wetenschapsfonds Amphia

Intervention

Outcome measures

Primary outcome

Child’s anxiety score (measured right after the plaster intervention), using the Child Fear Scale (CFS)

Secondary outcome

- Anxiety reduction (child) (difference between the CFS before and after the plaster intervention)
- NRS Pain (child) and pain reduction (right before and after the plaster intervention)
- NRS Satisfaction (child and parent/guardian) (right after the plaster intervention)
- Heart rate (child) (during the plaster intervention)

Study description

Background summary

Rationale: Fractures occur frequently in children in the Netherlands. In our hospital, we see about 2000 fractures in children each year. The most fractures are treated with plaster, some in combination with k-wires. For children the application or removal of plaster (and the potential k-wires) is often an anxious experience [Katz et al. 2001, Carmichael et al. 2005]. 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 [Won et al. 2017, Rao et al. 2019, Eijlers et al. 2019, Özalp et al. 2019, Chen et al 2020]. As far as we know, the effect of VR goggles and headphones during plastering has not yet been investigated. Our hypothesis is that the use of VR goggles connected to headphones will lower the anxiety of children in the plaster room.

Objective: This study aims to evaluate the effect of VR goggles on the anxiety level of children aged between 5 and 17 years in the plaster room that undergo application, replacement of removal of plaster with or without k-wires in situ.

Study design: Randomised controlled trial

Study population: Children between the age of 5 and 17 years who need treatment with, replacement or removal of plaster (with or without k-wires in situ) due to a fracture in the arm or leg.

Intervention: One group gets VR goggles and headphones during the plaster application/replacement/removal and the other group receives usual care without the VR goggles and headphones.

Main study parameters/endpoints: Primary outcome: Anxiety (child) (measured after the plaster intervention) using the Child Fear Scale (CFS).

Secondary outcome measure: Anxiety reduction (child) (difference between the CFS score before and after the plaster intervention), NRS Pain (child) (immediately before and after the plaster intervention), NRS Satisfaction (child and parent/guardian) (immediately after the plaster intervention), Heart rate (child) (during the plaster intervention).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Subjective scores to fill out, and a (non-invasive) measurement of the heart rate. The benefit of the study is to provide an answer to the question if the use of VR goggles and headphones reduces anxiety in children with fractures in the plaster room. There is a minimal risk during the procedure, complications of the procedure are very rare.

Study objective

Our hypothesis is that the use of VR goggles with headphones will lower the anxiety of children in the plaster room.

Study design

Only one scheduled visit for the plaster intervention and questionnaires.

Intervention

Control group: Standard care with an additional finger pulse oximeter.
Intervention group: Standard care with additional virtual Reality goggles, connected headphones, and a finger pulse oximeter.

Contacts

Public
Amphia Stichting FORCE
Lisa van der Water

0765955815
Scientific
Amphia Stichting FORCE
Lisa van der Water

0765955815

Eligibility criteria

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2020
Enrollment:	300
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	20-11-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 54162
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9065
CCMO	NL75353.100.20
OMON	NL-OMON54162

Study results