

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

Gepubliceerd: 20-11-2020 Laatste bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28930

Bron

Nationaal Trial Register

Verkorte titel

VR study

Aandoening

Fracture

Ondersteuning

Primaire sponsor: N/A

Overige ondersteuning: Wetenschapsfonds Amphia

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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 or 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.

Doel van het onderzoek

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

Onderzoeksopzet

Only one scheduled visit for the plaster intervention and questionnaires.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Amphia Stichting FORCE
Lisa van der Water

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Wetenschappelijk

Amphia Stichting FORCE
Lisa van der Water

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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 dioptries or presbyopia > 5 dioptries)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2020
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	20-11-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54162

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten