Virtual reality exposure before elective pediatric day-care surgery: effects on pre- and postoperative anxiety and pain

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1) Virtual Reality Exposure (VRE) will be significantly more efficacious than care as usual (CAU) on both the primary outcome (child’s situational anxiety during induction of anesthesia) and secondary outcomes. 2) Children with unfavorable...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26527

Bron
Nationaal Trial Register

Aandoening

Virtual Reality, Exposure, Anxiety, Children, Surgery, Anesthesia

Ondersteuning

Primaire sponsor: Erasmus Medical Center, Sophia Children's Hospital
Overige ondersteuning: Stichting Theia
Stichting Coolsingel

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Children’s state anxiety level during induction of anesthesia (measured by the mYPAS, continuous score).

Toelichting onderzoek

Achtergrond van het onderzoek

About 50% to 70% of children undergoing surgery experience elevated levels of anxiety. Children's preoperative anxiety is associated with adverse outcomes, such as an increased risk of emergence delirium, more intense and prolonged postoperative pain, and poorer recovery.

It is well established that gradual exposure to feared situations is a very effective way to reduce anxiety. However, gradually exposing children to the aspects of the pre- and postoperative procedures and environment is not feasible, because this would interfere significantly with daily clinical practice. Virtual Reality Exposure (VRE) provides a unique opportunity to prepare children for their surgery in a very realistic, child friendly and interactive way.

VRE intervention encompasses an animated virtual, three dimensional (3D) environment that mimics the environment of the operation theatre in the Sophia Children's Hospital. Children will look at the specific procedures they will experience in the holding area, operating and recovery room. Children will receive the VRE preparation using virtual reality 3D glasses within one hour after hospital admission.

In this RCT, patients will be randomly allocated to a) VRE intervention or b) care as usual (CAU). All patients will receive adequate medical care.

The objective is to (1) test the efficacy of VRE versus CAU in 200 children (aged 4-12 years) undergoing day care elective surgery (for dental, oral, or Ear-Nose-Throat problems) – and (2) to examine predictors of VRE efficacy.

Doel van het onderzoek

1) Virtual Reality Exposure (VRE) will be significantly more efficacious than care as usual (CAU) on both the primary outcome (child's situational anxiety during induction of anesthesia) and secondary outcomes.

2) Children with unfavorable predictor variables will benefit more from VRE.
Unfavorable predictor variables that will be examined are: SES, age, sex, type of surgery, number of prior surgeries, child anxiety, parental anxiety, and child psychopathology in the previous six months.

Onderzoeksopzet

There will be five moments of assessment:

1) At admission to the hospital before the children will go to the holding area (before the intervention)

2) After the VRE intervention, approximately 15 minutes prior to entering the surgery room. In case of CAU; without intervention, approximately 15 minutes prior to entering the surgery room

3) During induction of anesthesia, in the surgery room

4) Postoperatively, in the recovery room

5) Three days after surgery, at home

Onderzoeksproduct en/of interventie

VRE preparation encompasses an animated virtual, three dimensional (3D) environment that mimics the environment of the operation theatre in the Sophia Children's Hospital. In the VRE environment, children will look at the specific procedures they will experience in the holding area, operating and recovery room. Children will receive the VRE preparation using 3D glasses within one hour after hospital admission.

The control group will receive care as usual, which means that children and their parents are advised by their anesthesiologist or attending physician to watch the informative online movie of the Erasmus MC-Sophia.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Consecutive pediatric patients:

- aged 4-12 years

- undergoing day care elective surgery (i.e. ear-, nose-, throat, dental, or oral surgery) at the Sophia Children’s Hospital

- ASA classification I-III

- undergoing surgery between February 2017 and August 2018

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Mental retardation (due to a specified syndrome)

- Inability of parents to read or write Dutch

- Epilepsy

- Visual impairment

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2017
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	03-11-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47228
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5935
NTR-old	NTR6116

Register	ID
CCMO	NL58728.078.16
OMON	NL-OMON47228

Resultaten