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

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Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON47228

Source
ToetsingOnline

Brief title
Virtual reality before pediatric surgery

Condition

- Other condition
- Congenital ear disorders (excl deafness)
- Respiratory tract therapeutic procedures

Synonym
dental, or ear-nose-throat problems, oral

Health condition

tandheelkundige/kaakchirurgische ingrepen

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Stichting Coolsingel (project nr. 401) en Stichting Theia (project nr. 2015233)

Intervention

Keyword: Anesthesia, Anxiety, Child, Virtual Reality Exposure Therapy

Outcome measures

Primary outcome

(Please also see METC protocol par. 8, which also includes references)

The primary outcome is the child's state anxiety level during induction of

anesthesia assessed with the mYPAS (modified Yale Preoperatieve Anxiety Scale).

Secondary outcome

(Please also see METC protocol par. 8, which also includes references)

The secondary outcomes are:

- children*s pre- and postoperative anxiety

- postoperative pain

- emergence delirium (ED)

- use of analgesics

- health care use, and

- pre- and postoperative parental anxiety

Study description

Background summary

(Please also see METC protocol par. 1, which includes references)

Every year about 6000 children undergo surgery under general anesthesia in the Erasmus MC - Sophia Children*s Hospital. About 50% to 70% of children undergoing surgery experience elevated levels of anxiety and stress. Parents are often anxious, which negatively influences the child*s anxiety. Children*s preoperative anxiety is associated with less cooperation during induction of anesthesia, increased risk of postoperative emergence delirium (ED), more intense and prolonged postoperative pain, analgesic use, postoperative maladaptive behavior, poorer recovery, and sleep disturbance. These adverse outcomes indicate the urgent need to develop effective strategies to minimize preoperative anxiety in children, and reduce postoperative pain.

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 preoperative (e.g. waiting room, operating room, anesthesia) and the postoperative (e.g. recovery room) 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. This study will be the first, worldwide, to develop and test the efficacy of VRE preparation for children undergoing surgery. This study is in line with the renewed emphasis on patient- and family-centered care of the Sophia Children*s Hospital.
Our hypotheses are: (1) VRE will be significantly more efficacious than care as usual (CAU) on both the primary outcome (the child*s situational preoperative anxiety) and secondary outcomes, and (2) children with unfavorable predictor variables will benefit more from VRE.

Study objective

The objective is:
(1) To test the efficacy of VRE versus CAU in 200 children undergoing surgery on the anxiety level of the child during induction of anesthesia (primary outcome), pre- and postoperative child anxiety, pre- and postoperative parental anxiety, postoperative pain, postoperative ED, analgesic use, and health care use (secondary outcomes).
(2) To examine predictors of VRE efficacy: socioeconomic status (SES), age, sex, type of surgery, number of prior surgeries, child and parental anxiety, and psychopathology in the previous six months.

Study design

(Please also see METC protocol par. 3 and fig. 1)

Single blinded randomised controlled trial (RCT) involving a psychosocial intervention.

There will be five moments of assessment:
T1. At admission to the hospital (before intervention)
After T1 randomization will take place.
T2. After the VRE intervention or in case of CAU, without intervention, approximately 15 minutes prior to entering the surgery room
T3. During induction of anesthesia, in the surgery room
T4. Postoperatively, in the recovery room
T5. Three days after surgery, at home

Intervention

(Please also see METC protocol par. 5)

One group will receive Virtual Reality Exposure (VRE) preparation. VRE preparation encompasses an animated virtual environment, using 3D glasses, that mimics the environment of the operation theatre in the Sophia Children*s Hospital, as well as procedures regarding induction of anesthesia.

The other group will receive care as usual (CAU).

Study burden and risks

The risks associated with participation can be considered negligible and the burden can be considered minimal.

Risks: The aim of the study is that this Virtual Reality Exposure (VRE) approach will diminish anxiety in children. However, it cannot be ruled out that some children will become stressed and anxious during the VRE. If this is the case, we will immediately terminate the VR procedure and comfort the child. Therefore the risk associated with participation is negligible.

Burden: There are no extra visits to the hospital needed. All questionnaires will be filled out at the day of admission to the hospital, or at home, three days after surgery.
The burden for children is minimal, as they only rate their anxiety on a Visual Analogue Scale (VAS) and pain on a Faces Pain Scale (FPS). The burden for parents is also minimal, as they only fill out a number of questionnaires. In total, the study will take about 45 minutes: VRE will take approximately 15

minutes - the other time will be spend on filling out questionnaires.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Eligible are: consecutive pediatric patients (aged 4-12 years), undergoing day care elective surgery (i.e. dental, oral, or Ear-Nose-Throat surgery) under general anesthesia, at the Sophia Children*s Hospital, between February 2017 and August 2018.

Exclusion criteria

Mental retardation, inability of parents to read or write Dutch, epilepsy, visual impairment, or anxiolytic premedication, preoperatively.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	04-04-2017
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	30-11-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-05-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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: 26527
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL58728.078.16
OMON	NL-OMON26527