Smartphone virtual reality exposure before paediatric surgery: effects on pre- and post-procedural pain and anxiety

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

Summary

ID

NL-OMON53806

Source
ToetsingOnline

Brief title
Smartphone virtual reality before paediatric surgery

Condition

- Other condition
- Bone and joint therapeutic procedures

Synonym
ear-nose-throat problems, scoliosis

Health condition

KNO ingrepen

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Vrienden van Sophia

Intervention

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

Outcome measures

Primary outcome

The main study parameter is postoperative pain upon awakening from anaesthesia

(T4) assessed with a Numeric Rating Scale (NRS) from 0 (no pain) to 10 (worst

imaginable pain) and the observational, Face, Legs, Activity, Cry,

Consolability (FLACC) scale.

Secondary outcome

Secundary outcome measurements include:

- postoperative analgesics use

- anxiety level of the child during induction of anaesthesia

- compliance during induction of anaesthesia

- user experience

- postoperative sleep problems

- length of hospital stay

Study description

Background summary

Fifty percent of children and 80% of adolescents experience anxiety and distress prior to surgery. Preoperative anxiety is related to higher levels of post-operative pain and sleep problems. We recently showed that half as many

children that received preoperative Virtual Reality Exposure (VRE) prior to anaesthesia for tonsillectomy needed morphine compared to children who did not receive this preparation. However, there are some disadvantages to this VRE, e.g. it is installed on a PC at the Sophia Children*s Hospital, which limits the implementation of this intervention. Therefore, we further developed this VRE into a smartphone app with the aim of improved exposure to the VRE (at home, at a child*s own pace) and reducing healthcare costs.

This study aims to test the efficacy of this smartphone VRE application (sVRE) versus care as usual (CAU) in children undergoing major and/or painful surgery on postoperative pain and analgesia. Our hypotheses are: (1) sVRE will be significantly more efficacious than care as usual (CAU) on both primary (postoperative pain) and secondary outcomes, and (2) children with unfavourable predictor variables will benefit more from sVRE.

Study objective

The objectives of this study are to (1) test the efficacy of sVRE versus CAU in 180 children undergoing surgery on the postoperative pain of the child (primary outcome), postoperative analgesics use, anxiety level of the child during induction of anaesthesia, compliance during induction of anaesthesia, postoperative sleep problems, and length of hospital stay (secondary outcomes). (2) To examine predictors of VRE efficacy, including socioeconomic status (SES), age, sex, number of prior surgeries, preoperative child and parental anxiety, and preoperative sleep problems.

Study design

A multicentre, randomized controlled trial (RCT) in which 180 participants (128 patients undergoing (adeno)tonsillectomy and 52 patients undergoing scoliosis surgery) will be allocated to either the sVRE intervention condition (n=90) or CAU (n=90). The longitudinal design will include six measurements points: Pre-intervention, one week before surgery (T0); post-intervention, prior to entering surgery room (T1); during induction of anaesthesia (T2); postoperatively in the recovery room (T3); 5 days postoperative (T4); 21 days postoperative (only for scoliosis surgery.

Intervention

sVRE preparation encompasses a virtual, three-dimensional environment that replicates the operating rooms of the Sophia Children*s Hospital and the Maasstad Hospital. This virtual 3D environment contains the waiting room, corridor to the operating room, operating room and recovery room. The procedures children will undergo before they are induced for anaesthesia are also animated in the sVRE environment. Children can use the VR preparation at home with a smartphone VR app and cardboard VR glasses. The smartphone app

provides the child the opportunity to fully look around in the virtual 3D environment and thus explore the sVRE environment at his own pace, in a child-friendly way, as often as the child wants.

Study burden and risks

The risks are negligible and the burden is minimal. All children receive care as usual, and those who are randomized to the sVRE condition will wear VR glasses to use the sVRE application. Since this VRE is performed at home, there is a risk that children run into tables, chairs or other furniture. To limit this risk, parents and children are instructed to only use the sVRE intervention when an adult/guardian is present. Moreover, it cannot be ruled out that some children will become stressed and anxious during the VR. If this is the case, parents are instructed to immediately terminate the sVRE procedure and comfort the child. If there is a need for acute psychosocial care, adequate referral will be arranged. If children will be allocated to the CAU group, no risks are incurred beyond those associated with CAU.

The only potential burden for parents and children are the short assessments. The burden for children is minimal, as they only rate their pain and anxiety on a NRS and Visual Analogue Scale (VAS) and complete questionnaires on the user experience and sleep. The burden for parents is also minimal, as they only complete a number of questionnaires.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)

Inclusion criteria

Eligible are: consecutive pediatric patients (aged 6-18 years) undergoing (adeno)tonsillectomy at Maasstad ziekenhuis or scoliosis surgery at Sophia Children's Hospital under general anesthesia, between October 2022 and December 2023.

Exclusion criteria

Mental retardation, severe visual disability, preoperative use of anxiolytic medication, inability to read and write Dutch

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: Recruiting

Start date (anticipated):	24-01-2024
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO Date:	01-05-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-01-2025
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

No registrations found.

In other registers

Register	ID
CCMO	NL81990.078.22