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Smartphone virtual reality exposure before paediatric surgery (tonsillectomy)

Submission date	Recruitment status	[_] Prospectively registered
17/01/2024	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/03/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
11/03/2025	Surgery	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

Among children, 50% and among adolescents, 80% undergo feelings of anxiety and distress before undergoing surgery. Preoperative anxiety is related to higher levels of post-operative pain and sleep problems. In earlier work, half as many children who received preoperative virtual reality exposure (VRE) before 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 analgesics use. The 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.

Who can participate?

Children aged 6 to 18 years scheduled for surgery at Sophia Children's Hospital, Maasstad Hospital and IJsselland Hospital between January 2024 and December 2025 are eligible to participate.

What does the study involve?

The researchers aim to investigate if utilizing a virtual reality (VR) environment benefits children undergoing surgery. A comparison will be made between the sVRE experience and the standard care children receive. The focus is on assessing factors such as postoperative pain, sleep quality, and hospital stay duration. Additionally, the study seeks to understand if variables like age, previous surgeries, or anxiety levels influence the effectiveness of sVRE.

Procedure:

The whole multicentre study involves 180 children, including those undergoing tonsillectomy and scoliosis surgery; this record involves only the tonsillectomy surgery patients. The second

group consisting of 52 scoliosis surgery patients (site: Erasmus MC-Sophia Children's Hospital) will be identified separately. For this purpose, a separate record with be registered in ISRCTN, ensuring the individual registration of each group.

Half of the participants will engage in a special sVRE program at home before surgery, while the other half will receive regular care. Evaluations will occur at different points, such as before surgery, during anaesthesia, after surgery and at home.

sVRE Experience:
Children will use a dedicated VR app on their smartphones with VR glasses to explore a virtual representation of the hospital where they will have surgery. This virtual environment includes the waiting room, the pathway to the surgery room, the surgery room, and the recovery room. The experience is designed to be enjoyable and child-friendly, allowing children to explore at their own pace.

Assessment Criteria:
The primary focus is on understanding the level of pain experienced by children upon waking from surgery. Pain levels will be assessed using a scale where children rate their pain from 0 (no pain) to 10 (the worst pain imaginable). The study will also investigate if sVRE has positive effects on other aspects, such as sleep, anxiety, and the duration of hospital stay.

What are the possible benefits and risks of participating?
This study will assess the efficacy of sVRE. It is hypothesized that sVRE will be significantly more efficacious than CAU on children’s pain scores and pain medication use post-surgery, as well as on secondary outcomes. Moreover, children with unfavourable predictor variables will benefit more from sVRE.

The risks are negligible and the burden is minimal. All children receive care as usual, and those who are assigned to the sVRE condition will wear plastic 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 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, an adequate referral will be arranged. If children are allocated to the CAU group, no risks are incurred beyond those associated with CAU.

The only potential burden for parents and children is the short assessments. The burden for children is minimal, as they only rate their pain on an FPS and anxiety on a Numeric Rating Scale (NRS) and complete questionnaires on the user experience and sleep (if aged 8 years or older). The burden for parents is also minimal, as they only complete some questionnaires.

Where is the study run from?
Friends of Sophia (Vrienden van het Sophia) (The Netherlands)

When is the study starting and how long is it expected to run for?
February 2022 to August 2026

Who is funding the study?
Friends of Sophia Foundation (Stichting Vrienden van het Sophia) (The Netherlands)

Who is the main contact?
Dr Bram Dierckx, b.dierckx@erasmusmc.nl (The Netherlands)

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
NL81990.078.22

Study information

Scientific Title
Smartphone virtual reality exposure before paediatric surgery: effects on pre- and post-procedural pain and anxiety. A multicentre study

Acronym
Preview-2 study

Study objectives
It is hypothesized that (1) smartphone Virtual Reality Exposure (sVRE) will be significantly more efficacious than CAU on both primary and secondary outcomes, and that (2) children with unfavourable predictor variables will benefit more from sVRE.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 01/05/2023, De Medisch Ethische Toetsings Commissie Erasmus MC (Dr. Molewaterplein 40, Rotterdam, 3015 GD, Netherlands; +31 010-7034428; metc@erasmusmc.nl), ref: MEC-2022-0763

2. Approved 28/01/2025, De Medisch Ethische Toetsings Commissie Erasmus MC (Dr. Molewaterplein 40, Rotterdam, 3015 GD, Netherlands; +31 010-7034428; metc@erasmusmc.nl), ref: MEC-2022-0763/ A-0001 NL81990.078.22 v03

Primary study design
Interventional

Study design
Multicentre randomized controlled trial

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Postoperative pain in children undergoing tonsillectomy surgery

Interventions
Intervention: Virtual reality environment for pediatric surgical patients
The objectives of this study are to assess the efficacy of a virtual reality environment (sVRE) compared to Care As Usual (CAU) in children undergoing surgery, focusing on primary outcomes such as postoperative pain and secondary outcomes including postoperative analgesics use, child anxiety during anaesthesia induction, compliance during anaesthesia induction, postoperative sleep problems, and length of hospital stay. The study will also investigate predictors of sVRE efficacy, including socioeconomic status (SES), age, sex, number of prior surgeries, preoperative child and parental anxiety, and preoperative sleep problems.

The whole study is a multicentre, randomized controlled trial (RCT) with 180 participants (128 (adeno)tonsillectomy (A(TE) and 52 scoliosis surgery patients); this record involves only the (A (TE) surgery patients. Participants will be randomly assigned to either the sVRE intervention condition (n=64) or CAU (n=64).

Intervention:
sVRE preparation involves a virtual, three-dimensional environment replicating the operating rooms at Sophia Children's Hospital. This includes the waiting room, corridor, operating room, and recovery room. Children utilize a smartphone VR app and plastic VR glasses at home, enabling them to explore the virtual environment at their own pace, in a child-friendly manner.

Main Study Parameters/Endpoints:
The main study parameter is postoperative pain upon awakening from anaesthesia (T3), assessed using the observational Face, Legs, Activity, Cry, Consolability (FLACC) scale and a Faces Pain Scale (FPS) ranging from 0 (no pain) to 10 (worst imaginable pain).

There will be six moments of assessment:
1. Baseline, approximately one week before surgery (T0).
2. Before entering the surgery room (T1).
3. During induction of anaesthesia, in the operating room (T2).
4. Postoperatively, in the recovery room (T3).
5. Five days postoperatively (T4).
T0 and T4 include questionnaires for the child and parent, which will be assessed at home on a secure website. If applicable, T5 includes an online questionnaire for the parent and returning

the pain medication diary. T1 and T3 include FPS on pain and NRS on anxiety, which will be verbally assessed by the research psychologist. T1 also includes a questionnaire about the user experience, which will be completed on paper. The observational assessments at T2 and T3 are performed by the research psychologist.
Primary outcome measure:
The primary outcome of this study is postoperative pain upon awakening from anaesthesia (T3). Pain will be assessed with the Faces, Legs, Activity, Cry, Consolability scale (FLACC)17 as an observational measurement of postoperative pain upon awakening from anaesthesia (T3). The FLACC includes behavioural items related to pain that can be scored from 0 (no painful behaviour present; i.e. no cry) to 2 (painful behaviour present, i.e. crying steadily). The total scores range from 0 (no pain) to 10 (a lot of pain). The scale was originally developed and proven valid and reliable for infants and children aged 2 months to 7 years. This assessment is used as a primary outcome for the (A)TE patients.

Postoperative analgesic use is a secondary endpoint of this trial. Data will be collected from medical records (analgesics given during hospitalization) and via a questionnaire for the parents (analgesics used at home). Parents will be asked whether their child used the prescribed analgesics or if the child used more or less analgesics.
Postoperative pain upon awakening after anaesthesia [FPS-R] pre-intervention, two weeks before surgery (T0); post-intervention, before entering the surgery room (T1); during induction of anaesthesia (T2); postoperatively in the recovery room (T3); 5 days postoperative (T4)

Secondary outcome measure
We will investigate whether the following factors influence smartphone VR effectivity:
Medical outcomes including type of surgery, ASA score, analgesic use and length of hospital stay will be derived from the child's medical file. Socio-demographic data such as sex and age of the child, presence of brothers/sisters who have been operated on, socioeconomic status and the number of prior surgeries of the child will be collected in a baseline questionnaire completed by the parent.

Postoperative analgesic use is a secondary endpoint of this trial. Data will be collected from medical records (analgesics given during hospitalization) and via a questionnaire for the parents (analgesics used at home). Parents will be asked whether their child used the prescribed analgesics or if the child used more or less analgesics. The parents of participants who underwent scoliosis surgery will receive a pain medication diary to keep track of the medication used for answering these questions. Another secondary endpoint is pre-operative anxiety. The modified Yale Preoperative Anxiety Scale (mYPAS) will be used to observe anxiety during the induction of anaesthesia. This instrument has been translated from English to Dutch and has already been used in two previous research projects of our research team. The mYPAS has good reliability and validity.

Anxiety will also be assessed by using a global score (single score), the Numeric Rating Scale (NRS). In this study, the NRS consist of a 100 mm horizontal line with two behavioural extremes: 'no anxiety or fear at all' versus 'the worst possible anxiety or fear'. The NRS is a reliable instrument to score state anxiety. In addition, compliance with the induction of anaesthesia is a secondary endpoint. Compliance will be measured with the Induction Compliance Checklist (ICC). The ICC is an observational scale that includes several categories of behaviour that can occur during induction (e.g. "Turns head away from mask"). The total score is the number of categories checked and ranges from 0 (perfect compliance) to 11 (poor behavioural compliance). The user experience will be assessed with a self-developed questionnaire. Participants are asked whether

they have used the app, how often they used it, whether their parents used it, what the aim of the app was, which grade they would give the app and whether they would advise a friend to use the app.

Sleep will be assessed with the Patient Reported Outcomes Measurement Information System (PROMIS) Sleep Disturbance item bank. The sleep disturbance item bank consists of 15 items and gives an overview of a participant's sleep problems All items are rated on a 5-point Likert scale from 1 (not at all or never) to 5 (very much or always). Scores can be transformed into T-scores via the official Health Measures scoring service tool. T-scores are anchored on the US general population, with a mean of 50 and a standard deviation of 10. Higher scores represent more sleep problems. Psychometric testing of the Dutch items showed good reliability and validity. For children aged 6 and 7 years, a parent proxy of the PROMIS Sleep Disturbance scale will be used. For children aged 8 years and older, a self-report children's version of the PROMIS Sleep Disturbance scale will be used.

Intervention Type
Behavioural

Primary outcome(s)
Postoperative pain upon awakening from anaesthesia measured using the Faces, Legs, Activity, Cry, Consolability scale (FLACC) Postoperatively, in the recovery room (T3)

Key secondary outcome(s)
1. Postoperative analgesic use measured using data will be collected from medical records (analgesics given during hospitalization) and via a questionnaire for the parents (analgesics use at home)
2. Pre-operative anxiety measured using the modified Yale Preoperative Anxiety Scale (mYPAS)
3. Anxiety measured using the Numeric Rating Scale (NRS)
4. Compliance with the induction of anaesthesia measured using the Induction Compliance Checklist (ICC)
5. The user experience measured using a self-developed questionnaire
6. Sleep measured using the Patient Reported Outcomes Measurement Information System (PROMIS) Sleep Disturbance item bank

We will investigate whether the following factors influence smartphone VR effectivity:
1. Medical outcomes including type of surgery, ASA score, analgesic use and length of hospital stay will be derived from the child's medical file. Socio-demographic data such as sex and age of the child, presence of brothers/sisters who have been operated on, socioeconomic status and the number of prior surgeries of the child will be collected in a baseline questionnaire completed by the parent.

The secondary objective is to identify which variables predict the efficacy of sVRE.

Predictor variables that will be examined are at:
1. Socioeconomic status (SES) (questionnaire timepoint T0)
2. Age (questionnaire timepoint T0)
3. Sex (questionnaire timepoint T0)
4. Type of surgery (questionnaire timepoint T0)
5. Number of prior surgeries (questionnaire timepoint T0)

6. Preoperative child anxiety (NRS timepoint T0, T1)
7. Preoperative parental anxiety (mYPAS timepoint T0)
8. Sleep problems before surgery (PROMIS, T0)

Completion date
31/08/2026

Eligibility

Key inclusion criteria
1. Consecutive pediatric patients
2. Aged 6 up to < 18 years old at baseline
3. Undergoing surgery for (adeno)tonsillectomy between January 2024 and December 2024

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 Years

Upper age limit
17 Years

Sex
All

Key exclusion criteria
1. Mental retardation
2. Severe visual disability
3. Preoperative use of anxiolytic medication.
4. Inability to read and write Dutch

Date of first enrolment
24/01/2024

Date of final enrolment
01/01/2026

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus MC - Sophia Children's Hospital
Dr. Molewaterplein 40
Rotterdam
Netherlands
3015 GD

Study participating centre
Maasstad Hospital
Maasstadweg 21
Rotterdam
Netherlands
3079 DZ

Study participating centre
IJsselland Hospital
Prins Constantijn 2
Capelle aan den IJssel
Netherlands
2906 ZC

Sponsor information

Organisation
Vrienden van het Sophia

ROR
https://ror.org/03tdgzq48

Funder(s)

Funder type
Research organisation

Funder Name
Stichting Vrienden van het Sophia

Alternative Name(s)
Friends of the Sophia Foundation, Sport for Sophia, Sporten voor Sophia

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3.0	03/03/2023	02/02/2024	No	No