



Study Title: Immersive virtual reality exposure for reducing preoperative anxiety in children – a randomized controlled trial

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Study Protocol

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Title

Immersive virtual reality exposure for reducing preoperative anxiety in children – a randomized controlled trial

Introduction

Undergoing an operation is a major stress for both children and their families, with up to 50% of the children reported to have significant perioperative anxiety (1). High levels of perioperative anxiety in children manifest as tension, irritability and increased autonomic nervous system activity (2,3); and are associated with a multitude of adverse clinical outcomes, including increased postoperative analgesia requirement, increased postoperative emergence delirium, increased postoperative behavioural changes (e.g. nightmares, postoperative separation and general anxiety, eating problems that can persist up to 2 weeks after surgery). (1) Furthermore, it impacts patient and parental satisfaction, creating an overall negative experience for families and staff.

The multifaceted risk factors of perioperative anxiety in children warrant a multi-modal array of tools up anaesthesiologists' sleeves to tailor for different children's needs based on age, understanding of instructions, and temperament (3). While pharmacological anxiolytics, e.g. Dexmedetomidine and Midazolam, are commonly deployed and effective, it has its limitations, such as time to effect, patient's age, as well as paradoxical agitation reported up to 10% for Midazolam, as well as taking away a learning opportunity for children to cope with stress. (4) Common non-pharmacological approaches include parental presence during induction of anaesthesia, distraction techniques, and educational approaches.

Traditional educational approaches often involve providing information to children and parents/legal guardians by written pamphlets, either physical or video tour of the operating room, recovery area, and orientation of medical equipment. With the advance of technology, children are often familiar and easily engaged with technological devices, including smart phones, tablets, video games, and even immersive virtual reality (VR). VR is increasingly utilized in clinical setting, providing a fun and engaging educational experience for children.

VR utilizes a head-mounted display with visual, auditory and tactile stimuli to simulate a fully immersive 3-dimensional environment. Its application in the paediatric perioperative setting can be either as distraction during painful procedures or during induction of anaesthesia, or as an exposure

tool in preoperative education. A meta-analysis of the effect of VR on preoperative anxiety shows a significant reduction of preoperative anxiety in paediatric patients (5). Ryu et al. utilized a famous cartoon character in the VR preoperative educational video and showed significant reduction in preoperative anxiety when compared to children receiving information through conventional means. (6,7) This benefit of VR exposure in reducing preoperative anxiety is not only evident in numerous studies (8-10) measuring anxiety score, but also demonstrated in studies measuring salivary cortisol concentration. (11, 12)

In a joint project involving the Department of Computing of Hong Kong Polytechnic University, the Department of Computer science Center for Innovative Applications of Internet and Multimedia Technologies of the City University of Hong Kong and the Hong Kong Children's Hospital (HKCH), an immersive VR operating theatre tour will be designed as part of preoperative education for children. A simulation of the perioperative journey in HKCH operating theatre will be created to help children form realistic expectations of their perioperative journey, and virtual exposure of different medical equipment helps children cope with their worries for the anticipated procedures. Parents/legal guardians will be able to monitor the VR experience on tablets via the monitoring software, which displays what the children see in VR. Given the fact that the capacity of conventional approaches, e.g. child-play involvement by child-life specialists are hugely limited now due to COVID pandemic, such a VR-enabled approach may help to alleviate patient's anxiety.

Aims and objectives

This study hopes to demonstrate the clinical effectiveness of virtual reality exposure in reducing children's perioperative anxiety in Hong Kong Children's Hospital.

Design and setting

This is a prospective and randomized controlled trial.

Children who are planned to undergo elective surgeries in Hong Kong Children's Hospital will be recruited in the study upon pre-anaesthetic assessment at clinic where written parental informed consent and paediatric assent (for patients ≥ 7 years old) will be obtained. For patients aged 5-6, assent would be carried out by the study team through verbal communication. Everyone will receive standard medical care and provided with information regarding the perioperative journey as per usual practice, including watching an introductory video in the waiting room area with accompanying adults, receiving perioperative education by a pre-anaesthetic nurse, as well as having an opportunity to have any questions answered by an anaesthesiologist in the pre-anaesthetic assessment clinic.

On the day of surgery where they are admitted for pre-surgery preparation, participants will complete a baseline anxiety assessment using the modified Yale Perioperative Anxiety Scale (mYPAS) (T0) (14) by a blinded researcher, after which they will be randomly assigned to intervention group (VR group) and conventional group (Non-VR group). Children assigned to the VR group will watch the designed VR immersive experience with headset, whereas children assigned to the non-VR group will receive standard medical care without any additional intervention. (Figure 1)

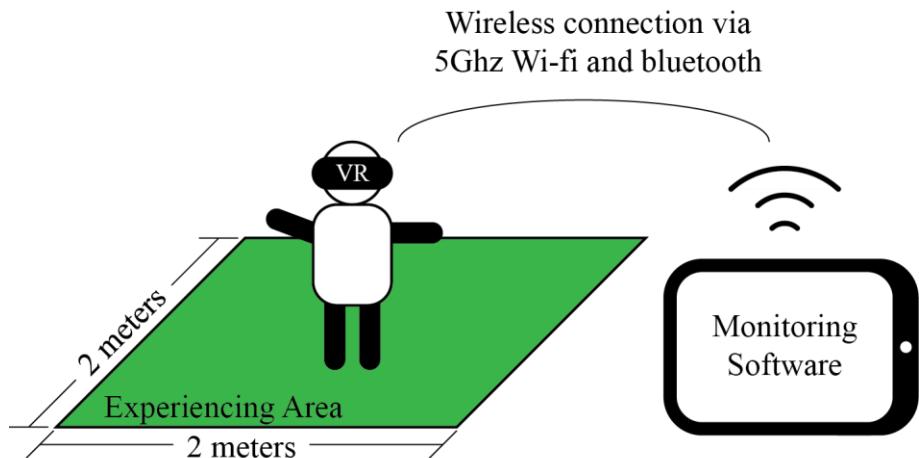


Figure 1. The overall hardware setup and connections.

All children will receive local anaesthetic cream to their dorsum of hands (EMLA or Ametop for those with contraindications to EMLA). Parents/legal guardians will accompany their children into the operating theatre until children are induced and unconscious unless parental refusal to do so. Patients will be allowed to lie down on the operating table, or sit up if preferred, when monitors including SpO₂ probe, Blood pressure cuff, and 3-lead ECG are applied. Anaesthesiologists, who are blinded by the allocation, will conduct induction using either intravenous induction or inhalation induction. Inhalation induction would be used for those who refuse intravenous cannula placement or those who have received >1 failed attempt of intravenous cannula placement. Another set of mYPAS (T1), Induction compliance checklist and Procedure behaviour rating scale will be performed by a blinded researcher (either research assistant or anaesthesiologist involved) on the patient when they are on the operating table right before induction of anaesthesia. Parents/legal guardians will be asked to fill in the State-Trait Anxiety Inventory (STAI) after accompanying their child during induction and while waiting outside.

As primary outcome is measured at the start of induction and anaesthesiologists are blinded from the allocation, the conduct of anaesthesia, including drugs of choice for induction and maintenance, analgesia, and airway intervention, will be performed as per usual practice which is not standardized. Intravenous induction will comprise of an opioid (either Remifentanil 0.1-0.2mcg/kg/min or 1-2mcg/kg Fentanyl), Propofol (either 2-4mg/kg bolus or TCI Paedfusor starting with Cp 5mcg/mL titrated until patient is unconscious) with 1mL of 0.5% Lignocaine to alleviate sting caused by propofol, +/- muscle relaxant of choice as required. Inhalational induction will comprise of using a mask smeared with artificial flavouring of choice, administering O₂/N₂O/ Sevoflurane mixture. After securing airway with either laryngeal mask or endotracheal tube, patients will be maintained on total intravenous anaesthesia with Propofol under Paedfusor Cp model or Sevoflurane/O₂/Air. Patients will be given adequate multi-modal analgesia and anti-emetic as per usual practice, and will be extubated in operating theatre after the surgery. Parents/legal guardians will accompany the patients again in the recovery room as soon as possible. Lastly, parents/legal guardians will provide feedback by completing a parental satisfactory score.

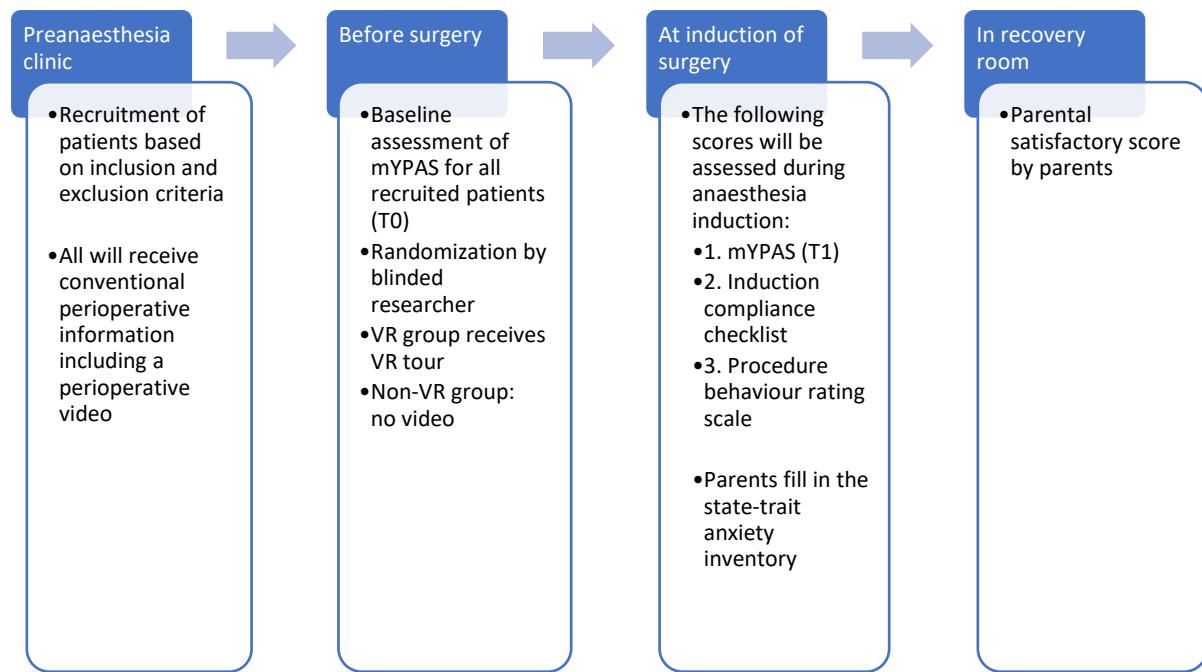


Figure 2: Flowchart of assessments and interventions for recruited patients

Hypothesis

We hypothesize that virtual reality preparation can significantly reduce anxiety in children, defined as 20% reduction in mYPAS score at induction compared to control group.

Inclusion and exclusion criteria

Inclusion criteria:

- Age 5-12years old
- American Society of Anaesthesiologist (ASA) physical status I or II
- Undergo elective surgical procedures which requires general anaesthesia
- No previous experience of anaesthesia or surgery

Exclusion criteria:

- Patients who are undergoing ultra-major surgery requiring postoperative intensive care unit care.
- Patients who are blind, or with hearing impairment
- Patients with significant developmental or cognitive delays, ADHD or autism
- Patients with history or current symptoms of vertigo
- Patients with history of epilepsy or seizures
- Patients who require anxiolytic premedication
- Patients who have physical conditions that prohibit use of headsets e.g. head / facial injuries, open skin or infectious condition on head/face, head/ facial malformation that precludes proper fitting of the VR headset
- Non-Cantonese speaking patients (due to limited resources of having Cantonese speaking VR design)
- Patients and/or parents/legal guardians who refuse to participate in study

Sample size and statistical analysis

A previous study (17) measuring perioperative anxiety in children at induction reported a mean mYPAS of 30.1 with a SD of 8.4. Using this data, a sample size of 30.1 for each arm is at least required to detect a 20% reduction in mYPAS score to achieve an alpha of 0.5 and power of 80%. We aim to recruit 96 children-parent pairs in order to account for 37.5% dropout rate due to change of surgery or anaesthesia plan, or loss to follow-up, as well as to increase the power for studying secondary outcomes.

Mann-Whitney U test will be applied to compare non-parametric data such as mYPAS score, induction compliance checklist, procedural behaviour rating scale and parental satisfactory score. Statistical significance will be accepted for $p < 0.05$. Baseline categorical variables will be analyzed using the X² test or the Fisher exact test.

Outcome and measurements

Primary outcome is whether there is a significant reduction of anxiety of children at induction, defined by a 20% reduction in the modified Yale Preoperative Anxiety Scale (mYPAS) between control group and intervention group at T1.

mYPAS is considered the gold standard in assessing preoperative anxiety in children (14), consisting of 27 items divided into five domains: activity, emotional expressivity, state of arousal, vocalization and use of parents/legal guardians, ranging from 23.3 to 100. A cut-off of $>/= 30$ indicates a high anxiety level in children.

This instrument has been considered as a gold standard instrument for measuring preoperative anxiety and had been administered in many previous studies. mYPAS will be assessed by a blinded researcher or anaesthesiologist, at induction in the operating theatre.

Secondary outcomes include baseline preoperative anxiety score using mYPAS at T0 (conducted before randomization by a blinded researcher), Induction compliance checklist, procedural behaviour rating scale, parental anxiety is evaluated by State-trait anxiety inventory (STAI), and parental satisfactory score.

Randomization and Blinding

Block randomization with stratification of age groups (5-8 years old, 9-12 years old) will be performed in a 1:1 allocation ratio.

The study will be single-blinded where the assessors and anaesthesiologists conducting the anaesthesia will be blinded by the following arrangement: The preoperative baseline mYPAS will be conducted before allocation, and the assessor at induction will not be involved in the allocation process. Anaesthesiologists and recovery nurses are blinded and encouraged not to actively discuss the use of VR with patients and parents/legal guardians.

Data handling and record keeping

To protect patient privacy, all research data would be handled in line with HA/Hospital's policy in handling/storage/destruction of patients' medical records. They would be locked in cabinets where the department keep confidential information. Electronic data should be saved in secured computer of the hospital with restricted access. Data collected will be destroyed after 3 years of publication.

Ethical Implication

All patients will receive standard medical care including information regarding the perioperative journey. VR itself is a non-invasive intervention, and patients will be reassured that they can terminate the VR appliance any time if they experience any discomfort. Although concerns of the risk of false memory formation have been raised, as children of young age may not be able to differentiate actual experience and imaginary play, adverse events are rarely reported. Risks of physical injury through collision into nearby objects while using the VR headset can be minimized by monitoring children in a spacious empty room devoid of obstacles.

Besides, the issue of confidentiality is the major ethical issue, and will be solved by recording the data in a manner that does not allow the participants to be identified (i.e. using a non-recognizable code for each participants).

This study will be conducted in compliance with Declaration of Helsinki and ICH-GCP.

Study significance

VR is an innovative technology with extensive applications in procedural anxiety and pain alleviation. Showing its effect on perioperative anxiety in children in our locality will give us a sustainable, simple, and non-pharmacological option of improving children's coping and the perioperative journey for children and parents/legal guardians.

Appendix:

Modified Yale Perioperative Anxiety Scale (14)

Calculation of score: Highest score of the observed behaviour is the score of each category. A partial weighted score is calculated by dividing the score by the total items of that category. All categories used are added together, multiply by 100 and divided by the number of categories used.

Activity
<ol style="list-style-type: none"> 1. Looking around, curious, playing with toys, reading (or other age-appropriate behavior); moves around holding area/treatment room to get toys or to go to parent; may move toward operating room equipment 2. Not exploring or playing, may look down, fidget with hands, or suck thumb (blanket); may sit close to parent while waiting, or play has a definite manic quality 3. Moving from toy to parent in unfocused manner, non-activity-derived movements; frenetic/frenzied movement or play; squirming, moving on table; may push mask away or cling to parent 4. Actively trying to get away, pushes with feet and arms, may move whole body; in waiting room, running around unfocused, not looking at toys, will not separate from parent, desperate clinging
Vocalizations
<ol style="list-style-type: none"> 1. Reading (nonvocalizing appropriate to activity), asking questions, making comments, babbling, laughing, readily answers questions but may be generally quiet; child too young to talk in social situations or too engrossed in play to respond 2. Responding to adults but whispers, "baby talk," only head nodding 3. Quiet, no sounds or responses to adults 4. Whimpering, moaning, groaning, silently crying 5. Crying or may be screaming "no" 6. Crying, screaming loudly, sustained (audible through mask)
Emotional expressivity
<ol style="list-style-type: none"> 1. Manifestly happy, smiling, or concentrating on play 2. Neutral, no visible expression on face 3. Worried (sad) to frightened, sad, worried, or tearful eyes 4. Distressed, crying, extreme upset, may have wide eyes
State of apparent arousal
<ol style="list-style-type: none"> 1. Alert, looks around occasionally, notices or watches what anesthesiologist does (could be relaxed) 2. Withdrawn, sitting still and quiet, may be sucking on thumb or have face turned into adult 3. Vigilant, looking quickly all around, may startle to sounds, eyes wide, body tense 4. Panicked whimpering, may be crying or pushing others away, turns away
Use of parents

1. Busy playing, sitting idle, or engaged in age-appropriate behavior and doesn't need parent; may interact with parent if parent initiates the interaction
2. Reaches out to parent (approaches parent and speaks to otherwise silent parent), seeks and accepts comfort, may lean against parent
3. Looks to parent quietly, apparently watches actions, doesn't seek contact or comfort, accepts it if offered or clings to parent
4. Keeps parent at distance or may actively withdraw from parent, may push parent away or desperately clinging to parent and not let parent go

Induction Compliance Checklist (16)

Checklist	Score (1 for each category)
Crying, tears in eyes	
Turns head away from mask	
Verbal refusal, says "no"	
Verbalization indicating fear or worry, "where's mommy?" or "will it hurt?"	
Pushes mask away with hands, pushes nurse/ anaesthetist with hands / feet	
Covers mouth/ nose with hands / arms or buries face	
Hysterical crying, may scream	
Kicks / flails legs / arms, arches back, and/or general struggling	
Requires physical restraint	
Complete passivity, either rigid or limp	

Procedure Behaviour Rating Scale (PBRS)

	Description	Score
Cry	Tears in eyes or running down face	
Cling	Physically holds on to parent, significant other, or nurse	
Fear verbal	Says "I'm scared", "I'm afraid" etc	
Pain verbal	Says "Ow", "Ouch," "It hurts," "You're hurting me," etc.	
Groan	Nonverbal, vocal expression of pain or discomfort	
Scream	No tears, raises voice, verbal or nonverbal	
Laugh	Smiling with a chuckling sound	
Stall	Verbal expression of delay ("Wait a minute," "I'm not ready yet", etc or behavioural delay (ignores nurse's instructions)	
Stoic silence	Child does not respond to questions or remarks of others, may appear "trancelike"	
Carry	Has to be physically carried into or out of room or placed on table, not because of physical inability to do so on his or her own	
Flail	Random gross movements of arms or legs, without intention to make aggressive contact	
Nausea verbal	Says "I'm sick," "I feel nauseous," "My stomach feels like I'm going to throw up"	
Vomit	Includes retching, dry heaves	
Urinate/defecate	Soils or wets self	
Kick	Intentional movement of leg(s) to make aggressive physical contact	
Hit	Intentional movement of arm(s) or hand(s) to make aggressive physical contact	

Bite	Intentional closing of jaw to make aggressive physical contact	
Verbal hostility	Says "I hate you," "You're mean," etc.	
Refusal position	Does not follow instructions with regard to body placement on treatment table	
Restrain	Has to be held down because of lack of cooperativeness	
Curse	Verbally utters profanity	
Muscular rigidity	Any of following behaviors: clenched fists, white knuckles, gritted teeth, clenched jaw, wrinkled brow, eyes clenched shut, contracted limbs, body stiffness	
Questions	Nondelay, information-seeking verbal behavior ("What are you doing now?" Is it over yet? etc.)	
Emotional support	Verbal or nonverbal solicitation of hugs, physical comfort, or expression of empathy from parent, significant other, or nurse	
Requests termination	Verbally asks/pleads that procedure be stopped	
Total Score (25):		

- State Trait Anxiety Inventory for Adults
- Read each statement and select the appropriate response to indicate how you feel right now, that is, at this very moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

State Anxiety Scale Items	0 Not at all	1 A little	2 Somewhat	3 Very much so
1. I feel calm				
2. I feel secure				
3. I am tense				
4. I feel strained				
5. I feel at ease				
6. I feel upset				
7. I am presently worrying over possible misfortunes				
8. I feel satisfied				
9. I feel frightened				
10. I feel comfortable				
11. I feel self-confident				
12. I feel nervous				
13. I am jittery				
14. I feel indecisive				
15. I am relaxed				
16. I feel content				
17. I am worried				
18. I feel confused				
19. I feel steady				
20. I feel pleasant				
Trait Anxiety Scale Items	0 Almost never	1 Sometimes	2 Often	3 Almost always

21. I feel pleasant				
22. I feel nervous and restless				
23. I feel satisfied with myself				
24. I wish I could be as happy as others seem to be				
25. I feel like a failure				
26. I feel rested				
27. I am 'calm, cool, and collected'				
28. I feel that difficulties are piling up so that I cannot overcome them				
29. I worry too much over something that really doesn't matter				
30. I am happy				
31. I have disturbing thoughts				
32. I lack self confidence				
33. I feel insecure				
34. I make decisions easily				
35. I feel inadequate				
36. I am content				
37. Some unimportant thought runs through my mind and bothers me				
38. I take disappointments so keenly that I can't put them out of my mind				
39. I am a steady person				
40. I get in a state of tension or turmoil as I think about my recent concerns and interests				

Parental Satisfactory Score

English version: Please tick the most appropriate box for each question.

	Very satisfied (4)	Satisfied (3)	Not satisfied (2)	Very Unsatisfied (1)
Are you satisfied with our preadmission service? (Pre-anaesthetic assessment/Pre-anaesthesia clinic)				
Are you satisfied with our preoperative instructions?				
Are you satisfied with the operating theatre service?				
Are you satisfied with postoperative service?				

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