**Research Protocol**

**Title: Active Engagement Game Versus Passive Media During Pediatric Inhalational Induction: A Pragmatic Randomized Trial**

**NTC: pending**

**Date: May 26, 2026**

## Introduction

Preoperative anxiety is a highly prevalent complication in pediatric anesthesia, occurring in up to 50–60% of children undergoing surgery. High anxiety during the induction of anesthesia—particularly during the application of the face mask—is strongly correlated with poor induction compliance, increased risk of emergence delirium, higher postoperative analgesic requirements, and long-term negative behavioral changes.

To mitigate these risks, non-pharmacological behavioral interventions are widely integrated into routine pediatric perioperative care. While tablet-based audiovisual distraction (e.g., watching cartoons or playing games) has been shown to be a safe and effective alternative to pharmacological premedication, it is fundamentally limited by the physical realities of inhalational induction. Specifically, once the anesthesia mask is applied, children lose the physical ability to interact with standard digital games. Consequently, active distraction strategies frequently revert to passive observation at the exact moment when the child experiences the highest sensory distress.

Emerging evidence suggests that active cognitive engagement is superior to passive observation for sustained anxiolysis. However, there is a lack of specialized active distraction tools that safely integrate with the hands-on airway management workflow of the anesthesiologist. To address this gap, we developed a novel, two-phase interactive iPad/phone game. During the awake pre-induction phase, the child interacts directly with the screen. As the anesthesia mask is applied, control of the game seamlessly transfers to a phone remote operated by the anesthesiologist. The anesthesiologist synchronizes the remote to the child's spontaneous respiratory rate, providing the child with active, breath-driven visual feedback on the iPad/phone screen without requiring their physical interaction.

The primary objective of this pragmatic randomized controlled trial is to determine whether this breath-synchronized active engagement game reduces the need for physical restraint during pediatric mask induction compared to standard passive media distraction.

## Study Design

This study is a prospective and single-center, pragmatic, parallel-group, unblinded randomized controlled trial with a 1:1 allocation ratio. Pragmatic trial methods were selected to preserve real-world perioperative workflows and maximize the external validity of the findings to routine clinical practice.

## Study Setting

The trial will be conducted at Hong Kong Children's Hospital in the preoperative holding area and operating room. To reflect standard pediatric anesthesia practice, patient positioning during induction will not be rigidly standardized. Depending on the child's comfort, parental preference, and standard clinical judgment, children may undergo induction while seated on a parent's lap or lying supine on the operating bed.

## Participants

Children aged 3 to 8 years scheduled for elective surgery or sedation requiring planned inhalational induction without pharmacological premedication will be screened for eligibility. In routine clinical practice, children considered for enrolment are those judged by the attending anesthesiologist to be sufficiently calm and cooperative to undergo mask induction without premedication.

**Inclusion criteria**

- Age 3 to 8 years
- American Society of Anesthesiologists (ASA) physical status I or II
- Elective surgery or sedation requiring general anesthesia
- Planned mask (inhalational) induction
- Assessed by the attending anesthesiologist as sufficiently calm and cooperative to participate without pharmacological premedication for anxiolysis

**Exclusion criteria**

- Receipt of pharmacological premedication for anxiolysis (e.g., intranasal dexmedetomidine, oral midazolam)
- Developmental, cognitive, or communication impairment severe enough to preclude engagement with the interactive game or understanding of instructions
- Profound visual or hearing impairment that would prevent participation in the game or usual care distraction
- Any clinical airway scenario in which the attending anesthesiologist determines that study participation poses a safety risk

**Hypothesis**

The active engagement game will reduce the need for physical restraint during pediatric mask induction compared to standard passive media distraction. We hypothesize a 50% relative reduction in this primary outcome, from a baseline restraint rate of 23% in the control group to 11.5% in the intervention group.

**Randomization and Allocation Concealment**

Participants will be randomized in a 1:1 ratio to either the intervention or control group using block randomization. Randomization will be stratified by age group (3 to <6 years and 6 to 8 years) to account for known developmental differences in baseline mask acceptance and anxiety. The randomization schedule will be generated by an investigator not involved in enrollment. Allocation concealment will be maintained using a secure electronic randomization system, accessed only after informed consent is obtained.

**Blinding**

Due to the visible and interactive nature of the intervention, blinding of the clinical team and the patient is not possible. However, the primary outcome (use of physical restraint) is an objective binary clinical event, which is less vulnerable to observer interpretation bias. To mitigate observer bias for the subjective secondary outcome (the Induction Compliance Checklist, ICC), outcome assessors will be trained independent researchers positioned to minimize direct visualization of the iPad/phone screen during induction.

**Interventions**

**Control Group:** Participants will receive standard care consisting of parental presence, a scented anesthesia mask, and passive audiovisual distraction on a hospital iPad (e.g., cartoons or music) chosen by the child.

**Intervention Group:** Participants will receive standard care plus the active engagement distraction game delivered on a hospital iPad/phone. In the pre-induction phase, the child interacts with the game via direct screen tapping. During mask breathing, game progression is driven by an anesthesiologist-operated phone remote synchronized to the child's spontaneous breathing pattern.

**Study Procedures**

Following written informed consent and age-appropriate child assent, the assigned distraction modality will be introduced in the preoperative holding area or upon arrival to the operating room. In the control group, passive media will continue through mask application. In the intervention group, the child will initially engage with the game on the iPad/phone, followed by the remote-assisted breathing phase during mask induction. As the study will be done at the scheduled anesthesia session, no extra visits will be required.

To minimize confounding variables related to anesthetic technique, the inhalational induction process will be standardized for all participants. Once the patient has physically accepted the face mask, induction will commence with a wash-in of 50–70% nitrous oxide ($N_2O$) in oxygen. Once the child is breathing the $N_2O$ mixture calmly and end-tidal $N_2O$ concentrations are established, sevoflurane will be introduced into the circuit and titrated upward (e.g., up to 8%) according to the anesthesiologist's clinical judgment until loss of consciousness.

Because the trial is pragmatic, physical device setup will be adapted to the clinical situation. For lap inductions, the iPad/phone may rest on the child's lap and the phone remote on a nearby flat surface. For supine inductions, the iPad/phone will be held by an assistant in the child's line of sight, and the phone remote positioned near the child's head. In all intervention cases, the anesthesiologist will remain the sole operator of the remote.

The intervention period will continue until loss of consciousness. The distraction game will be stopped immediately once the child is asleep or if airway obstruction, breath-holding, or any other clinical event requires the anesthesiologist's full two-handed attention to airway management.

**Outcomes**

**Primary Outcome:** The incidence and degree of physical restraint required during inhalational induction. Restraint will be analyzed both as a binary threshold (Yes/No) to align with institutional baseline data, and as an ordinal variable to capture the clinical severity of the child's distress. The degree of restraint will be prospectively graded by the independent observer on a 4-point pragmatic clinical scale:

- **0 = No restraint:** The patient is cooperative or requires only verbal guidance; no physical holding is needed to apply the mask.
- **1 = Mild restraint:** Gentle holding of the child's hands or arms (usually by one person) to prevent interference with the mask, accompanied by minimal physical resistance from the child.
- **2 = Moderate restraint:** Firm holding of the limbs and/or torso by one or two individuals due to active physical resistance or attempts to sit up.

- **3 = Severe restraint:** Forceful holding of multiple body parts, including the head or full torso, often requiring multiple clinical staff and/or parents/legal guardians due to vigorous struggling, flailing, or combative behavior.

**Secondary Outcomes:**

1. Induction compliance measured by the Induction Compliance Checklist (ICC) during mask application.
2. Parent satisfaction and acceptability collected postoperatively via a structured Likert-scale questionnaire.
3. Child self-reported acceptability collected postoperatively via an age-appropriate visual smiley-face scale.

**Outcome assessment:**

The primary outcome (incidence and degree of physical restraint) and the secondary behavioral outcome (Induction Compliance Checklist [ICC]) will be recorded contemporaneously by an independent, trained study observer. No video or audio recordings will be made.

To maximize inter-rater reliability and minimize observer bias, assessor training and Inter-Rater Reliability (IRR) validation will be conducted using a standardized, de-identified video library. This library will be exclusively comprised of AI-generated clinical video clips and publicly available, open-access medical training videos. These training videos will encompass a full spectrum of pediatric behaviors, ranging from perfectly compliant inductions to severe panic requiring multi-person restraint.

During the training phase, assessors will independently score the training videos for both the 4-point degree of restraint scale and the 10-item ICC. Their scores will be compared against a "gold standard" reference key established by two senior pediatric anesthesiologists. Assessors will be required to achieve a predefined minimum inter-rater reliability threshold (Cohen's kappa or intraclass correlation coefficient (ICC) of $\geq 0.8$) with the gold standard key before they are permitted to score live inductions in the trial. Discrepancies during training will be resolved through group review and discussion of the specific behavioral anchors.

During the trial, to further reduce expectancy bias, the observer will be positioned to avoid direct visualization of the iPad/phone screen whenever feasible. The ICC will be scored as a single, cumulative behavioral assessment covering the awake induction window, defined as beginning at the exact moment the face mask makes physical contact with the patient and ending at the loss of consciousness (defined by the loss of the eyelash reflex). Behaviors occurring after the loss of consciousness, such as Stage II involuntary excitement movements, will not be included in the ICC score.

Parent feedback will be collected postoperatively using a brief structured questionnaire (2-minute) with Likert-scale items addressing satisfaction, perceived child calmness, and acceptability of the induction method. Child feedback, when developmentally appropriate, will be obtained in the day ward prior to discharge using a simple visual smiley-face scale to assess whether the child liked the distraction method, and it may take around 3 minutes. Both parent and child questionnaires should take around 5 minutes in total, and no further follow-up required. Upon completion, patients and parents/legal guardians will return questionnaires to the nurse.

**Sample Size**

Institutional baseline data (2024–2025) demonstrated an overall physical restraint rate (grades 1–3) of 23% (92/401) among children aged 3 to 8 years undergoing standard inhalational induction. After age stratification, the proportion of children *not* requiring restraint (grade 0) was 73.9% (aged 3 to <6 years) and 79.7% (aged 6 to 8 years).

The trial is statistically powered on the binary threshold of requiring *any* physical restraint (grades 1–3 versus grade 0). We hypothesize a 50% relative reduction in this primary outcome, from a baseline restraint rate of 23% in the control group to 11.5% in the intervention group. Using a two-sided comparison of proportions (Chi-square test) with 80% power and an alpha level of 0.05, 55 participants are required per group. Allowing for a 10–15% buffer for protocol deviations or cancellations, the planned sample size is 64 participants per group (N = 128).

**Statistical Analysis**

Analyses will be performed on an intention-to-treat basis. Baseline characteristics will be summarized descriptively.

To analyze the primary outcome, the binary incidence of physical restraint (Scale > 0) will be compared between groups using a Chi-square test, or Fisher's exact test if expected cell counts are small, with absolute risk reduction and relative risk reported with 95% confidence intervals. Furthermore, to evaluate the severity of distress, the ordinal degree of restraint (Scale 0–3) will be compared between groups using the Mann-Whitney U test.

The ordinal secondary outcome (ICC score) will also be compared using the Mann-Whitney U test. Prespecified exploratory subgroup analyses by age stratum (3 to <6 years and 6 to 8 years) will be conducted to evaluate whether the intervention effect differs by developmental age. A p-value of <0.05 will indicate statistical significance.

**Ethical Considerations**

No major ethical issues are anticipated beyond those ordinarily encountered in routine pediatric anesthesia care, except that for the issue of confidentiality, 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 participant). Other main ethical considerations are peri-induction distress, the possibility that a child may dislike the assigned distraction method, confidentiality of study data and the need to ensure that randomization does not interfere with standard clinical care. These issues are addressed by parental informed consent, child assent where appropriate, immediate discontinuation of the study intervention if clinically indicated, use of standard anesthetic management at all times and secure handling of pseudo-anonymized study data.

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

The study protocol has been approved by the institutional ethics board and registered prior to enrollment. The intervention is a non-pharmacologic behavioral adjunct delivered within the scope of routine peri-induction care. To ensure patient safety, the protocol mandates immediate cessation of the intervention if full clinical attention to airway management is required.

**Data Handling and Record Keeping**

To protect patient privacy, all research and personal 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 or ward keeps patients' confidential information. Electronic data should be saved in secured computer of the hospital with restricted access. No data will be stored on unencrypted portable storage devices or personal devices. After the study, the password-protected Excel file will remain securely stored on the hospital network for the designated retention period.

**References:**


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3. Rodriguez ST, Jang O, Hernandez JM, George AJ, Caruso TJ, Simons LE. Varying screen size for passive video distraction during induction of anesthesia in low-risk children: A pilot randomized controlled trial. Paediatr Anaesth. 2019;29(6):648-655. doi:10.1111/pan.13636

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