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Individual Cartoon Video for Alleviating Perioperative Anxiety and Reducing Emergence Delirium in Children: A Prospective Randomized Trial

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Title page**Individual Cartoon Video for Alleviating Perioperative Anxiety and Reducing Emergence Delirium in Children: A Prospective Randomized Trial****Authors**

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Abstract

BACKGROUND: Perioperative anxiety and emergence delirium may cause a series of adverse events, which are worth investigating. Pharmacological treatments remain uncertain, while nonpharmacological treatments lack personalization and pertinence.

AIMS: The aim of this study was to determine whether an individual cartoon video is capable of alleviating perioperative anxiety and reducing emergence delirium in preschool children.

METHODS: Children between 3 and 7 years old undergoing adenoidectomy and tonsillectomy were randomly assigned to an individual cartoon video group (group V) or a control group (group C). In group V, an individual cartoon video was played throughout the whole waiting, anesthesia induction and anesthesia recovery periods. The children in group C were contacted through verbal conversation. The primary outcomes were perioperative pediatric anxiety measured by the Modified Yale Preoperative Anxiety Scale (mYPAS) and emergence delirium assessed by the Pediatric Anesthesia Emergence Delirium (PAED) scale. The secondary outcomes included cooperation during induction, postoperative pain and adverse events.

RESULTS: The mYPAS scores were comparable in the two groups ($P = 0.583$) at the holding area (T0), but the mYPAS scores of group V were significantly lower than those of group C at the time of entering the operating room (T1), during the induction of anesthesia (T2) and leaving the PACU (T6) ($P < 0.001$, $P < 0.001$, $P = 0.001$) after intervention. The incidence of emergence delirium ($PAED \geq 10$) in group V was significantly lower than that in group C after extubation (T3) and upon arrival at the PACU (T4) (55% vs. 77.5%, $P = 0.033$; 32.5% vs. 55%, $P = 0.043$). We found no differences in cooperation during induction, postoperative pain or the incidence of adverse events between the groups.

CONCLUSIONS: The individual cartoon video is an effective method of alleviating perioperative anxiety and reducing the incidence of emergence delirium in children.

Ethics Approval Statement

This clinical trial was approved by the Ethics Committee of the Second Hospital of Anhui Medical University (Reference number: YX2022-084 (F1))

Clinical Trial Registration Identifier

ChiCTR2200062300 (<https://www.chictr.org.cn/index.aspx>)

KEY WORDS : individual cartoon video ; anxiety ; emergence delirium ; pediatrics;

What is already known about the topic?

Anxiety and emergence delirium are commonly observed in young children and cause many adverse effects.

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3 Pharmacological treatments of anxiety and emergence delirium remain uncertain, while
4 nonpharmacological treatments lack personalization and pertinence.
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7 **What new information this study adds?**

8 The patients' favorite cartoon video was played as the intervention for anxiety, which will be targeted, and
9 the effect will be maximized.

10 The individual cartoon video can not only alleviate perioperative anxiety, but reduce the incidence of
11 emergence delirium in children.
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14 **How this study might affect the practice?**

15 The patients' favorite cartoon video can be played as the intervention for anxiety and emergence delirium,
16 which will be targeted, easy-accessed and the effect will be maximized.
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20 **Introduction**

21 Emergence delirium (ED) is described as a complex of perceptual disturbances and psychomotor agitation
22 in young children in the early postanesthetic period following a sevoflurane-based anesthetic^[1]. Delirium
23 may arise upon emergence from anesthesia, with a variable incidence of 10–80%^[2-4]. ED can exert a negative
24 impact on patient safety because there can be injury to the surgical site, tearing of drains or dressings, or
25 accidental removal of intravenous catheters, which can even prolong the hospital length of stay. Therefore,
26 reducing ED is a worthy clinical issue in pediatric anesthesia. Anxiety is a common abnormal psychological
27 state before pediatric anesthesia and surgery. Due to their immature physical and mental development,
28 children are often in a state of psychological stress during the perioperative period, which is defined as
29 anxiety. It has been reported that up to 65% of children in the holding area and during the induction of
30 anesthesia experience intense anxiety about anesthesia and surgery^[5]. Severe anxiety easily causes
31 noncompliance during anesthesia induction, severe pain and even delirium during the recovery period.
32 Therefore, alleviating anxiety and reducing the incidence of ED in children are of great significance for
33 ensuring perioperative safety and improving surgical prognosis.
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40 The current clinical measures to prevent ED in children include pharmacological and nonpharmacological
41 preventions. The preventive and therapeutic drugs commonly used are propofol, opioids, ketamine, α_2
42 receptor agonists and benzodiazepines^[6]. However, the efficacy of these drugs is not clear, and the optimal
43 dosage is unknown. In addition, due to the immaturity of children's physical and psychological development,
44 pharmacological treatment has side effects and potential risks, and the compliance of young children in
45 taking medication is low. Compared with it, nonpharmacological interventions are more comfortable, safer
46 and free of drug side effects. Nonpharmacological measures include age-appropriate preoperative education,
47 family-centered preoperative preparation, parental company during anesthesia induction and distraction of
48 children. Although parents' company and family-centered preoperative preparation can alleviate children's
49 preoperative anxiety to a certain extent^[7], children cannot be accompanied by their parents after entering the
50 surgical isolation area due to the aseptic requirements. As a result, pediatric patients are often nervous and
51 anxious, and it is hard for them to cooperate with medical staff. Preschool children usually enjoy watching
52 cartoons. Although previous studies have suggested that cartoon videos can be a good distraction for children
53 and may improve their preoperative anxiety and compliance with medical procedures^[8, 9], the cartoon videos
54 used in previous studies lack personalization and pertinence. The preferred cartoon videos in each age group
55 and even in children one year apart are different. Therefore, it is difficult to ensure the same level of attraction
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3 for the children when using impersonalized cartoon videos. Meanwhile, most previous studies have
4 suggested that the causes of emergence and postoperative delirium are related to preoperative anxiety and
5 that reducing preoperative anxiety can reduce the incidence of postoperative delirium. Therefore, some
6 studies have focused only on how to reduce preoperative anxiety, while few have continued to pay attention
7 to the anxiety of children who are awakening in the PACU^[1].
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11 Therefore, this study was performed to determine whether individual cartoon videos are capable of
12 alleviating perioperative anxiety and reducing emergence delirium in preschool children.
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15 **Methods**

16 This clinical trial was approved by the Ethics Committee of the Second Hospital of Anhui Medical
17 University (Reference number: YX2022-084 (F1)) and was registered at the Chinese Clinical Trial Registry
18 (Reference number: ChiCTR2200062300). Written consent was obtained from parents (or guardians). This
19 single-center, randomized clinical trial was conducted from August to September 2022 in accordance with
20 the principles of the Helsinki Declaration.
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24 Ninety-five patients aged between 3 and 7 years with an American Society of Anesthesiologists physical
25 status I-II and who were scheduled for their first elective adenoidectomy or adenotonsillectomy under
26 general anesthesia were enrolled. Children having emergency surgery and those with previous anesthetic
27 experience, developmental delays, mental retardation, sedative medication or chronic illnesses were
28 excluded from the study.
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32 The day before surgery, the eligible patients were visited by a trained anesthesiologist, and their general
33 information and favorite cartoon videos were recorded. On the day of surgery, all of the patients were brought
34 to the holding area 30 min before surgery and treated according to the group assignment. The enrolled
35 children were randomized into two groups using a computer-generated randomization program: group V
36 (distraction by watching an individual cartoon video) and group C (control). The patients in group V began
37 to watch a favorite cartoon video on iPad throughout the whole waiting and anesthesia induction process.
38 Patients in group C were contacted by the medical staff through verbal conversation to relieve their anxiety.
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42 The surgery and anesthesia were always performed by the same professionals (two surgeons and an
43 anesthesiologist), and standard anesthetic regimens and techniques were used for all patients. After the
44 application of standard monitoring, including blood pressure, electrocardiography and
45 blood oxygen saturation, inhalation anesthesia induction was performed at tidal volume, with incrementing
46 sevoflurane up to 8% with a 50% mixture of air and oxygen (6 L/min). Peripheral IV access was obtained,
47 and an appropriately sized laryngeal tube was inserted after a suitable anesthetic depth was obtained by the
48 injection of propofol (2 mg/kg), sufentanil (0.2 µg/kg) and cisatracurium (0.1 mg/kg). Then, atropine (0.02
49 mg/kg) and dexamethasone (0.1 mg/kg) were administered, and anesthesia was maintained with remifentanyl
50 0.2-0.3 µg/kg/min and sevoflurane 3%-5%. At the end of surgery, the children were extubated after
51 awakening with adequate spontaneous ventilation and were transferred to the postanesthetic care unit (PACU)
52 for observation. In group V, the individual cartoon video was continuously played in the early recovery stage
53 until the children left the PACU and were reunited with their parents.
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57 The primary outcomes were anxiety measured by the Modified Yale Preoperative Anxiety Scale (mYPAS)
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3 and ED assessed by the Pediatric Anesthesia Emergence Delirium (PAED) scale. The mYPAS is a validated
4 perioperative pediatric anxiety instrument with observational measurements of anxiety in 5 categories
5 (activity, emotional expressivity, state of arousal, vocalization, and use of parents)^[10]. Scores range from
6 23.33 to 100, with higher scores indicating higher levels of anxiety^[11]. The mYPAS was administered at 4
7 time points: in the preoperative holding area (baseline, or T0), upon entering the operating room (T1), during
8 the induction of anesthesia (T2) and upon leaving the PACU (T6). Behavior on emergence was measured
9 using the PAED scale. The PAED scale was assessed at 4 time points: immediately after extubation (T3), on
10 arriving in the PACU (T4), 30 min after arriving in the PACU (T5) and T6. ED was defined as PAED scores
11 ≥ 10 . The PAED scale was also used to measure the intensity of ED, where 0 represents no ED and 20 is the
12 maximum intensity of ED. The induction compliance checklist (ICC) was used to assess the cooperation of
13 the children at T2. A validated simplified 3-point scoring system for ICC [perfect (ICC = 0), moderate (ICC
14 = 1–3), and poor (ICC ≥ 4)] was used in our trial^[12]. The FLACC assessment tool was also administered to
15 measure postoperative pain at the same time as PAED. The FLACC scale scores the pain intensity by rating
16 five behaviors (face, legs, activity, consolability and cry) to derive a score out of 10.^[13] All assessments were
17 completed by the same trained anesthesiologist who is blinded to the group allocation. For the patients
18 suffering from ED, the first measure was to comfort the patients with words. When this failed, the patients
19 were treated with propofol (10–20 mg IV). If a child exhibited signs of pain with a FLACC scale > 4 ,
20 sufentanil (0.05 $\mu\text{g}/\text{kg}$ IV) was administered as rescue medication.
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29 For the sample size calculation, we used a proportion of ED and anxiety of 50%, as reported in previously
30 published studies^[3, 5]. Therefore, 40 subjects per group would have a significance level of 5% and a power
31 of 80% in detecting a 30% reduction in ED incidence between the groups. While anticipating a 15% dropout
32 rate, we estimated that 46 patients were needed in each group.
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36 SPSS 26.0 statistical software was used to statistically process and analyze the data. The measurement data
37 conforming to the normal distribution were expressed as the mean \pm standard deviation, and the comparison
38 between the groups was performed by two independent samples t test. Enumeration data were expressed by
39 the number of patients (percentage) [n(%)], and the comparison was made by χ^2 test. The comparison of
40 measurement data that did not conform to a normal distribution was expressed by a nonparametric test and
41 is shown as the median (25th percentile, 75th percentile). Taking $\alpha=0.05$ as the test level, $P<0.05$ indicates
42 a statistically significant difference.
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46 Results

47 As shown in the Consort flow chart (Figure 1), 95 children were enrolled in our study, and 15 children were
48 excluded because of withdrawal of consent, loss of follow-up, discontinued intervention or extra medication.
49 Thus, 80 participants completed the study and were included in the final data analysis. There were no
50 statistically significant differences between the groups in terms of age, gender, height, weight, duration of
51 surgery and anesthesia or the type of surgery (Table 1).
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55 Compared with the baseline, the mYPAS score of group V was found to be significantly changed at T1
56 ($P<0.001$). In group C, the increase in mYPAS scores showed statistically significant differences at T1, T2
57 and T6 ($P=0.002$, $P<0.001$ and $P<0.001$) (Figure 2). The mYPAS scores at T0 exhibiting baseline anxiety
58 were not statistically different between the groups ($P = 0.583$) before the intervention. After the intervention,
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3 the mYPAS scores were different between the groups at T1 ($P < 0.001$), T2 ($P < 0.001$) and T6 ($P=0.001$).
4 Meanwhile, both the peak mYPAS scores and the incidence of anxiety (mYPAS score >40) showed
5 significant differences between the two groups ($P<0.001$; $P=0.013$) (Table 2). The individual cartoon video
6 not only reduced the level of anxiety but also shortened the duration of anxiety.
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10 The incidence of ED (PAED ≥ 10) in group V was significantly lower than that in group C at T3 and T4 (55%
11 vs. 77.5%, $P=0.033$; 32.5% vs. 55%, $P=0.043$). The peak of PAED in group C was significantly higher than
12 that in group V. Additionally, the overall incidence of severe ED (PAED ≥ 15) showed a significant difference
13 between group C and group V (15% vs. 35%, $P=0.039$), while the incidence of ED showed no significant
14 difference (60% vs. 80%, $P=0.051$) (Table 3). The individual cartoon video may reduce the severity of ED
15 and the overall incidence of severe ED.
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21 The FLACC scores were not different between the two groups at T3, T4, T5 and T6. Similarly, the ICC and
22 the incidence of adverse events were not found to be different (Table 4).
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25 Discussion

26 In the present study, we found that individual cartoon videos can significantly alleviate perioperative anxiety
27 and reduce the incidence of ED in pediatric patients undergoing adenoidectomy and adenotonsillectomy.
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30 Up to 65% of all children undergoing anesthesia and surgery develop intense anxiety and fear in the
31 preoperative holding area and during the induction of anesthesia. This anxiety can be attributed to parental
32 separation and uncertainty about the procedure. Many studies^[14] have confirmed that preoperative anxiety
33 in young children undergoing surgery is associated with a more painful postoperative recovery and a higher
34 incidence of sleep and other problems. A number of pharmacological and nonpharmacological measures are
35 frequently used to prevent or alleviate anxiety in pediatrics. Although pharmacologic intervention with a
36 sedative (i.e., midazolam) to alleviate children's anxiety is regarded as an effective method, it has been
37 associated with delays in hospital discharge and maladaptive behavioral changes. Additionally, the difficulty
38 in administering premedication to children due to their reluctance or refusal is still a problem that cannot be
39 ignored. Manyande A^[15] showed that the presence of parents during induction of general anesthesia does not
40 diminish their child's anxiety and that playing videos of the child's choice during induction is a potentially
41 promising nonpharmacological intervention.
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47 Most preschool children are very fond of watching cartoon videos. Gamze Inan^[7] demonstrated 3 different
48 distraction techniques on the pain and anxiety levels of children during venipuncture, in which there are only
49 several popular fixed options, whether in cartoon movies or video games. Jeongwoo Lee^[16] similarly
50 preselected 10 movies, including 4 action movies, 4 comics, 1 science fiction and Cinderella, in his study
51 about the effect of cartoon distraction on pediatric surgical patients. In our study, we did not limit the number
52 and types of cartoon videos. We determined the patients' favorite cartoon video one day before the operation
53 and downloaded it in advance. A favorite cartoon can immerse children in videos and distract their attention
54 from the unfamiliar environment and the absence of their parents. Meanwhile, many popular cartoons are
55 freely available with public access. Therefore, the intervention of watching individual cartoons to reduce
56 anxiety can be used without increasing health care costs. In this way, the intervention for anxiety will be
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3 targeted, and the effect will be maximized.
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6 Katherine A^[17] showed that the children in the group with video distraction displayed significantly less
7 anxiety at anesthetic induction and had a smaller increase in anxiety from the holding area to induction than
8 those in the standard care group. Patel^[18] et al. also demonstrated that animated cartoon distraction produced
9 a significant reduction in anxiety in children aged 4 to 12 years compared with the intervention of oral
10 premedication or parental presence. These findings are consistent with our findings. We noticed that many
11 studies focused only on preoperative anxiety and ignored the postoperative status of the patient's anxiety.
12 After surgery, pediatric patients often cry and scream because they long for their parents' company, which
13 is also seen as a form of anxiety. In our study, we found that the pediatric patients in the group without
14 cartoon video distraction displayed more anxiety when they departed from the PACU than the patients in the
15 cartoon video group. As a result, the individual cartoon videos play a key role in alleviating anxiety in the
16 whole perioperative period.
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21 Kain^[19] pointed out an important correlation between emergence delirium and preoperative anxiety in
22 children: for every 10-point increase in the mYPAS, the risk of delirium increases by 10%. A previous
23 study^[20] suggested that preoperative anxiety was one of the risk factors for ED. Thus, interventions aimed
24 at alleviating preoperative anxiety are of great significance for preventing ED. In this study, the individual
25 cartoon video is an easy and effective modality to alleviate anxiety and prevent ED. The outcome of this
26 study showed that the overall incidence of ED in the individual cartoon video group was 20% lower than
27 that in the control group. Specifically, the incidence of ED in the two groups showed a large difference at
28 the time of extracting the tracheal tube and arriving at the PACU. However, the differences between the two
29 groups at 30 min after arriving in the PACU and departing from the PACU were not statistically significant.
30 A possible explanation for this might be that during the period when the patient is not fully awake, there is
31 a high incidence of emergence agitation. Because the patient is not fully conscious, the sound or scene of
32 their favorite cartoon video makes it easier for them to calm them down.
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38 There were no significant differences in the incidence of adverse events between the two groups. However,
39 previous studies^[21] have found that ED increases the risk of these adverse events. The possible reason is that
40 our study may be limited by the sample size. We calculated the sample size with the incidence of ED and
41 anxiety, and a larger sample size is required for determining differences in adverse events.
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45 **Conclusion**

46 We concluded that the individual cartoon video could significantly alleviate perioperative anxiety and reduce
47 the incidence of emergence delirium in pediatric patients.
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Assistance with the study

none.

Author contributions

Xinyu Tang and Muchun Zhang contributed equally to this paper.

All authors contributed to the study conception and design. Material preparation and data collection were performed by Xinchun Tao, Yamei Li, Yi Wang and Xin Wang. Data analysis was conducted by Xinyu Tang and Muchun Zhang. The first draft of the manuscript was written by Xinyu Tang and Muchun Zhang and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Competing interests statement

All authors declare that they have no competing interests.

Ethics Statement

This clinical trial was approved by the Ethics Committee of the Second Hospital of Anhui Medical University (Reference number: YX2022-084 (F1)) and was registered at the Chinese Clinical Trial Registry (Reference number: ChiCTR2200062300). The study was performed in accordance with the Helsinki Declaration of 1964, and its later amendments. Written consent was obtained from parents (or guardians).

Data availability statement

The data to support the results of this study is available from the corresponding author on reasonable request.

Prior presentation

none

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Table 1. Demographic and surgical characteristics of the patients

	Individual cartoon video (n = 40)	Control (n = 40)	P value
Age (years)	5.75 ± 1.21	5.68 ± 1.58	0.812
Gender (male) [n (%)]	17 (42.5)	23 (57.5)	0.180
Height (cm)	114.43 ± 9.24	108.10 ± 11.92	0.319
Weight (kg)	21.47 ± 6.18	21.63 ± 5.26	0.271
Surgery length (min)	34.45 ± 12.07	34.63 ± 12.20	0.596
Anesthesia length (min)	47.35 ± 15.16	46.23 ± 14.09	0.691
Surgery [n (%)]			0.875
Adenoidectomy	15 (37.5)	17 (42.5)	
Tonsillectomy	10 (25)	10 (25)	
Adenoidectomy+ Tonsillectomy	15 (37.5)	13 (32.5)	

Data are presented as frequency (percentage) or mean ± SD (Standard Deviation).

Table 2. Perioperative pediatric anxiety between the two groups

	Individual cartoon video (n = 40)	Control (n = 40)	P value
mYPAS			
T0	44.60 [36.36~50.00]	42.09 [33.36~50.00]	0.583
T1	34.32 [32.15~38.89]	46.76 [40.04~62.94]	0.000 [†]
T2	38.89 [33.33~44.27]	59.58 [48.44~80.00]	0.000 [†]
T6	39.86 [33.33~59.73]	56.93 [45.85~78.81]	0.001 [†]
Peak_mYPAS	51.00 [41.67~60.89]	64.14 [53.57~85.47]	0.000 [†]
Anxiety [n (%)]	32 (80)	39 (97.5)	0.013 [†]

Data are presented as frequency (percentage) or median [25th percentile to 75th percentile] as appropriate.

[†]P < 0.05 versus the control group

mYPAS, Modified Yale Preoperative Anxiety Scale

T0, preoperative holding area

T1, entry to the operating room

T2, induction of anesthesia

T6, leaving the PACU

Peak_mYPAS refers to the highest score of mYPAS in the four time points of T0, T1, T2 and T6.

mYPAS score > 40 is considered as the occurrence of anxiety .

Table 3. Emergence delirium between the two groups

	Individual cartoon video (n = 40)	Control (n = 40)	P value
PAED			
T3 [n (%)]	22 (55)	31 (77.5)	0.033 [†]
T4 [n (%)]	13 (32.5)	22 (55)	0.043 [†]
T5 [n (%)]	9 (22.5)	10 (25)	0.793
T6 [n (%)]	6 (15)	5 (12.5)	0.745
Peak_PAED	12.00 [9.00~13.00]	13.50 [10.00~15.00]	0.016 [†]
ED [n (%)]	24 (60)	32 (80)	0.051
Severe ED [n (%)]	6 (15)	14 (35)	0.039 [†]

Data are presented as frequency (percentage) or median [25th percentile to 75th percentile] as appropriate.

[†]P < 0.05 versus the control group

PAED, the Pediatric Anesthesia Emergence Delirium scale

T3, immediately after extubation

T4, arriving in the PACU

T5, 30 min after arriving in the PACU

T6, leaving the PACU

Peak_PAED refers to the highest score of PAED in the four time points of T3, T4, T5 and T6.

PAED score ≥ 10 is considered as the occurrence of ED.

PAED score ≥ 15 is considered as the occurrence of severe ED

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2 **Table 4.** Secondary outcomes of the patients

	Individual cartoon video (n = 40)	Control (n = 40)	P value
FLACC			
T3	3.00 [1.25~4.75]	3.50 [2.00~5.00]	0.599
T4	3.00 [1.00~5.00]	3.50 [2.00~5.75]	0.061
T5	2.50 [1.00~4.00]	3.00 [2.00~5.00]	0.058
T6	2.00 [1.00~3.75]	3.00 [1.00~4.00]	0.300
ICC	2.00 [0.00~4.00]	3.00 [1.25~4.00]	0.110
Adverse events [n (%)]	3 (7.5)	4 (10)	0.692

3 Data are presented as frequency (percentage) or median [25th percentile to 75th percentile] as
4 appropriate.

5 FLACC, Face, Legs, Activity, Consolability, Cry scale

6 T3, immediately after extubation

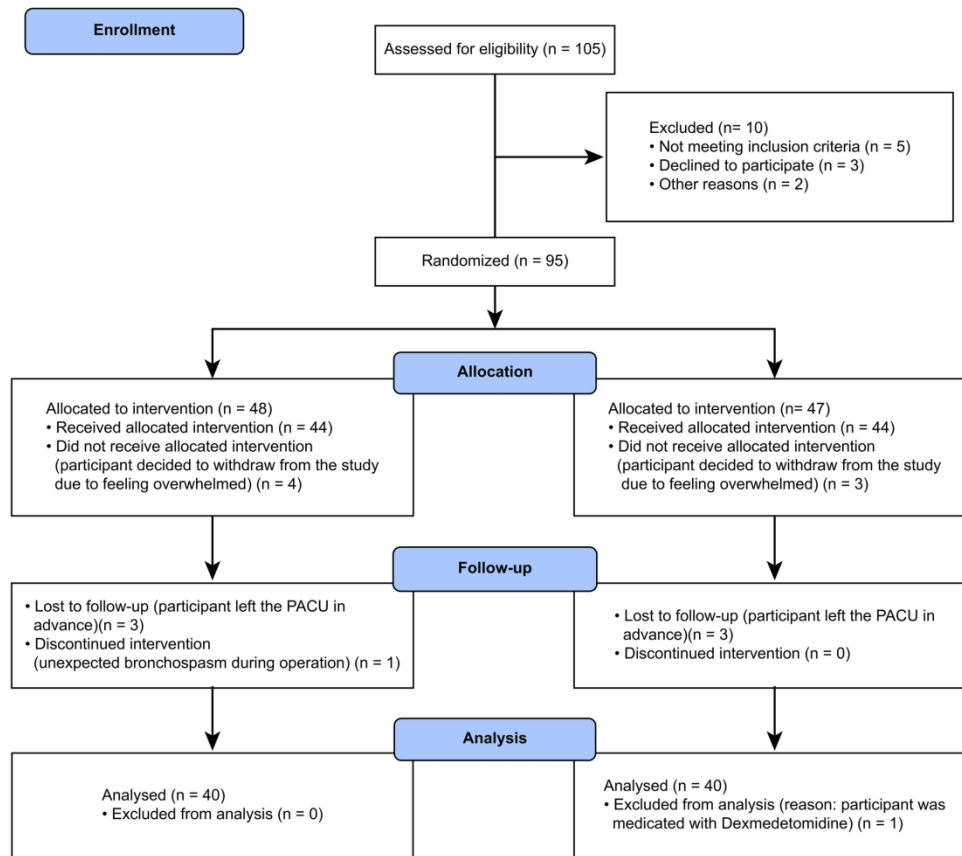
7 T4, arriving in the PACU

8 T5, 30 min after arriving in the PACU

9 T6, leaving the PACU

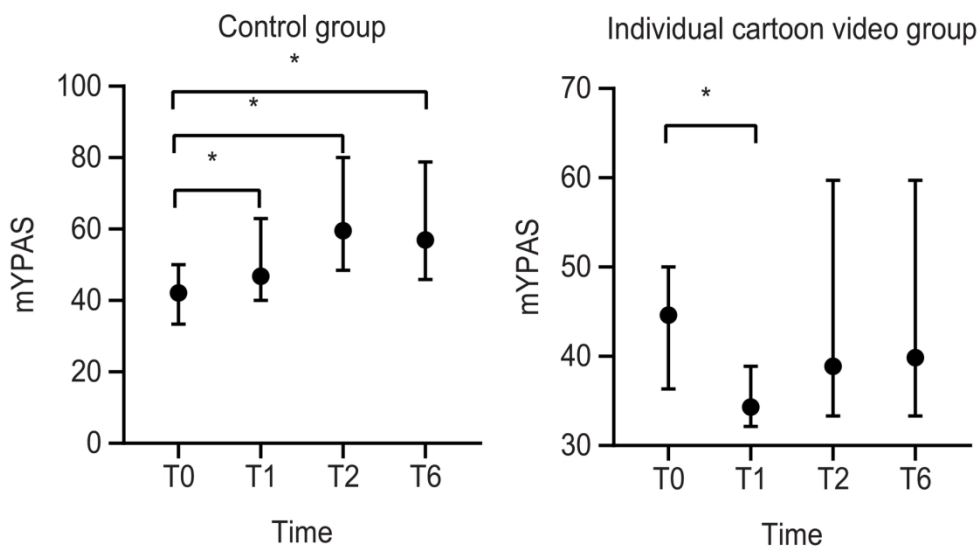
10 ICC, induction compliance checklist

11 Adverse events refer to severe hypoxemia, bronchospasm, postoperative bleeding, etc.



CONSORT flow diagram of the study.

179x157mm (300 x 300 DPI)



mYPAS score differences at T1, T2 and T6 compared with T0 in control group and individual cartoon group.

*P < 0.01 versus T0

mYPAS, Modified Yale Preoperative Anxiety Scale

T0, preoperative holding area

T1, entry to the operating room

T2, induction of anesthesia

T6, leaving the PACU

79x46mm (600 x 600 DPI)

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Individual Cartoon Video for Alleviating Perioperative Anxiety and Reducing Emergence Delirium in Children: A Prospective Randomized Trial

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4 **Title page**
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6 **Individual Cartoon Video for Alleviating Perioperative Anxiety and Reducing Emergence**
7 **Delirium in Children: A Prospective Randomized Trial**
8

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Confidential: For Review Only

Abstract

BACKGROUND: Perioperative anxiety and emergence delirium in young children may cause a series of adverse events, which are worth investigating. Pharmacological treatments of anxiety and delirium remain uncertain, while nonpharmacological treatments lack personalization and pertinence.

AIMS: The aim of study was to determine whether an individual cartoon video can alleviate perioperative anxiety and reduce emergence delirium in young children undergoing adenoidectomy and tonsillectomy.

METHODS: Children between 3 and 7 years old undergoing adenoidectomy and tonsillectomy were randomly assigned to an individual cartoon video group (group V) or a control group (group C). In group V, an individual cartoon video of the child's own choice was played throughout the whole waiting, anesthesia induction and recovery periods. The children in group C were contacted through verbal conversation. The primary outcomes were anxiety measured by the Modified Yale Preoperative Anxiety Scale (mYPAS) and emergence delirium assessed by the Pediatric Anesthesia Emergence Delirium (PAED) scale. The secondary outcomes included cooperation during induction, postoperative pain and adverse events.

RESULTS: The incidence of anxiety were comparable in group V and group C at the holding area (T0)(26% vs. 22%, $P=0.323$), but the incidence of anxiety of group V were significantly lower than those of group C at the time of entering the operating room (T1), during the induction of anesthesia (T2) and leaving the PACU (T6) ($P<0.001$, $P<0.001$, $P<0.001$) after intervention. The peak PAED score in group V was significantly lower than that in group C (12.00 [9.00~13.00] vs. 13.50 [10.00~15.00], $P=0.016$). We found no significant differences in cooperation during induction, postoperative pain or the incidence of adverse events between the groups (2.00 [0.00~4.00] vs. 3.00 [1.25~4.00], $P=0.110$; $F=0.059$, $P_{\text{group}}=0.808$; 3 (7.5%) vs. 4 (10), $P=0.692$).

CONCLUSIONS: The individual cartoon video is an effective method of reducing perioperative anxiety and alleviating emergence delirium in children.

Ethics Approval Statement

This clinical trial was approved by the Ethics Committee of the Second Hospital of Anhui Medical University (Reference number: YX2022-084 (F1))

Clinical Trial Registration Identifier

ChiCTR2200062300 (<https://www.chictr.org.cn/index.aspx>)

KEY WORDS : individual cartoon video ; anxiety ; emergence delirium ; pediatrics;

What is already known about the topic?

Anxiety and emergence delirium are commonly observed in young children and cause many adverse effects.

Pharmacological treatments of anxiety and emergence delirium remain uncertain, while nonpharmacological treatments lack personalization and pertinence.

What new information this study adds?

Using a child's favorite cartoon video can reduce the incidence of perioperative anxiety.

Using a child's favorite cartoon video may alleviate emergence delirium.

How this study might affect the practice?

The patients' favorite cartoon video can be played as the intervention for anxiety and emergence delirium, which will be targeted, easy-accessed and the effect will be maximized.

Introduction

Emergence delirium (ED) is described as a complex of perceptual disturbances and psychomotor agitation that most commonly observed in young children in the early postanesthetic period following a sevoflurane-based anesthetic^[1]. While, anxiety is a common abnormal psychological state before pediatric anesthesia and surgery. It has been reported that up to 65% of children in the holding area and during the induction of anesthesia experience intense anxiety about anesthesia and surgery^[2]. Severe anxiety easily causes uncooperative behavior, severe pain, emergence delirium, and higher doses of sedation or preoperative analgesia^[3-5]. Therefore, alleviating anxiety and reducing the incidence of ED in children are of great significance for ensuring perioperative safety and improving surgical prognosis.

Tailored treatment for perioperative anxiety of a pediatric patient can use either pharmacological or non-pharmacological methods, often in tandem. The use of anxiolytic premedication in particular is valuable for certain groups^[6], but the efficacy of these drugs is not clear, and the optimal dosage is unknown. In addition, due to the immaturity of children's physical and psychological development, pharmacological treatment has side effects and potential risks, and the compliance of young children in taking medication is low. Compared with pharmacological therapy, non-pharmacological interventions are more comfortable, safer and free of drug side effects^[7].

As a whole non-pharmacological modalities comprise education approaches, behavioral techniques, parental presence at induction of anesthesia (PPIA), and complementary and alternative medicine (CAM) techniques, with each category including a range of effective strategies for reducing anxiety^[7]. Research has increasingly focused on exploring the effects of technology devices, especially based on audiovisual interventions^[8]. These technology devices (eg, smartphones^[9, 10], video glasses^[11], streaming videoplayers^[12], portable computers^[13, 14], iPads^[15], and video games^[16]) have been widely used as a vehicle for streaming media content(eg, video games, streaming video clips, apps^[17], virtual reality, and cartoons) to reduce perioperative anxiety in children through distraction.

Cohen et al. used cartoons as an effective distraction tool during surgical procedures in children and in another study demonstrated that playing age-appropriate videos before medical procedures was

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3 a more effective distractor than was an interactive toy^[18, 19]. Compared with premedication or
4 parental presence only, a handheld video game with parental presence was found to be more
5 effective for reducing anxiety in children aged 4 to 12 years^[16]. A study also demonstrates that
6 pediatric patients who used VR were found to have significantly lower anxiety at the time of
7 induction of anesthesia compared to patients who did not use VR^[20]. However, we found that the
8 choices of the videos^[21], handheld video games^[16] or VR^[20] in previous studies seemed to be
9 impersonalized and limited. Most studies used the same media content as interventions, regardless
10 of the gender and age of patients^[20, 22]. Even if the selection is based on age and gender, it is possible
11 that the children cannot find his favorite cartoon video in the options of his age due to individual
12 differences. Meanwhile, it has been proved that the causes of emergence delirium are related to
13 preoperative anxiety and that reducing preoperative anxiety can reduce the incidence of
14 postoperative delirium^[1, 23]. Therefore, some studies have focused only on how to reduce
15 preoperative anxiety, while few have continued to pay attention to the anxiety of children who are
16 awakening in the PACU^[1].

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23 Therefore, this study was performed to determine whether individual cartoon videos are capable of
24 alleviating perioperative anxiety and reducing emergence delirium in young children undergoing
25 adenoidectomy and tonsillectomy.

26 27 28 **Methods**

29 30 31 **Ethics**

32 This clinical trial was approved by the Ethics Committee of the Second Hospital of Anhui Medical
33 University (Reference number: YX2022-084 (F1)) and was registered at the Chinese Clinical Trial
34 Registry (Reference number: ChiCTR2200062300). Written consent was obtained from parents (or
35 guardians). This single-center, randomized clinical trial was conducted from August to September
36 2022 in accordance with the principles of the Helsinki Declaration.

37 38 39 **Participants**

40 Ninety-five patients aged between 3 and 7 years with an American Society of Anesthesiologists
41 physical status I-II and who were scheduled for their first elective adenoidectomy or tonsillectomy
42 under general anesthesia were enrolled. Children having emergency surgery and those with previous
43 anesthetic experience, developmental delays, intellectual disability, sedative medication or chronic
44 illnesses were excluded from the study.

45 46 47 48 **Patient and Public Involvement**

49 Parents or the public were not directly involved in the design, conduct or plans for the
50 dissemination of our research.

51 52 53 **Procedures**

54 The day before surgery, the eligible patients were visited by a trained anesthesiologist, and their
55 general information was recorded. Most importantly, through conversations with children, their
56 favorite cartoon videos even specific to favorite clips were all recorded. There were no limits to the
57 scope of cartoons, which were freely chosen according to children's preferences. On the day of
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3 surgery, all of the patients were brought to the holding area 30 min before surgery and treated
4 according to the group assignment. The enrolled children were randomized into two groups using a
5 computer-generated randomization program: group V (distraction by watching an individual
6 cartoon video) and group C (control). The patients in group V began to watch a favorite cartoon
7 video on iPad throughout the whole waiting and anesthesia induction process. Patients in group C
8 were contacted by the medical staff through verbal conversation to relieve their anxiety.
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12 The surgical interventions and the administration of anesthesia were always performed by the same
13 professionals (two surgeons and an anesthesiologist), and standard anesthetic regimens and
14 techniques were used for all patients. After the application of standard monitoring, including blood
15 pressure, electrocardiography, blood oxygen saturation, and the bispectral index, inhalation
16 anesthesia induction was performed at tidal volume, with incrementing sevoflurane up to 8% with
17 a 50% mixture of air and oxygen (6 L/min). At the same time, the induction compliance checklist
18 (ICC) score was recorded by a trained nurse. Peripheral IV access was obtained, and an
19 appropriately sized laryngeal tube was inserted after a suitable anesthetic depth was obtained by the
20 injection of propofol (2 mg/kg), sufentanil (0.2 µg/kg) and cisatracurium (0.1 mg/kg). Then,
21 atropine (0.02 mg/kg) and dexamethasone (0.1 mg/kg) were administered, and anesthesia was
22 maintained with remifentanyl 0.2-0.3 µg/kg/min and sevoflurane 3%-5% with a BIS target range of
23 40-60. At the end of surgery, the children were extubated after awakening with adequate
24 spontaneous ventilation and were transferred to the postanesthetic care unit (PACU) for observation.
25 In group V, the individual cartoon video was continuously played in the early recovery stage until
26 the children left the PACU and were reunited with their parents.
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32 Measures

33 Every assessment was completed by the same trained anesthesiologist who is blinded to the group
34 allocation. The primary outcomes were perioperative pediatric anxiety measured by the Modified
35 Yale Preoperative Anxiety Scale (mYPAS) and ED assessed by the Pediatric Anesthesia Emergence
36 Delirium (PAED) scale. The mYPAS is a validated perioperative pediatric anxiety instrument with
37 22 items in 5 categories (activity, emotional expressivity, state of arousal, vocalization, and use of
38 parents)^[24]. In terms of activity, this domain measures the child's level of activity or restlessness,
39 for example, whether the child is fidgeting in their seat or moving around the room. The domain of
40 emotional expressivity estimates the child's emotional state and expression, for example, the child
41 is crying, worried or happy. In terms of state of arousal, this domain measures the child's
42 physiological arousal, such as vigilance, sucking on thumb or panicked whimpering. The domain
43 of vocalization investigates whether the child is reading, moaning, screaming, etc. And in terms of
44 use of parents, it measures the child's reliance on their parents for comfort and support. Scores range
45 from 23.33 to 100, with higher scores indicating higher levels of anxiety^[25]. The mYPAS was
46 administered at 4 time points: in the preoperative holding area (baseline, or T0), upon entering the
47 operating room (T1), during the induction of anesthesia (T2) and upon leaving the PACU (T6).
48 Behavior on emergence was measured using the pediatric anesthesia emergence delirium (PAED)
49 scale^[26]. A specially trained anesthesiologist assessed the PAED scale at 4 time points: immediately
50 after extubation (T3), on arriving in the PACU (T4), 30 min after arriving in the PACU (T5) and on
51 leaving the PACU (T6). ED was defined as PAED scores ≥ 10 , and PAED scores ≥ 15 is considered
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3 as the occurrence of severe ED^[26-30]. The PAED scale was also used to measure the intensity of ED,
4 where 0 represents no ED and 20 is the maximum intensity of ED. The induction compliance
5 checklist (ICC) was used to assess the cooperation of the children during the induction of anesthesia
6 (T2). A validated simplified 3-point scoring system for ICC [perfect (ICC = 0), moderate (ICC = 1–
7 3), and poor (ICC ≥ 4)] was used in our trial^[31]. The FLACC assessment tool was also administered
8 to measure postoperative pain at the same time as PAED. The FLACC scale scores the pain intensity
9 by rating five behaviors (face, legs, activity, consolability and cry) to derive a score out of 10.^[32]
10 For the patients suffering from ED, the first measure was to comfort the patients with words. When
11 this failed, the patients were treated with propofol (10-20 mg IV). If a child exhibited signs of pain
12 with a FLACC scale > 4, sufentanil (0.05 µg/kg IV) was administered as rescue medication.
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19 Statistical analysis

20 For the sample size calculation, we used a proportion of ED and anxiety of 50%, as reported in
21 previously published studies^[2, 33]. Therefore, 40 subjects per group would have a significance level
22 of 5% and a power of 80% in detecting a 30% reduction in ED incidence between the groups. While
23 anticipating a 15% dropout rate, we estimated that 46 patients were needed in each group.
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26 SPSS 26.0 statistical software was used to statistically process and analyze the data. The
27 measurement data conforming to the normal distribution were expressed as the mean ± standard
28 deviation, and the comparison between the groups was performed by two independent samples t
29 test. Enumeration data were expressed by the number of patients (percentage) [n(%)], and the
30 comparison was made by Chi-Squared Test. The comparison of measurement data that did not
31 conform to a normal distribution was expressed by a nonparametric test and is shown as the median
32 (25th percentile, 75th percentile).
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36 The changes of anxiety and emergence delirium over time between two groups were evaluated by
37 generalized linear mixed models (GLMM) with logistic link followed by pairwise comparisons with
38 Bonferroni correction. Linear mixed model (LMM) was used to evaluate the change of pain for
39 comparison of FLACC. Both GLMM with logistic link and LMM were adjusted for age, gender,
40 surgery type and length of surgery and anesthesia. Taking $\alpha=0.05$ as the test level, $P<0.05$ indicates
41 a statistically significant difference.
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46 Results

47 As shown in the Consort flow chart (Figure 1), 95 children were enrolled in our study, and 15
48 children were excluded because of withdrawal of consent, loss of follow-up, discontinued
49 intervention or extra medication. Thus, 80 participants completed the study and were included in
50 the final data analysis. There were no statistically significant differences between the groups in
51 terms of age, gender, height, weight, duration of surgery and anesthesia or the type of surgery (Table
52 1).
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56 The incidence of anxiety was significantly different over time among children ($F=3.212$, $P=0.023$).
57 There is also a significant difference in the incidence of anxiety between group V and group C
58 ($F=34.943$, $P < 0.001$) (Figure 2, Table 2). Moreover, the interaction effect between time and group
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4 was statistically significant ($F=8.126$, $P < 0.001$)(Table 2). The incidence of anxiety at T0 exhibiting
5
6 baseline anxiety was not statistically different between the groups ($P = 0.323$). After the intervention,
7 the incidence of anxiety of group V is significantly lower than that of group C at T1 ($P < 0.001$), T2
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9 ($P < 0.001$) and T6 ($P < 0.001$) (Figure 2) . Meanwhile, the peak mYPAS scores showed
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11 significant difference between the two groups ($P < 0.001$) (Table 2).
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14 The incidence of ED was significantly different over time among children ($F=15.688$, $P < 0.001$).
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16 However, the incidence of ED between the groups and the interaction effect between time and group
17 were not statistically different ($F=2.169$, $P=0.142$; $F=1.220$, $P=0.302$). Additionally, the peak of
18 PAED in group V was significantly lower than that in group C ($P=0.016$) (Table 3).
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21 The FLACC score was significantly decreased over time among children ($F=3.870$, $P=0.010$).
22
23 However, the FLACC scores between the groups and the interaction effect between time and group
24 were not statistically different ($F=0.059$, $P=0.808$; $F=1.381$, $P=0.249$). Similarly, the ICC and the
25 incidence of adverse events were not found to be significantly different ($P=0.110$, $P=0.692$) (Table
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27 4).
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29 Discussion

30 In the present study, we found that individual cartoon videos can significantly reduce the incidence
31 of perioperative anxiety and alleviate ED in pediatric patients undergoing adenoidectomy and
32 adenotonsillectomy.
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36 As demonstrated in Figure2, the incidence of anxiety at T0 was not significantly different between
37 the two groups. The individual cartoon video helped the children in group V reduce anxiety at T1.
38 While the incidence of anxiety at T1 in group C was higher than that at T0. This indicates that
39 simply watching the individual cartoon video at holding area may have been sufficient to reduce
40 anxiety during entry into the operation room. Without the impact of intervention measure, the
41 children in group C showed the increasing levels of anxiety. While children who watched the
42 individual cartoon video had lower levels of anxiety at T1, T2 and T6 compared to that at T0. These
43 findings are sufficient to demonstrate a strong benefit of individual cartoon video by reducing the
44 anxiety of pediatric patients during the whole perioperative period. Kain^[4] pointed out an important
45 correlation between emergence delirium and preoperative anxiety in children: for every 10-point
46 increase in the mYPAS, the risk of delirium increases by 10%. A previous study^[34] suggested that
47 preoperative anxiety was one of the risk factors for ED. Thus, interventions aimed at alleviating
48 preoperative anxiety are of great significance for preventing ED. However, few studies evaluated
49 the effect of non-pharmacological approaches especially the technology devices in reducing the
50 emergence delirium. In our study, analyzing the emergence delirium in the generalized linear mixed
51 models (GLMM) with logistic link, we did not find the significant difference in the groups and the
52 interaction effect between time and group. When comparing the peak PAED scores between the
53 groups, we found that the degree of ED in group V is significantly lower than that in group C. These
54 results show that the individual cartoon video can only alleviate the severity of ED and fails to
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3 reduce the incidence of ED. Our study may not have been powered to fully demonstrate the
4 association of other factors with anxiety and emergence delirium, such as age, gender, surgery type
5 and length of surgery and anesthesia. In the study, these factors did not differ between the two
6 groups, had no impact in the multivariable analysis, and thus did not impact our conclusions. There
7 were no significant differences in the incidence of adverse events between the two groups. However,
8 previous studies^[35] have found that ED increases the risk of these adverse events. The possible
9 reason is that our study may be limited by the sample size. We calculated the sample size with the
10 incidence of ED and anxiety, and a larger sample size is required for determining differences in
11 adverse events.
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16 Most young children are very fond of watching cartoon videos. A favorite cartoon can immerse
17 children in videos and distract their attention from the unfamiliar environment and the absence of
18 their parents so that children will not cry because of fear and anxiety. Meanwhile, many popular
19 cartoons are freely available with public access. Therefore, the intervention of watching individual
20 cartoons to reduce anxiety can be used without increasing health care costs. Gamze Inan^[36]
21 demonstrated 3 different distraction techniques on the pain and anxiety levels of children during
22 venipuncture, in which there are only several popular fixed options, whether in cartoon movies or
23 video games. Jeongwoo Lee^[22] similarly preselected 10 movies, including 4 action movies, 4 comics,
24 1 science fiction and Cinderella, in his study about the effect of cartoon distraction on pediatric
25 surgical patients. In our study, we did not limit the number and types of cartoon videos. We
26 determined the patients' favorite cartoon video one day before the operation and downloaded it in
27 advance. In this way, the intervention for anxiety will be targeted, and the effect will be maximized.
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33 Katherine A^[12] showed that the children in the group with video distraction displayed significantly
34 less anxiety at anesthetic induction and had a smaller increase in anxiety from the holding area to
35 induction than those in the standard care group. Patel^[16] et al. also demonstrated that animated
36 cartoon distraction produced a significant reduction in anxiety in children aged 4 to 12 years
37 compared with the intervention of oral premedication or parental presence. These findings are
38 consistent with our findings. We noticed that many studies focused only on preoperative anxiety
39 and ignored the postoperative status of the patient's anxiety. In daily work, we observed that some
40 pediatric patients often cry and scream after surgery. We speculate that they may long for the
41 company of their parents, which could also be a form of anxiety. In our study, we found that the
42 pediatric patients in the control group displayed more anxiety when they departed from the PACU
43 than the patients who watched the individual cartoon videos. As a result, the individual cartoon
44 videos play a key role in alleviating anxiety in the whole perioperative period.
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50 Video display for pediatric patients has been an emerging audiovisual distraction modality to reduce
51 anxiety. Initial studies in audiovisual distraction during induction of anesthesia in pediatric patients
52 used video games, apps and streaming video clips to demonstrate reductions in mYPAS scores^{[12,}
53 ^{16, 17]}. We innovatively chose the individual cartoon video as the intervention throughout the whole
54 perioperative period to evaluate the anxiety and ED. Thus, the purpose and findings of this study
55 complement existing literature examining perioperative psychological and mental state of children
56 and offer a fresh approach to relieve perioperative anxiety and ED in pediatric patients.
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3 In terms of the strengths of this study, first of all, the individual cartoon video is an easy and effective
4 modality which can capture children's attention to the maximum extent and is freely available with
5 public access. Secondly, the established outcome scales we used are validated and behavior based
6 to reduce observer bias. Thirdly, we included a time point after surgery to evaluate the anxiety in
7 children and ultimately confirmed that the individual cartoon video can reduce anxiety throughout
8 the whole perioperative period.
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12 Several limitations related to this study should also be discussed. One limitation is that the outcomes
13 were limited to the immediate period. Though it has been proved that the negative psychological
14 impact of perioperative anxiety can stretch beyond the perioperative period and includes
15 maladaptive postoperative behaviors, such as separation anxiety, nightmares and eating disorders<sup>[37-
16 40]</sup>, it remains unclear whether interventions aimed at reducing preoperative anxiety would lead to a
17 decrease in such behaviors. Besides, the sample size of study is relatively limited. We found no
18 significant difference of adverse events between the two groups. The most likely reason is that we
19 calculated the sample size based on the incidence of ED and anxiety. Thus, the number of children
20 recruited may have been insufficient to detect the effects of the individual cartoon videos on
21 postoperative adverse events. Thirdly, though the trained investigator was blinded to the group
22 allocation before assessment, the blinding was impossible at some time points because cartoon video
23 watching were visible to the investigator. As a result, observer bias may have influenced
24 assessments of anxiety, emergence delirium, pain and compliance at induction of anesthesia.
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31 On the basis of our findings, future directions for further studies include longer postoperative
32 follow-up, larger sample size and more application fields, including pediatric cardiovascular and
33 cerebrovascular intervention therapies, radiological examinations and endoscopic examinations and
34 treatments outside the operation room.
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37 **Conclusion**

38 We concluded that the individual cartoon video was demonstrated to be an easy, effective and
39 noninvasive modality for perioperative anxiety and emergence delirium in pediatric patients.
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45

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51

52 **Assistance with the study**

53 none.
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55

56 **Author contributions**

57 Xinyu Tang and Muchun Zhang contributed equally to this paper.
58

59 All authors contributed to the study conception and design. Material preparation and data
60

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3 collection were performed by Xinchun Tao, Yamei Li, Yi Wang and Xin Wang. Data analysis was
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5 Xinyu Tang and Muchun Zhang and all authors commented on previous versions of the
6 manuscript. All authors read and approved the final manuscript.
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10 **Competing interests statement**

11 All authors declare that they have no competing interests.
12

13 **Ethics Statement**

14 This clinical trial was approved by the Ethics Committee of the Second Hospital of Anhui Medical
15 University (Reference number: YX2022-084 (F1)) and was registered at the Chinese Clinical Trial
16 Registry (Reference number: ChiCTR2200062300). The study was performed in accordance with
17 the Helsinki Declaration of 1964, and its later amendments. Written consent was obtained from
18 parents (or guardians).
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23 **Data availability statement**

24 The data to support the results of this study is available from the corresponding author on
25 reasonable request.
26

27 **Prior presentation**

28 none
29

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postoperative pain, and behavioral recovery in young children undergoing surgery [J].

		Individual cartoon video (n = 40)	Control (n = 40)	P value
Age (years) ^a		5.75 ± 1.21	5.68 ± 1.58	0.812
Gender (male) [n (%)] ^b		17 (42.5)	23 (57.5)	0.18
Height (cm) ^a		114.43 ± 9.24	108.10 ± 11.92	0.319
Weight (kg) ^a		21.47 ± 6.18	21.63 ± 5.26	0.271
Surgery length (min) ^a		34.45 ± 12.07	34.63 ± 12.20	0.596
Anesthesia length (min) ^a		47.35 ± 15.16	46.23 ± 14.09	0.691
Surgery [n (%)] ^b				0.875
	Adenoidectomy	15 (37.5)	17 (42.5)	
	Tonsillectomy	10 (25)	10 (25)	

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	Adenoidectomy+ Tonsillectomy	15 (37.5)	13 (32.5)	
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Table 1. Demographic and surgical characteristics of the pediatric patients between individual cartoon video group and control group

Data are presented as frequency (percentage) or mean \pm SD (Standard Deviation).

^atwo independent samples t test

^bChi-Squared Test

Table 2. Anxiety occurrence and levels in pediatric patients between individual cartoon video group and control group

		Individual cartoon video (n=40)	Control (n=40)	P value
Anxiety ^a				< 0.001*
	T0 [n(%)]	26(65)	22(55)	
	T1 [n(%)]	8(20)	32(80)	
	T2 [n(%)]	16(40)	36(90)	
	T6 [n(%)]	21(52.5)	35(87.5)	
Peak_mYPAS ^b		51.00 [41.67~60.89]	64.14 [53.57~85.47]	< 0.001 [†]

*P_{time}=0.023 *P_{group} < 0.001 *P_{interaction} < 0.001

Data are presented as frequency (percentage) or median [25th percentile to 75th percentile] as appropriate.

^aGeneralized Linear Mixed Model(GLMM) with logistic link was adjusted for age, gender, surgery type and length of surgery and anesthesia.

^bMann–Whitney U-test

mYPAS, Modified Yale Preoperative Anxiety Scale

T0, preoperative holding area

T1, entry to the operating room

T2, induction of anesthesia

T6, leaving the PACU

mYPAS > 40 is considered as the occurrence of anxiety.

Peak_mYPAS refers to the highest score of mYPAS in the four time points of T0, T1, T2 and T6.

*P < 0.05 is significant in GLMM with logistic link.

†P < 0.05 versus the control group.

Table3. Emergence delirium occurrence and levels in pediatric patients between individual cartoon video group and control group

		Individual cartoon video (n=40)	Control (n=40)	P value
ED ^a				0.302
	T3 [n(%)]	22(55)	31(77.5)	
	T4 [n(%)]	13(32.5)	22(55)	
	T5 [n(%)]	9(22.5)	10(25)	
	T6 [n(%)]	6(15)	5(12.5)	
Peak_PAED ^b		12.00 [9.00~13.00]	13.50 [10.00~15.00]	0.016 [†]

*P_{time} < 0.001 P_{group}=0.142 P_{interaction}=0.302

Data are presented as frequency (percentage) or median [25th percentile to 75th percentile] as appropriate.

^aGeneralized Linear Mixed Model (GLMM) with logistic link was adjusted for age, gender, surgery type and length of surgery and anesthesia.

^bMann–Whitney U-test

PAED, the Pediatric Anesthesia Emergence Delirium scale

T3, immediately after extubation

T4, arriving in the PACU

T5, 30 min after arriving in the PACU

T6, leaving the PACU

Peak_PAED refers to the highest score of PAED in the four time points of T3, T4, T5 and T6.

PAED \geq 10 is considered as the occurrence of emergence delirium.

*P < 0.05 is significant in GLMM with logistic link.

†P < 0.05 versus the control group.

Table 4. Secondary outcomes of the pediatric patients between individual cartoon video group and control group

		Individual cartoon video (n = 40)	Control (n = 40)	P value
FLACC ^a				0.249
	T3	3.00 [1.25~4.75]	3.50 [2.00~5.00]	
	T4	3.00 [1.00~5.00]	3.50 [2.00~5.75]	
	T5	2.50 [1.00~4.00]	3.00 [2.00~5.00]	
	T6	2.00 [1.00~3.75]	3.00 [1.00~4.00]	

ICC ^b		2.00 [0.00~4.00]	3.00 [1.25~4.00]	0.11
Adverse events ^c [n (%)]		3 (7.5)	4 (10)	0.692

*P_{time}=0.010 P_{group}=0.808 P_{interaction}=0.249

Data are presented as frequency (percentage) or median [25th percentile to 75th percentile] as appropriate.

^aLinear Mixed Model(LMM) was adjusted for age, gender, surgery type and length of surgery and anesthesia.

^bMann–Whitney U-test

^cChi-Squared Test

FLACC, Face, Legs, Activity, Consolability, Cry scale

T3, immediately after extubation

T4, arriving in the PACU

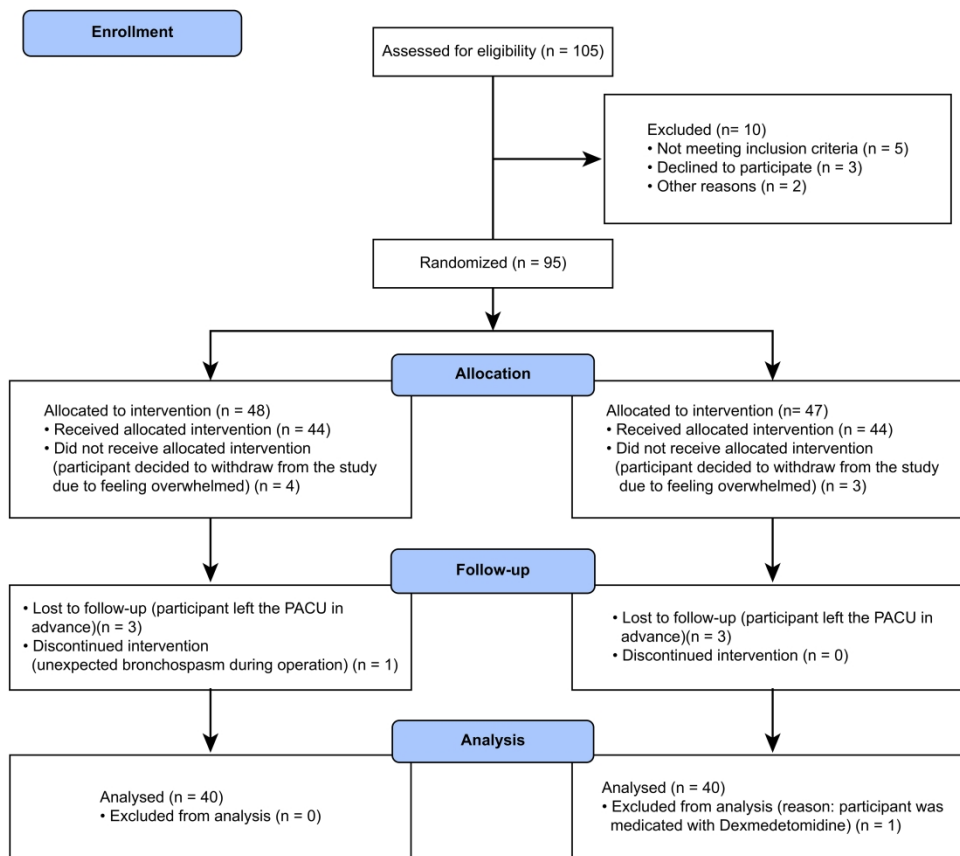
T5, 30 min after arriving in the PACU

T6, leaving the PACU

ICC, induction compliance checklist

Adverse events refer to severe hypoxemia, bronchospasm, postoperative bleeding, etc.

*P < 0.05 is significant in LMM.



CONSORT flow diagram of the study.

179x157mm (580 x 580 DPI)

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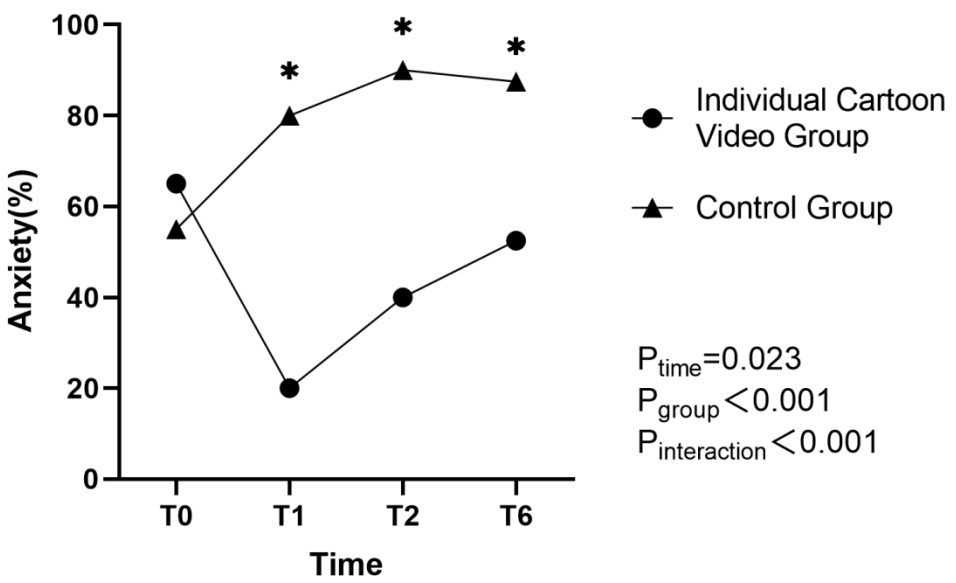


Figure2: Anxiety occurrence in pediatric patients in the perioperative period
□P<0.001 versus the control group

132x84mm (300 x 300 DPI)

BMJ Paediatrics Open

Individual Cartoon Video for Alleviating Perioperative Anxiety and Reducing Emergence Delirium in Children: A Prospective Randomized Trial

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4 **Title page**
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6 **Individual Cartoon Video for Alleviating Perioperative Anxiety and Reducing Emergence**
7 **Delirium in Children: A Prospective Randomized Trial**
8

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Confidential: For Review Only

Abstract

BACKGROUND: Perioperative anxiety and emergence delirium in young children may cause a series of adverse events, which are worth investigating. Pharmacological treatments of anxiety and delirium remain uncertain, while nonpharmacological treatments lack personalization and pertinence.

AIMS: The aim of study was to determine whether an individual cartoon video can alleviate perioperative anxiety and reduce emergence delirium in young children undergoing adenoidectomy and tonsillectomy.

METHODS: Children between 3 and 7 years old undergoing adenoidectomy and tonsillectomy were randomly assigned to an individual cartoon video group (group V) or a control group (group C). In group V, an individual cartoon video of the child's own choice was played throughout the whole waiting, anesthesia induction and recovery periods. The children in group C were contacted through verbal conversation. The primary outcomes were anxiety measured by the Modified Yale Preoperative Anxiety Scale (mYPAS) and emergence delirium assessed by the Pediatric Anesthesia Emergence Delirium (PAED) scale. The secondary outcomes included cooperation during induction, postoperative pain and adverse events.

RESULTS: The incidence of anxiety were comparable in group V and group C at the holding area (T0)(26% vs. 22%, $P=0.323$), but the incidence of anxiety of group V were significantly lower than those of group C at the time of entering the operating room (T1), during the induction of anesthesia (T2) and leaving the PACU (T6) ($P<0.001$, $P<0.001$, $P<0.001$) after intervention. The peak PAED score in group V was significantly lower than that in group C (12.00 [9.00~13.00] vs. 13.50 [10.00~15.00], $P=0.016$). We found no significant differences in cooperation during induction, postoperative pain or the incidence of adverse events between the groups (2.00 [0.00~4.00] vs. 3.00 [1.25~4.00], $P=0.110$; $F=0.059$, $P_{\text{group}}=0.808$; 3 (7.5%) vs. 4 (10), $P=0.692$).

CONCLUSIONS: The individual cartoon video is an effective method of reducing perioperative anxiety and alleviating emergence delirium in children.

Ethics Approval Statement

This clinical trial was approved by the Ethics Committee of the Second Hospital of Anhui Medical University (Reference number: YX2022-084 (F1))

Clinical Trial Registration Identifier

ChiCTR2200062300 (<https://www.chictr.org.cn/index.aspx>)

KEY WORDS : individual cartoon video ; anxiety ; emergence delirium ; pediatrics;

What is already known about the topic?

Anxiety and emergence delirium are commonly observed in young children and cause many adverse effects.

The effectiveness of pharmacological treatments of anxiety and emergence delirium remains uncertain, while the effectiveness of nonpharmacological treatments lacks personalization and pertinence.

What new information this study adds?

Using a child's favorite cartoon video can reduce the incidence of perioperative anxiety.

Using a child's favorite cartoon video may alleviate emergence delirium.

How this study might affect the practice?

The patients' favorite cartoon video can be played as the intervention for anxiety and emergence delirium, which will be targeted, easy-accessed and the effect will be maximized.

Introduction

Emergence delirium (ED) is described as a complex of perceptual disturbances and psychomotor agitation that most commonly observed in young children in the early postanesthetic period following a sevoflurane-based anesthetic^[1]. While, anxiety is common in children before anesthesia and surgery. It has been reported that up to 65% of children in the holding area and during the induction of anesthesia experience intense anxiety about anesthesia and surgery^[2]. Severe anxiety easily causes uncooperative behavior, severe pain, emergence delirium, and higher doses of sedation or preoperative analgesia^[3-5]. Therefore, alleviating anxiety and reducing the incidence of ED in children are of great significance for ensuring perioperative safety and improving surgical prognosis.

Tailored treatment for perioperative anxiety of a pediatric patient can use either pharmacological or non-pharmacological methods, often in tandem. The use of anxiolytic premedication in particular is valuable for certain groups^[6], but the efficacy of these drugs is not clear, and the optimal dosage is unknown. In addition, due to the immaturity of children's physical and psychological development, pharmacological treatment has side effects and potential risks, and the compliance of young children in taking medication is low. Compared with pharmacological therapy, non-pharmacological interventions are more comfortable, safer and free of drug side effects^[7].

As a whole non-pharmacological modalities comprise education approaches, behavioral techniques, parental presence at induction of anesthesia (PPIA), and complementary and alternative medicine (CAM) techniques, with each category including a range of effective strategies for reducing anxiety^[7]. Research has increasingly focused on exploring the effects of technology devices, especially based on audiovisual interventions^[8]. These technology devices (eg, smartphones^[9, 10], video glasses^[11], streaming videoplayers^[12], portable computers^[13, 14], iPads^[15], and video games^[16]) have been widely used as a vehicle for streaming media content(eg, video games, streaming video clips, apps^[17], virtual reality, and cartoons) to reduce perioperative anxiety in children through distraction.

Cohen et al. used cartoons as an effective distraction tool during surgical procedures in children and in another study demonstrated that playing age-appropriate videos before medical procedures was

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3 a more effective distractor than was an interactive toy^[18, 19]. Compared with premedication or
4 parental presence only, a handheld video game with parental presence was found to be more
5 effective for reducing anxiety in children aged 4 to 12 years^[16]. A study also demonstrates that
6 pediatric patients who used Virtual Reality (VR) were found to have significantly lower anxiety at
7 the time of induction of anesthesia compared to patients who did not use VR^[20]. However, we found
8 that the choices of the videos^[21], handheld video games^[16] or VR^[20] in previous studies seemed to
9 be impersonalized and limited. Most studies used the same media content as interventions,
10 regardless of the gender and age of patients^[20, 22]. Even if the selection is based on age and gender,
11 it is possible that the children cannot find his favorite cartoon video in the options of his age due to
12 individual differences. Meanwhile, it has been proved that one of the causes of emergence delirium
13 was preoperative anxiety and that reducing preoperative anxiety can reduce the incidence of
14 postoperative delirium^[1, 23]. Therefore, some studies have focused only on how to reduce
15 preoperative anxiety, while few have continued to pay attention to the anxiety of children who are
16 awakening in the Post Anesthesia Care Unit (PACU)^[1].

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23 Therefore, this study was performed to emphatically determine whether individual cartoon videos
24 are capable of alleviating perioperative anxiety and reducing emergence delirium in young children
25 undergoing adenoidectomy and tonsillectomy. Simultaneously, the study also investigated the
26 impact of individual cartoon videos on induction compliance, postoperative pain and adverse events.

27 **Methods**

28 **Ethics**

29
30 This clinical trial was approved by the Ethics Committee of the Second Hospital of Anhui Medical
31 University (Reference number: YX2022-084 (F1)) and was registered at the Chinese Clinical Trial
32 Registry (Reference number: ChiCTR2200062300). Written consent was obtained from parents (or
33 guardians). This single-center, randomized clinical trial was conducted from August to September
34 2022 in accordance with the principles of the Helsinki Declaration.

35 **Participants**

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37 After the introduction and invitation of the clinical trial leader, ninety-five patients aged between 3
38 and 7 years with an American Society of Anesthesiologists physical status I-II and who were
39 scheduled for their first elective adenoidectomy or tonsillectomy under general anesthesia were
40 enrolled. Children having emergency surgery and those with previous anesthetic experience,
41 developmental delays, intellectual disability, sedative medication or chronic illnesses were excluded
42 from the study.

43 **Patient and Public Involvement**

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45 Parents or the public were not directly involved in the design, conduct or plans for the
46 dissemination of our research.

47 **Procedures**

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49 The day before surgery, the eligible patients were visited by a trained anesthesiologist, and their
50 general information was recorded. Most importantly, through conversations with children, their
51 favorite cartoon videos even specific to favorite clips were all recorded. There were no limits to the
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3 scope of cartoons, which were freely chosen according to children's preferences. On the day of
4 surgery, all of the patients were brought to the holding area 30 min before surgery and treated
5 according to the group assignment. The enrolled children were randomized into two groups using a
6 computer-generated randomization program: group V (distraction by watching an individual
7 cartoon video) and group C (control). The patients in group V began to watch a favorite cartoon
8 video on iPad throughout the whole waiting and anesthesia induction process. Patients in group C
9 were contacted by the medical staff through verbal conversation to relieve their anxiety.
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14 The surgical interventions and the administration of anesthesia were always performed by the same
15 professionals (two surgeons and an anesthesiologist), and standard anesthetic regimens and
16 techniques were used for all patients. After the application of standard monitoring, including blood
17 pressure, electrocardiography, blood oxygen saturation, and the bispectral index, inhalation
18 anesthesia induction was performed at tidal volume, with incrementing sevoflurane up to 8% with
19 a 50% mixture of air and oxygen (6 L/min). At the same time, the induction compliance checklist
20 (ICC) score was recorded by a trained nurse. Peripheral IV access was obtained, and an
21 appropriately sized laryngeal tube was inserted after a suitable anesthetic depth was obtained by the
22 injection of propofol (2 mg/kg), sufentanil (0.2 µg/kg) and cisatracurium (0.1 mg/kg). Then,
23 atropine (0.02 mg/kg) and dexamethasone (0.1 mg/kg) were administered, and anesthesia was
24 maintained with remifentanyl 0.2-0.3 µg/kg/min and sevoflurane 3%-5% with a BIS target range of
25 40-60. At the end of surgery, the children were extubated after awakening with adequate
26 spontaneous ventilation and were transferred to the postanesthetic care unit (PACU) for observation.
27 In group V, the individual cartoon video was continuously played in the early recovery stage until
28 the children left the PACU and were reunited with their parents.
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34 Measures

35 Every assessment was completed by the same trained anesthesiologist who is blinded to the group
36 allocation. The primary outcomes were perioperative pediatric anxiety measured by the Modified
37 Yale Preoperative Anxiety Scale (mYPAS) and ED assessed by the Pediatric Anesthesia Emergence
38 Delirium (PAED) scale. The mYPAS is a validated perioperative pediatric anxiety instrument with
39 22 items in 5 categories (activity, emotional expressivity, state of arousal, vocalization, and use of
40 parents)^[24]. In terms of activity, this domain measures the child's level of activity or restlessness,
41 for example, whether the child is fidgeting in their seat or moving around the room. The domain of
42 emotional expressivity estimates the child's emotional state and expression, for example, the child
43 is crying, worried or happy. In terms of state of arousal, this domain measures the child's
44 physiological arousal, such as vigilance, sucking on thumb or panicked whimpering. The domain
45 of vocalization investigates whether the child is reading, moaning, screaming, etc. And in terms of
46 use of parents, it measures the child's reliance on their parents for comfort and support. Scores range
47 from 23.33 to 100, with higher scores indicating higher levels of anxiety^[25]. The mYPAS was
48 administered at 4 time points: in the preoperative holding area (baseline, or T0), upon entering the
49 operating room (T1), during the induction of anesthesia (T2) and upon leaving the PACU (T6).
50 Behavior on emergence was measured using the pediatric anesthesia emergence delirium (PAED)
51 scale^[26]. A specially trained anesthesiologist assessed the PAED scale at 4 time points: immediately
52 after extubation (T3), on arriving in the PACU (T4), 30 min after arriving in the PACU (T5) and on
53 leaving the PACU (T6). ED was defined as PAED scores ≥ 10 , and PAED scores ≥ 15 is considered
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3 as the occurrence of severe ED^[26-30]. The PAED scale was also used to measure the intensity of ED,
4 where 0 represents no ED and 20 is the maximum intensity of ED. The induction compliance
5 checklist (ICC) was used to assess the cooperation of the children during the induction of anesthesia
6 (T2). A validated simplified 3-point scoring system for ICC [perfect (ICC = 0), moderate (ICC = 1–
7 3), and poor (ICC ≥ 4)] was used in our trial^[31]. The FLACC assessment tool was also administered
8 to measure postoperative pain at the same time as PAED. The FLACC scale scores the pain intensity
9 by rating five behaviors (face, legs, activity, consolability and cry) to derive a score out of 10.^[32]
10 For the patients suffering from ED, the first measure was to comfort the patients with words. When
11 this failed, the patients were treated with propofol (10-20 mg IV). If a child exhibited signs of pain
12 with a FLACC scale > 4, sufentanil (0.05 µg/kg IV) was administered as rescue medication.
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19 Statistical analysis

20 For the sample size calculation, we used a proportion of ED and anxiety of 50%, as reported in
21 previously published studies^[2, 33]. Therefore, 40 subjects per group would have a significance level
22 of 5% and a power of 80% in detecting a 30% reduction in ED incidence between the groups. While
23 anticipating a 15% dropout rate, we estimated that 46 patients were needed in each group.
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26 SPSS 26.0 statistical software was used to statistically process and analyze the data. The
27 measurement data conforming to the normal distribution were expressed as the mean ± standard
28 deviation, and the comparison between the groups was performed by two independent samples t
29 test. Enumeration data were expressed by the number of patients (percentage) [n(%)], and the
30 comparison was made by Chi-Squared Test. The comparison of measurement data that did not
31 conform to a normal distribution was expressed by a nonparametric test and is shown as the median
32 (25th percentile, 75th percentile).
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36 The changes of anxiety and emergence delirium over time between two groups were evaluated by
37 generalized linear mixed models (GLMM) with logistic link followed by pairwise comparisons with
38 Bonferroni correction. Linear mixed model (LMM) was used to evaluate the change of pain for
39 comparison of FLACC. Both GLMM with logistic link and LMM were adjusted for age, gender,
40 surgery type and length of surgery and anesthesia. Taking $\alpha=0.05$ as the test level, $P<0.05$ indicates
41 a statistically significant difference.
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46 Results

47 As shown in the Consort flow chart (Figure 1), 95 children were enrolled in our study, and 15
48 children were excluded because of withdrawal of consent, loss of follow-up, discontinued
49 intervention or extra medication. Thus, 80 participants completed the study and were included in
50 the final data analysis. There were no statistically significant differences between the groups in
51 terms of age, gender, height, weight, duration of surgery and anesthesia or the type of surgery (Table
52 1).
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56 The incidence of anxiety was significantly different over time among children ($F=3.212$, $P=0.023$).
57 There is also a significant difference in the incidence of anxiety between group V and group C
58 ($F=34.943$, $P < 0.001$) (Figure 2, Table 2). Moreover, the interaction effect between time and group
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4 was statistically significant ($F=8.126$, $P < 0.001$)(Table 2). The incidence of anxiety at T0 exhibiting
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6 baseline anxiety was not statistically different between the groups ($P = 0.323$). After the intervention,
7 the incidence of anxiety of group V is significantly lower than that of group C at T1 ($P < 0.001$), T2
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9 ($P < 0.001$) and T6 ($P < 0.001$) (Figure 2) . Meanwhile, the peak mYPAS scores showed
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11 significant difference between the two groups ($P<0.001$) (Table 2).
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14 The incidence of ED was significantly different over time among children ($F=15.688$, $P < 0.001$).
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16 However, the incidence of ED between the groups and the interaction effect between time and group
17 were not statistically different ($F=2.169$, $P=0.142$; $F=1.220$, $P=0.302$). Additionally, the peak of
18 PAED in group V was significantly lower than that in group C ($P=0.016$) (Table 3).
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21 The FLACC score was significantly decreased over time among children ($F=3.870$, $P=0.010$).
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23 However, the FLACC scores between the groups and the interaction effect between time and group
24 were not statistically different ($F=0.059$, $P=0.808$; $F=1.381$, $P=0.249$). Similarly, the ICC and the
25 incidence of adverse events were not found to be significantly different ($P=0.110$, $P=0.692$) (Table
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27 4).
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29 Discussion

30 In the present study, we found that individual cartoon videos can significantly reduce the incidence
31 of perioperative anxiety and alleviate ED in pediatric patients undergoing adenoidectomy and
32 adenotonsillectomy.
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36 As demonstrated in Figure2, the incidence of anxiety at T0 was not significantly different between
37 the two groups. The individual cartoon video helped the children in group V reduce anxiety at T1.
38 While the incidence of anxiety at T1 in group C was higher than that at T0. This indicates that
39 simply watching the individual cartoon video at holding area may have been sufficient to reduce
40 anxiety during entry into the operation room. Without the impact of intervention measure, the
41 children in group C showed the increasing levels of anxiety. While children who watched the
42 individual cartoon video had lower levels of anxiety at T1, T2 and T6 compared to that at T0. These
43 findings are sufficient to demonstrate a strong benefit of individual cartoon video by reducing the
44 anxiety of pediatric patients during the whole perioperative period.
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49 Katherine A^[12] showed that the children in the group with video distraction displayed significantly
50 less anxiety at anesthetic induction and had a smaller increase in anxiety from the holding area to
51 induction than those in the standard care group. This finding is consistent with our findings. We
52 noticed that many studies focused only on preoperative anxiety and ignored the postoperative status
53 of the patient's anxiety. In daily work, we observed that some pediatric patients often cry and scream
54 after surgery. So we speculate that they may long for the company of their parents, which could also
55 be a form of anxiety. In our study, we found that the pediatric patients in the control group displayed
56 more anxiety when they departed from the PACU than the patients who watched the individual
57 cartoon videos. As a result, the individual cartoon videos play a key role in alleviating anxiety in
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3 the whole perioperative period.
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6 Kain^[4] pointed out an important correlation between emergence delirium and preoperative anxiety
7 in children: for every 10-point increase in the mYPAS, the risk of delirium increases by 10%. A
8 previous study^[34] suggested that preoperative anxiety was one of the risk factors for ED. Thus,
9 interventions aimed at alleviating preoperative anxiety are of great significance for preventing ED.
10 However, few studies evaluated the effect of non-pharmacological approaches especially the
11 technology devices in reducing the emergence delirium.
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15 In our study, analyzing the emergence delirium in the generalized linear mixed models (GLMM)
16 with logistic link, we did not find the significant difference in the groups and the interaction effect
17 between time and group. When comparing the peak PAED scores between the groups, we found
18 that the degree of ED in group V is significantly lower than that in group C. These results show that
19 the individual cartoon video can only alleviate the severity of ED and fails to reduce the incidence
20 of ED. Our study may not have been powered to fully demonstrate the association of other factors
21 with anxiety and emergence delirium, such as age, gender, surgery type and length of surgery and
22 anesthesia. In the study, these factors did not differ between the two groups, had no impact in the
23 multivariable analysis, and thus did not impact our conclusions. There were no significant
24 differences in the incidence of adverse events between the two groups. However, previous studies^[35]
25 have found that ED increases the risk of these adverse events. The possible reason is that our study
26 may be limited by the sample size. We calculated the sample size with the incidence of ED and
27 anxiety, and a larger sample size is required for determining differences in adverse events.
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33 Most young children are very fond of watching cartoon videos. A favorite cartoon can immerse
34 children in videos and distract their attention from the unfamiliar environment and the absence of
35 their parents so that children will not cry because of fear and anxiety. Meanwhile, many popular
36 cartoons are freely available with public access. Therefore, the intervention of watching individual
37 cartoons to reduce anxiety can be used without increasing health care costs. Gamze Inan^[36]
38 demonstrated 3 different distraction techniques on the pain and anxiety levels of children during
39 venipuncture, in which there are only several popular fixed options, whether in cartoon movies or
40 video games. In our study, we did not limit the number and types of cartoon videos. We determined
41 the patients' favorite cartoon video one day before the operation and downloaded it in advance. In
42 this way, the intervention for anxiety will be targeted, and the effect will be maximized.
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48 Video display for pediatric patients has been an emerging audiovisual distraction modality to reduce
49 anxiety. Initial studies in audiovisual distraction during induction of anesthesia in pediatric patients
50 used video games, apps and streaming video clips to demonstrate reductions in mYPAS scores^{[12,}
51 ^{16, 17]}. We innovatively chose the individual cartoon video as the intervention throughout the whole
52 perioperative period to evaluate the anxiety and ED. Thus, the purpose and findings of this study
53 complement existing literature examining perioperative psychological and mental state of children
54 and offer a fresh approach to relieve perioperative anxiety and ED in pediatric patients.
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58 In terms of the strengths of this study, first of all, the individual cartoon video is an easy and effective
59 modality which can capture children's attention to the maximum extent and is freely available with
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3 public access. Secondly, the established outcome scales we used are validated and behavior based
4 to reduce observer bias. Thirdly, we included a time point after surgery to evaluate the anxiety in
5 children and ultimately confirmed that the individual cartoon video can reduce anxiety throughout
6 the whole perioperative period.
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10 Several limitations related to this study should also be discussed. One limitation is that the outcomes
11 were limited to the immediate period. Though it has been proved that the negative psychological
12 impact of perioperative anxiety can stretch beyond the perioperative period and includes
13 maladaptive postoperative behaviors, such as separation anxiety, nightmares and eating disorders<sup>[37-
14 40]</sup>, it remains unclear whether interventions aimed at reducing preoperative anxiety would lead to a
15 decrease in such behaviors. Besides, the sample size of study is relatively limited. We found no
16 significant difference of adverse events between the two groups. The most likely reason is that we
17 calculated the sample size based on the incidence of ED and anxiety. Thus, the number of children
18 recruited may have been insufficient to detect the effects of the individual cartoon videos on
19 postoperative adverse events. Thirdly, though the trained investigator was blinded to the group
20 allocation before assessment, the blinding was impossible at some time points because cartoon video
21 watching were visible to the investigator. As a result, observer bias may have influenced
22 assessments of anxiety, emergence delirium, pain and compliance at induction of anesthesia.
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28 On the basis of our findings, future directions for further studies include longer postoperative
29 follow-up, larger sample size and more application fields, including pediatric cardiovascular and
30 cerebrovascular intervention therapies, radiological examinations and endoscopic examinations and
31 treatments outside the operation room.
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34 **Conclusion**

35 We concluded that the individual cartoon video was demonstrated to be an easy, effective and
36 noninvasive modality for perioperative anxiety and emergence delirium in pediatric patients.
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50 **Assistance with the study**

51 none.
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54 **Author contributions**

55 Xinyu Tang and Muchun Zhang contributed equally to this paper.
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57 All authors contributed to the study conception and design. Material preparation and data
58 collection were performed by Xinchun Tao, Yamei Li, Yi Wang and Xin Wang. Data analysis was
59 conducted by Xinyu Tang and Muchun Zhang. The first draft of the manuscript was written by
60

Xinyu Tang and Muchun Zhang and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Competing interests statement

All authors declare that they have no competing interests.

Ethics Statement

This clinical trial was approved by the Ethics Committee of the Second Hospital of Anhui Medical University (Reference number: YX2022-084 (F1)) and was registered at the Chinese Clinical Trial Registry (Reference number: ChiCTR2200062300). The study was performed in accordance with the Helsinki Declaration of 1964, and its later amendments. Written consent was obtained from parents (or guardians).

Data availability statement

The data to support the results of this study is available from the corresponding author on reasonable request.

Prior presentation

none

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Table 1. Demographic and surgical characteristics of the pediatric patients between individual cartoon video group and control group

Data are presented as frequency (percentage) or mean \pm SD (Standard Deviation).

^atwo independent samples t test

^bChi-Squared Test

Table 2. Anxiety occurrence and levels in pediatric patients between individual cartoon video group and control group

		Individual cartoon video (n = 40)	Control (n = 40)	P value
Age (years) ^a		5.75 \pm 1.21	5.68 \pm 1.58	0.812
Gender (male) [n (%)] ^b		17 (42.5)	23 (57.5)	0.18
Height (cm) ^a		114.43 \pm 9.24	108.10 \pm 11.92	0.319
Weight (kg) ^a		21.47 \pm 6.18	21.63 \pm 5.26	0.271
Surgery length (min) ^a		34.45 \pm 12.07	34.63 \pm 12.20	0.596
Anesthesia length (min) ^a		47.35 \pm 15.16	46.23 \pm 14.09	0.691
Surgery [n (%)] ^b				0.875
	Adenoidectomy	15 (37.5)	17 (42.5)	
	Tonsillectomy	10 (25)	10 (25)	
	Adenoidectomy+ Tonsillectomy	15 (37.5)	13 (32.5)	
		Individual cartoon video (n=40)	Control (n=40)	P value
Anxiety ^a				< 0.001*
	T0 [n(%)]	26(65)	22(55)	
	T1 [n(%)]	8(20)	32(80)	

	T2 [n(%)]	16(40)	36(90)	
	T6 [n(%)]	21(52.5)	35(87.5)	
Peak_mYPAS ^b		51.00 [41.67~60.89]	64.14 [53.57~85.47]	< 0.001 [†]

*P_{time}=0.023 *P_{group} < 0.001 *P_{interaction} < 0.001

Data are presented as frequency (percentage) or median [25th percentile to 75th percentile] as appropriate.

^aGeneralized Linear Mixed Model(GLMM) with logistic link was adjusted for age, gender, surgery type and length of surgery and anesthesia.

^bMann–Whitney U-test

mYPAS, Modified Yale Preoperative Anxiety Scale

T0, preoperative holding area

T1, entry to the operating room

T2, induction of anesthesia

T6, leaving the PACU

mYPAS > 40 is considered as the occurrence of anxiety.

Peak_mYPAS refers to the highest score of mYPAS in the four time points of T0, T1, T2 and T6.

*P < 0.05 is significant in GLMM with logistic link.

[†]P < 0.05 versus the control group.

Table3. Emergence delirium occurrence and levels in pediatric patients between individual cartoon video group and control group

		Individual cartoon video (n=40)	Control (n=40)	P value
ED ^a				0.302
	T3 [n(%)]	22(55)	31(77.5)	
	T4 [n(%)]	13(32.5)	22(55)	

	T5 [n(%)]	9(22.5)	10(25)	
	T6 [n(%)]	6(15)	5(12.5)	
Peak_PAED ^b		12.00 [9.00~13.00]	13.50 [10.00~15.00]	0.016 [†]

*P_{time} < 0.001 P_{group}=0.142 P_{interaction}=0.302

Data are presented as frequency (percentage) or median [25th percentile to 75th percentile] as appropriate.

^aGeneralized Linear Mixed Model(GLMM) with logistic link was adjusted for age, gender, surgery type and length of surgery and anesthesia.

^bMann–Whitney U-test

PAED, the Pediatric Anesthesia Emergence Delirium scale

T3, immediately after extubation

T4, arriving in the PACU

T5, 30 min after arriving in the PACU

T6, leaving the PACU

Peak_PAED refers to the highest score of PAED in the four time points of T3, T4, T5 and T6.

PAED \geq 10 is considered as the occurrence of emergence delirium.

*P < 0.05 is significant in GLMM with logistic link.

[†]P < 0.05 versus the control group.

Table 4. Secondary outcomes of the pediatric patients between individual cartoon video group and control group

	Individual cartoon video (n = 40)	Control (n = 40)	P value
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FLACC ^a				0.249
	T3	3.00 [1.25~4.75]	3.50 [2.00~5.00]	
	T4	3.00 [1.00~5.00]	3.50 [2.00~5.75]	
	T5	2.50 [1.00~4.00]	3.00 [2.00~5.00]	
	T6	2.00 [1.00~3.75]	3.00 [1.00~4.00]	
ICC ^b		2.00 [0.00~4.00]	3.00 [1.25~4.00]	0.11
Adverse events ^c [n (%)]		3 (7.5)	4 (10)	0.692

*P_{time}=0.010 P_{group}=0.808 P_{interaction}=0.249

Data are presented as frequency (percentage) or median [25th percentile to 75th percentile] as appropriate.

^aLinear Mixed Model(LMM) was adjusted for age, gender, surgery type and length of surgery and anesthesia.

^bMann–Whitney U-test

^cChi-Squared Test

FLACC, Face, Legs, Activity, Consolability, Cry scale

T3, immediately after extubation

T4, arriving in the PACU

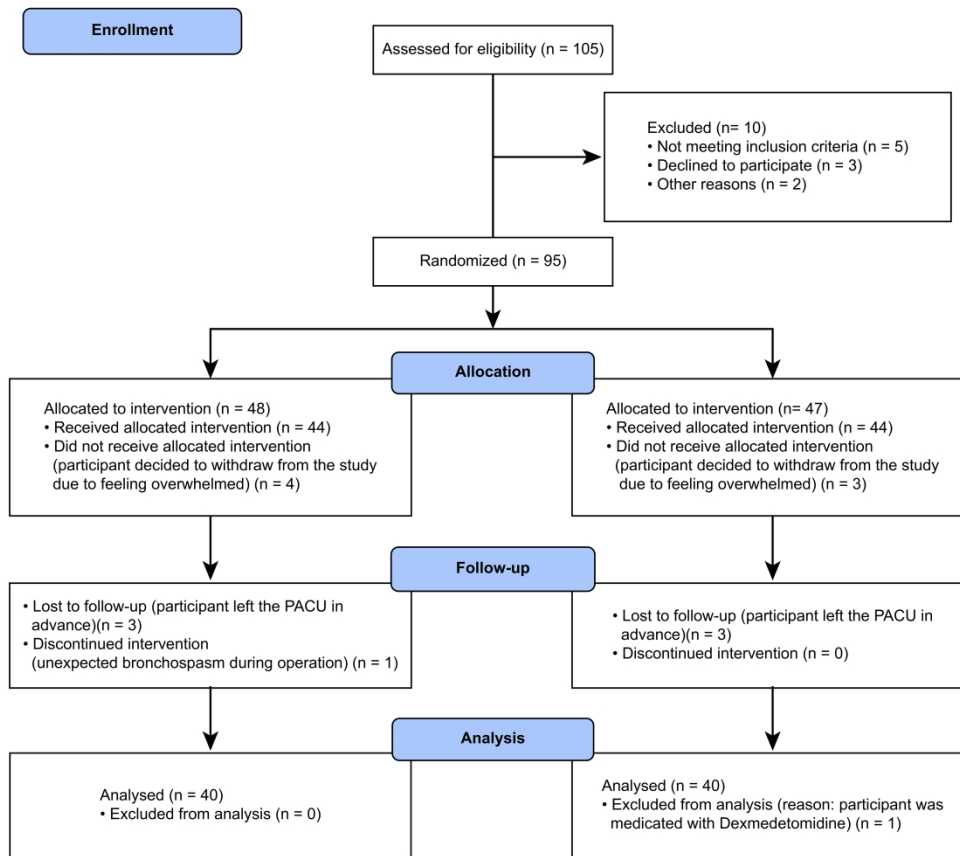
T5, 30 min after arriving in the PACU

T6, leaving the PACU

ICC, induction compliance checklist

Adverse events refer to severe hypoxemia, bronchospasm, postoperative bleeding, etc.

*P < 0.05 is significant in LMM.



CONSORT flow diagram of the study.

179x157mm (580 x 580 DPI)

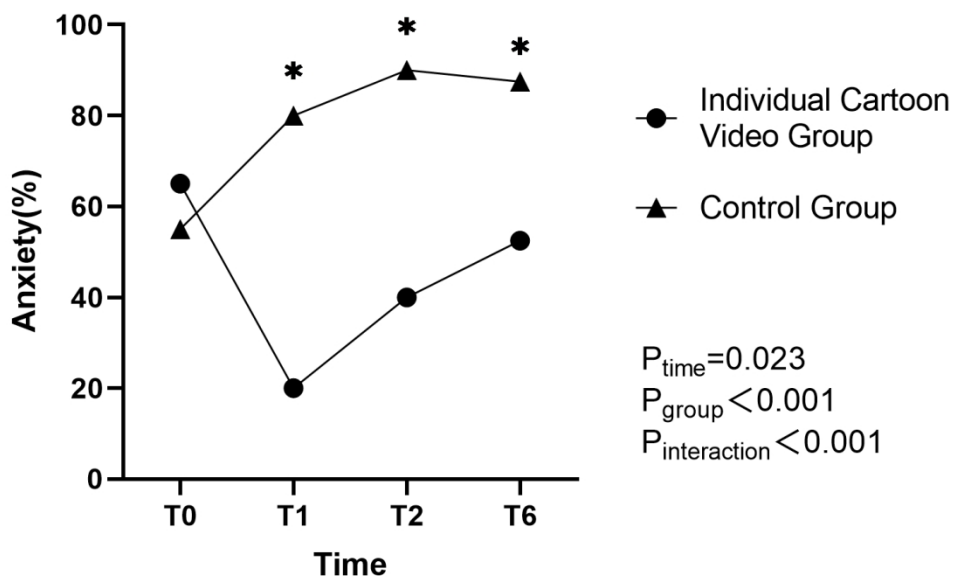


Figure2: Anxiety occurrence in pediatric patients in the perioperative period

□ $P < 0.001$ versus the control group

T0, preoperative holding area

T1, entry to the operating room

T2, induction of anesthesia

T6, leaving the PACU

mYPAS > 40 is considered as the occurrence of anxiety.

132x84mm (300 x 300 DPI)