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Play dough or balloon blowing? A clinical trial comparing creative interventions for reducing preoperative anxiety in children aged 4–8 years

Razie Vakili[1], Reza Feizi[2], Yahya Salimi[3], Mobin Mottahedi[4] and Parisa Rizevandi[1*]

Abstract

Background Preoperative anxiety is a significant concern for pediatric patients undergoing surgery, often leading to adverse physiological, emotional, and postoperative outcomes. Traditional pharmacological approaches, while effective, are associated with side effects, underscoring the need for age-appropriate non-pharmacological interventions. This study aimed to compare the effectiveness of play dough (PD) activities and balloon blowing (BB) in reducing preoperative anxiety in children.

Methods This randomized controlled trial included 90 children aged 4–8 years, a developmental stage characterized by responsiveness to play-based interventions, scheduled for elective surgeries at Besat Hospital, Hamedan, Iran, between November 2023 and January 2025. Participants were randomized into three groups: PD, BB, and Control (standard care with midazolam). Anxiety levels were assessed at baseline (T0), immediately before entering the operating room (T1), and during anesthesia induction (T2) using the Modified Yale Preoperative Anxiety Scale (m-YPAS) and the Visual Analog Scale for Anxiety (VAS-A). Each intervention was administered for 15 min under direct supervision by a trained researcher. Statistical analysis included ANOVA for continuous variables and chi-square tests for categorical variables. Post hoc comparisons were performed using Tukey's method.

Results At T1 and T2, children in the PD and BB groups exhibited significantly lower anxiety levels compared to the Control group ($P < 0.001$). For m-YPAS scores at T1, the PD group mean 36.05 ± 4.28, and the BB group 35.15 ± 2.94, compared to 54.55 ± 4.05 in the Control group. Similar trends were noted at T2. VAS-A analysis further supported these findings, with the PD and BB groups showing higher proportions of mild anxiety compared to the Control group. No significant differences were detected between the PD and BB groups, indicating that both interventions were comparably effective.

Conclusions PD and BB are effective non-pharmacological interventions for reducing preoperative anxiety in children. These cost-effective, engaging techniques offer safe alternatives to pharmacological treatments and promote emotional well-being. The findings support integrating age-appropriate, creative, play-based strategies into

*Correspondence:
Parisa Rizevandi
parisa335335@gmail.com

Full list of author information is available at the end of the article

pediatric surgical care, emphasizing their potential to enhance the preoperative experience and improve outcomes. Future research should investigate long-term impacts, applicability across diverse populations, and comparative efficacy in various clinical settings.

Trial registration Registered in the Iranian registry of clinical trials (https://irct.behdasht.gov.ir) in 19/11/2023 with the following code: IRCT20230514058183N1.

Keywords Preoperative anxiety, Playdough, Balloon blowing, Non-pharmacological interventions, Pediatric surgery

Introduction

Preoperative anxiety is a common condition among pediatric undergoing surgery [1]. It is characterized by increased fear, tension, and worry, often stemming from the anticipation of an unknown and potentially painful experience, such as separation from parents, fear of needles, or concerns about the surgical outcome [2]. Studies indicate that up to 60% of pediatrics experience significant levels of anxiety during the preoperative period, which can peak at any moment before the procedure [3, 4].

This anxiety is not merely a psychological discomfort; it can lead to harmful physiological and emotional consequences, such as increased heart rate, elevated stress hormone levels, and maladaptive behaviors like sleep disturbances, loss of appetite, and enuresis [5–7]. These effects not only complicate the surgical process but may also have long-term repercussions, including increased post-operative pain, delayed recovery, and the development of anxiety-related disorders [8].

Failure to manage preoperative anxiety can have profound implications for both pediatric patients and the medical team [9]. This anxiety may complicate the anesthesia process, increase the need for postoperative pain relief, and extend the hospital stay [10]. These challenges not only impose additional psychological and physical stress on pediatric patients and their families but also incur extra costs for the healthcare system [11]. Therefore, addressing preoperative anxiety is crucial from both clinical and economic perspectives.

Given the profound impact of preoperative anxiety, its reduction is a key concern for healthcare professionals, including anesthesiologists, surgeons, and nurses [2]. Pharmacological interventions such as sedatives have traditionally been used to alleviate anxiety [12]. However, these treatments are often associated with side effects, such as respiratory issues, drowsiness, and prolonged recovery times [13]. As a result, non-pharmacological interventions that are less invasive and more suitable for pediatric patients have gained increasing popularity [14].

Non-pharmacological methods, including music therapy [15], guided imagery [16], and relaxation exercises [17], are effective in reducing preoperative anxiety. Among these approaches, play-based strategies tailored to the developmental stage of pediatric patients, such as the use of toys [18], games [19], or creative activities [20], have proven particularly effective. This study focuses on two such methods: play dough (PD) activities and balloon blowing (BB).

Play-based interventions

Play-based interventions leverage pediatric patients' natural inclination toward play and creativity [21]. These interventions pursue two primary goals: redirect pediatric patients' attention away from anxiety-inducing stimuli and provide a sense of control and normalcy [22]. Among the various play-based techniques, PD activities [23] and BB [24] stand out due to their simplicity, accessibility, and potential therapeutic benefits.

- **Play Dough**: PD offers a tactile and creative outlet, allowing pediatric patients to create shapes, express their emotions, and channel their anxiety into a focused activity. Kneading and shaping the play dough can have a calming effect and may reduce stress [25].
- **Balloon Blowing**: BB involves deep, controlled breathing, which activates the parasympathetic nervous system and induces a relaxation response [26]. Additionally, blowing up a balloon can be perceived as a fun and satisfying challenge, enhancing its distracting and calming effects [27].

Objective

The objective of this study is to compare the effectiveness of PD and BB as non-pharmacological interventions for reducing preoperative anxiety in pediatric patients. By evaluating these two methods, the study aims to identify which approach is more effective in alleviating anxiety and improving the emotional well-being of pediatric patients. The findings are expected to contribute to the growing body of evidence supporting low-cost, child-friendly strategies for managing preoperative anxiety.

Hypotheses

- PD will significantly reduce preoperative anxiety levels in pediatric patients undergoing surgery.
- BB will significantly reduce preoperative anxiety levels in pediatric patients undergoing surgery.

- There will be no significant difference in preoperative anxiety levels between pediatric patients who engage in BB and those who engage in PD activities.

Materials and methods

Study design

This study was conducted as a parallel-group randomized controlled trial to evaluate and compare the effectiveness of PD and BB as non-pharmacological interventions for reducing preoperative anxiety in pediatric patients aged 4 to 8 years.

Setting and duration

The trial was carried out at Besat Hospital in Hamedan, Iran, between November 2023 and January 2025.

Population and sample size

The study population consisted of 90 pediatric patients aged 4–8 years who were scheduled for elective surgeries under general anesthesia. The sample size was determined based on the primary outcome measure—anxiety levels—using data from Bumin Aydın et al. [25] With a significance level (α) of 0.05, a power (1 – β) of 0.80, and a standard deviation (σ) of 4.5, the sample size required was calculated as 20 participants per group. However, to account for potential attrition and to ensure sufficient statistical power to detect significant differences, the sample size was increased to 30 participants per group, resulting in a total of 90 participants.

Randomization and allocation

Participants were randomized into three groups (PD, BB, and control) in a 1:1:1 allocation ratio using block randomization with a block size of 6 patients in each block. Randomization was performed using a computer-generated sequence from the sealedenvelope website. Allocation concealment was ensured using sealed, opaque envelopes containing group assignments.

Inclusion and exclusion criteria

Inclusion criteria

- Pediatric patients aged 4–8 years undergoing elective surgery under general anesthesia.
- Ability to communicate verbally and use hands and mouth.
- No psychiatric, neurological, or developmental disorders (confirmed by parental report).
- Physical health status is classified as ASA I or II (American Society of Anesthesiologists classification).
- No chronic pain or ongoing medical treatment that could influence anxiety levels.
- Parental consent was obtained.

Exclusion criteria

- Non-cooperation from the pediatric patient during the intervention (defined as refusal to participate despite multiple encouragement attempts by researchers).
- Withdrawal of parental consent at any stage.
- Medical emergencies requiring deviation from the planned protocol.
- Use of additional anxiety-reducing methods or medications before the intervention apart from the study protocol.

Blinding

This study did not employ blinding for participants or evaluators collecting data. However, data analysts were blinded to group assignments during statistical analysis.

Participant flow and study process

A diagram summarizing the study flow, including randomization, intervention, and follow-up steps, is provided for clarity (Fig. 1).

Data collection tool

Demographic information

Demographic characteristics, including age, sex, and parental education levels, previous hospitalization and surgery experiences were collected using a structured checklist [28, 29].

Anxiety assessment tools

Modified Yale preoperative anxiety scale (m-YPAS)

The tool used to assess preoperative anxiety was the Modified Yale Preoperative Anxiety Scale (m-YPAS). originally developed by Kain et al. in 1997 as an observational measure for children aged 2–12 years. The m-YPAS is considered the gold standard for evaluating preoperative anxiety in clinical settings, particularly in holding areas and operating rooms [30]. This validated scale consists of 22 items categorized into five domains: Activity (4 items), Vocalization (6 items), Emotional Expressivity (4 items), State of Arousal (4 items), and Use of Parents (4 items). Each item is scored on a Likert-type scale, with ratings ranging from 1 to 4 or 1 to 6, depending on the item. Higher scores reflect greater anxiety severity [31]. The total score is calculated by dividing each domain's raw score by its highest possible rating, yielding a final range of 23 to 100. A score above 30 is often classified as clinically significant anxiety [32, 33]. The m-YPAS has demonstrated strong validity and reliability across studies. For example: Moura et al. [34] reported Cronbach's alpha values of 0.88–0.95. Also In the Iranian children, Sadeghi and Raeisi [29] confirmed the scale's reliability

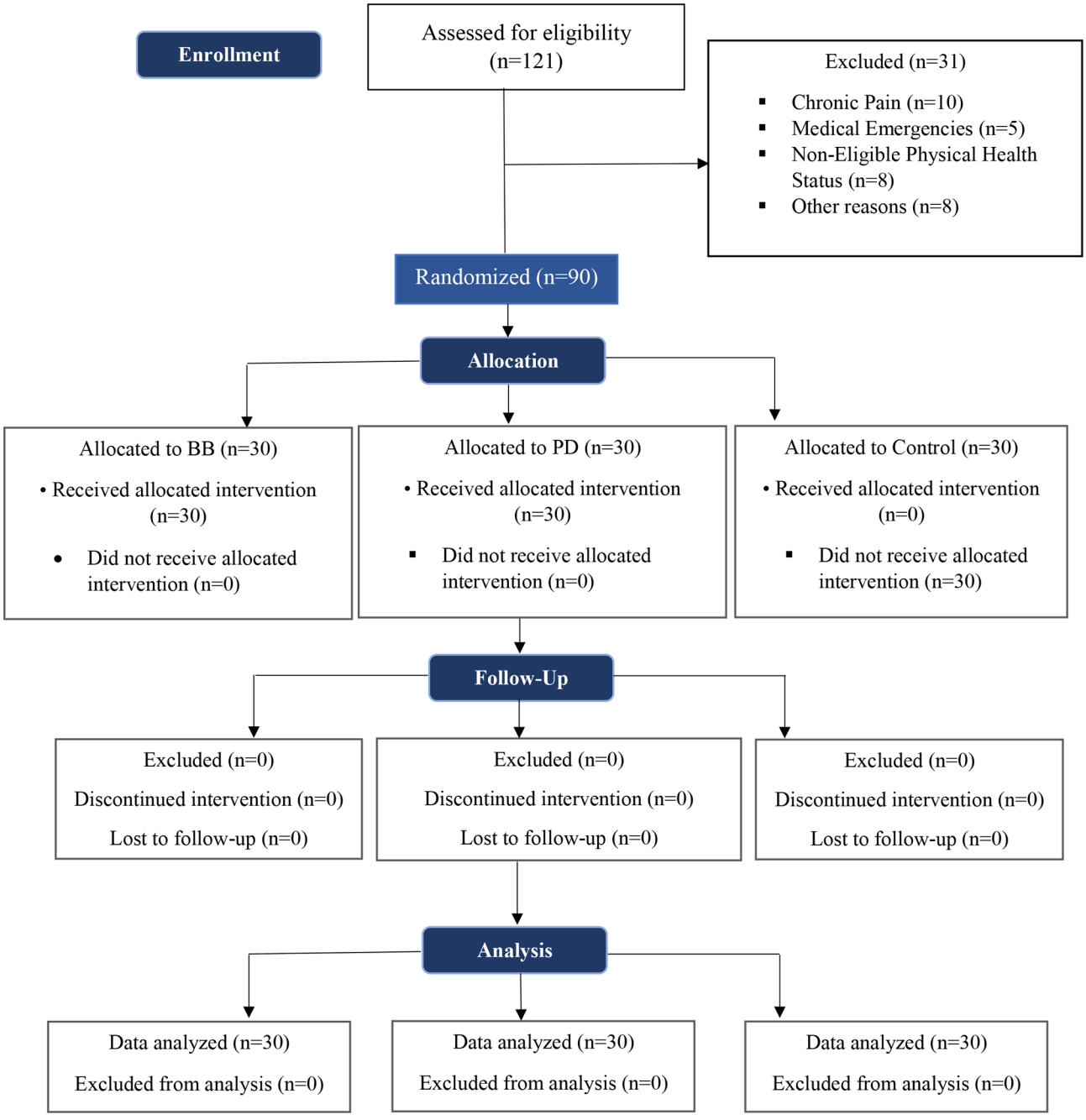

Fig. 1 Flow diagram of participant recruitment, allocation, follow-up, and analysis

with a Cronbach's alpha of 0.82, while Forouzandeh et al. [31] reported 0.85.

Visual analog scale for anxiety (VAS-A)

The second tool used to assess preoperative anxiety was the Visual Analog Scale for Anxiety (VAS-A). Originally developed by Aitken in 1969 [35], the VAS-A was later adapted for anxiety measurement in clinical settings. Its modern form, introduced by Kindler et al. in 2000, specifically validated the scale for preoperative anxiety assessment [36]. The VAS-A consists of a 100-millimeter horizontal line with endpoints representing the extremes of anxiety: "No anxiety at all" on the left and "The most anxiety imaginable" on the right. Validity and reliability of the VAS-A for anxiety measurement were confirmed by Kindler et al. in a study involving surgical patients [36]. Previous studies have confirmed the validity and reliability of VAS-A in assessing anxiety [37–39]. For pediatric patients, the scale is often modified to include a series of faces representing different levels of anxiety,

ranging from a smiling face (no anxiety) to a distressed face (severe anxiety). This graphical representation makes the tool more relatable and more manageable for pediatric patients to understand and use. In practice, pediatric patients are asked to point to or mark the face or position on the line that best represents their current level of anxiety [40, 41].

Interventions

PD group

Pediatric patients in the PD group were provided with non-toxic, colorful PD (manufactured by a certified brand such as Arya). Under researcher supervision, pediatric patients were encouraged to create shapes or objects of their choice for 15 min. Specific instructions were given to engage their imagination, and assistance was provided only when necessary. This activity was carried out in a quiet, private room without the presence of parents, ensuring focus on the task.

BB group

Pediatric patients in the BB group were presented with various colorful latex balloons. They were asked to select their favorite balloon and instructed on inflating it using deep breaths. The activity lasted 15 min, and pediatric patients were encouraged to blow up as many balloons as they could within this time. Supervision ensured safety and encouraged proper technique for maximum engagement.

Control group

Pediatric patients in the control group received standard care, including 0.05 mg/kg of midazolam IV as a standard preoperative anxiolytic. They were observed in a quiet, private room for 15 min before proceeding to surgery. Environmental conditions and interactions were kept consistent with the intervention groups.

Procedure

After obtaining informed consent from parents, pediatric patients were assessed for baseline (T0) anxiety using validated tools (m-YPAS and VAS-A). All participants received intravenous midazolam at a dose of 0.05 mg/kg, 30 min before surgery, in accordance with standard hospital protocol. This premedication was administered to all groups equally to reduce variability in baseline anxiety and ensure ethical preoperative care.

Fifteen minutes after midazolam administration—allowing for the onset of mild sedation but before deep sedation occurred—the non-pharmacological interventions (PD and BB) were introduced. Each intervention lasted for 15 min. During this time, children remained alert, responsive, and able to engage in creative or physical tasks as per their group allocation. No child was deeply sedated or unresponsive during the intervention or subsequent evaluations.

Post-intervention anxiety levels were assessed at two time points:

- **T1 (Immediately before entering the operating room)**: Assessed directly after the 15-minute intervention session (approximately 30 min after midazolam administration). At this stage, children remained conscious, cooperative, and able to respond to stimuli, though under mild sedation.
- **T2 (During induction of anesthesia)**: Assessed by observation as the child entered the operating room and anesthesia induction began using a standard protocol (mask induction with O_2, N_2O, and isoflurane).

The consistent timing and dosage of midazolam across all groups ensured a uniform pharmacological background, allowing the behavioral effects of the PD and BB interventions to be accurately compared. Clinical staff confirmed that children maintained sufficient awareness and interaction levels during assessments at T1 and T2, validating the reliability of the anxiety evaluations despite the presence of mild sedation.

Ethical considerations

The study protocol received approval from the Research Ethics Committee of Kermanshah University of Medical Sciences (approval code: IR.KUMS.REC.1402.177). The study was registered in the Iranian Registry of Clinical Trials (IRCT20230514058183N1). Written informed consent was obtained from parents, and confidentiality of all data was maintained. Data were stored securely, anonymized, and only accessible to authorized researchers.

Statistical analysis

The normality of continuous data was assessed and confirmed using the Shapiro-Wilk test. Statistical analyses were performed using ANOVA for continuous variables and chi-square tests for categorical variables. Post hoc comparisons were conducted using Tukey's method. Analyses were conducted using SPSS version 25.0. P-value < 0.05 was considered significant.

Results

Participant characteristics

A total of 90 pediatric patients were included in the study, with 30 participants in each group ([PD], [BB], and Control). There were no statistically significant differences in the demographic and clinical characteristics among the three groups, indicating that the groups were homogeneous and comparable at baseline ($P > 0.05$) (Table 1).

Table 1 Demographic and clinical characteristics of participants

Variables	Group (Mean ± SD)			*P* value
	PD (*n* = 30)	BB (*n* = 30)	Control (*n* = 30)	
Age (year)	5.65 ± 1.45	6.32 ± 1.43	6.21 ± 1.35	0.20**
Gender (Male/Female)	22/8	17/13	16/14	0.23*
History of surgery (Yes/No)	5/25	7/23	6/24	0.56*
Previous hospitalization (Yes/No)	3/27	3/27	5/25	0.66*
ASA physical status (I/II)	8/22	14/16	15/15	0.13*
Type of surgery, n (%)	11 (36.7)	11 (36.7)	14 (46.7)	0.33*
Tonsillectomy	8 (26.7)	10 (33.3)	12 (40.0)	
Adenoidectomy	11 (36.7)	9 (30.0)	4 (13.3)	
Myringotomy				
Parental education level, n (%)	2 (6.7)	5 (16.7)	5 (16.7)	0.79*
	9 (30.0)	6 (20.0)	9 (30.0)	
Illiterate	7 (23.3)	9 (30.0)	6 (20.0)	
Primary education	12 (40.0)	10 (33.3)	10 (33.3)	
High school				
Undergraduate				

ASA: American Society of Anesthesiologists, PD: Play Dough, BB: Balloon Blowing, SD: Standard Deviation, *Chi-square, **Analysis of Variance

Anxiety levels assessed by m-YPAS

Preoperative anxiety levels, assessed using the m-YPAS, revealed no statistically significant differences at baseline (T0) among the PD, BB, and Control groups ($P = 0.443$). However, important differences emerged at subsequent time points. At T1 (immediately before entering the operating room), the PD group exhibited significantly lower anxiety levels (36.05 ± 4.28) compared to the Control group (54.55 ± 4.05, $P < 0.001$). Similarly, the BB group (35.15 ± 2.94) demonstrated significantly reduced anxiety compared to the Control group ($P < 0.001$). These trends persisted at T2 (during the induction of anesthesia), with the PD group (37.75 ± 4.48) and BB group (37.25 ± 2.84) maintaining the lowest anxiety levels, significantly lower than the Control group (57.20 ± 4.09, $P < 0.001$). Post hoc analysis confirmed that the PD and BB interventions were comparably effective and superior to the Control group ($P < 0.001$ for both PD-Control and BB-Control comparisons). Changes in anxiety scores from baseline (T0) to T1 and T2 further emphasized the efficacy of the PD and BB interventions, with significantly greater reductions in anxiety observed in these groups compared to the Control group ($P < 0.001$ for all comparisons) (Table 2).

Anxiety levels categorized by VAS-A scores

The VAS-A provided additional insights into the categorical distribution of anxiety levels across the three groups. At baseline (T0), there were no significant differences in anxiety distributions among the groups ($P = 0.58$). At T1, the PD group exhibited the highest proportion of participants experiencing mild anxiety (60%, $n = 18/30$), whereas the majority of the Control group reported moderate anxiety (93%, $n = 28/30$). The BB group displayed an intermediate pattern, with a nearly equal distribution of mild (53%, $n = 16/30$) and moderate (47%, $n = 14/30$) anxiety levels ($P < 0.001$). At T2, the PD group continued to demonstrate the most favorable outcomes, with 63% ($n = 19/30$) of participants experiencing mild anxiety, compared to 50% ($n = 15/30$) in the BB group and the Control group. Moderate anxiety remained predominant in the Control group (100%, $n = 30/30$), while severe anxiety was not reported in any group. The chi-square analysis highlighted significant differences in the distribution of anxiety levels in T1 and T2 points, underscoring the effectiveness of the PD and BB interventions in mitigating preoperative anxiety compared to the Control group. (Table 3; Fig. 2).

Discussion

This study provides evidence that PD and BB are effective non-pharmacological interventions for reducing preoperative anxiety in children aged 4–8 years. To the best of our knowledge, this is the first study to demonstrate the beneficial effects of BB on preoperative anxiety compared with PD. At T1 and T2, children in the PD and BB groups exhibited significantly lower anxiety levels compared to the control group. These results underscore the utility of engaging, age-appropriate techniques in alleviating the anxiety of surgical preparation. Notably, no significant differences were observed between the PD and BB

Table 2 Comparison of preoperative anxiety levels in children assessed using m-YPAS across three groups at different time points

Measurement times	Groups (Mean ± SD)			*P* value*	Two-by-Two comparison		
	PD (n = 30)	BB (n = 30)	Control (n = 30)		Control BB	Control PD	PD BB
T_0	61.30 ± 3.97	60.70 ± 5.28	59.40 ± 4.98	0.443	–	-	-
T_1	36.05 ± 4.28	35.15 ± 2.94	54.55 ± 4.05	$P < 0.001$	$P < 0.001^{\&}$	$P < 0.001^{\&}$	$P = 0.736^{\&}$
T_2	37.75 ± 4.48	37.25 ± 2.84	57.20 ± 4.09	$P < 0.001$	$P < 0.001^{\&}$	$P < 0.001^{\&}$	$P = 0.912^{\&}$
T_1-T_0	-25.25 ± 7.55	-25.55 ± 5.61	-4.85 ± 3.15	$P < 0.001$	$P < 0.001^{\&}$	$P < 0.001^{\&}$	$P = 0.985^{\&}$
T_2-T_0	-23.55 ± 7.74	-23.45 ± 5.33	-2.20 ± 3.15	$P < 0.001$	$P < 0.001^{\&}$	$P < 0.001^{\&}$	$P = 0.998^{\&}$

m-YPAS: Modified Yale Preoperative Anxiety Scale, PD: Play Dough, BB: Balloon Blowing, SD: Standard Deviation, *Analysis of Variance, &Post hoc analysis, using Tukey's method

Table 3 Comparison of preoperative anxiety levels categorized by VAS-A scores across three groups at different time points

Measurement times	Groups ($n=90$)	No anxiety (0)	Mild anxiety (10–30)	Moderate anxiety (40–70)	Severe anxiety (80–100)	*P* value *
T_0	BB ($n=30$)	0	14	16	0	$X^2=1.07, 2, P=0.58$
	PD($n=30$)	0	16	14	0	
	Control($n=30$)	0	12	18	0	
T_1	BB($n=30$)	0	16	14	0	$X^2=21.11, 2,$ $P<0.001$
	PD($n=30$)	0	18	12	0	
	Control($n=30$)	0	2	28	0	
T_2	BB($n=30$)	0	15	15	0	$X^2=19.57, 2,$ $P<0.001$
	PD($n=30$)	0	19	11	0	
	Control($n=30$)	0	0	30	0	

VAS-A: Visual Analogue Scale for Anxiety, PD: Play Dough, BB: Balloon Blowing, *Chi-square

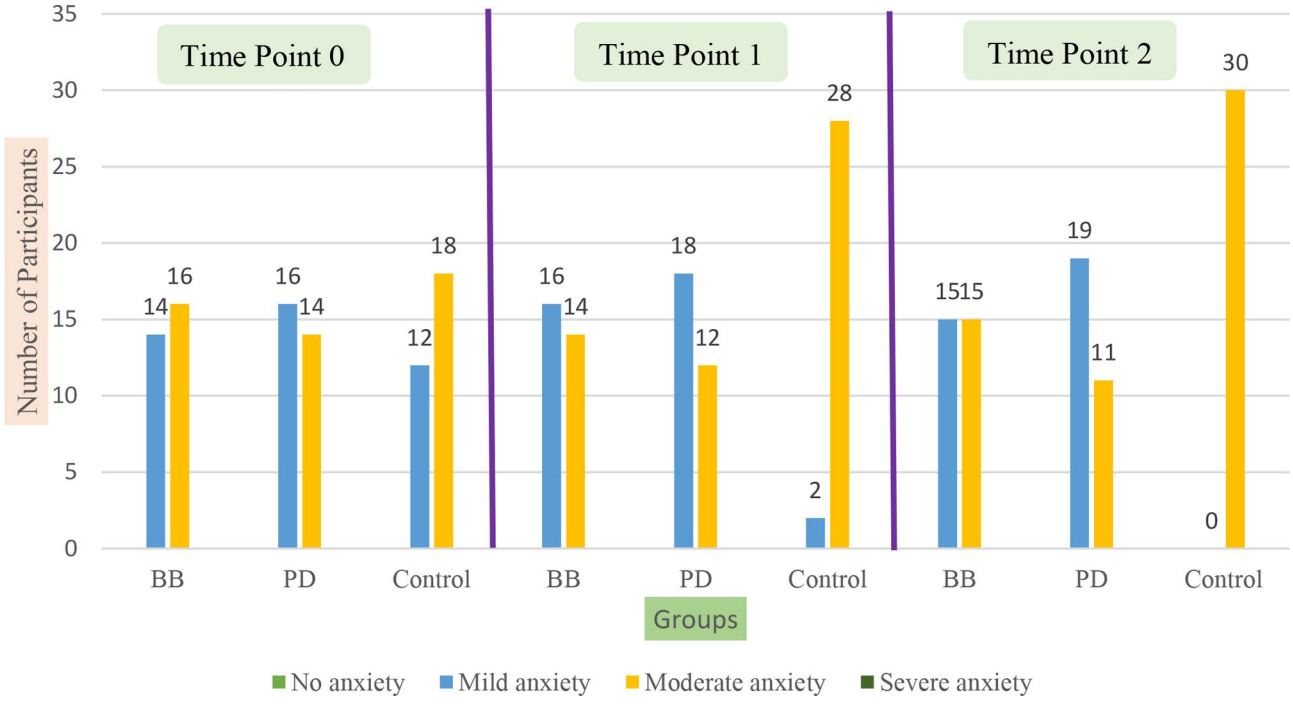

Fig. 2 Comparison of Preoperative Anxiety Levels (VAS-A Scores) Across Groups and Time Points

groups, suggesting that both interventions are comparably effective.

The anxiety-reducing effects of PD and BB interventions can be explained by their ability to engage children's sensory and cognitive processes [42]. PD activities offer tactile stimulation and creative engagement, allowing children to redirect nervous energy into a productive and soothing activity. Such sensory engagement is known to lower stress by promoting a sense of control and focus [25]. On the other hand, BB facilitates deep, rhythmic breathing, which likely activates the parasympathetic nervous system, inducing a calming physiological response. This mechanism is similar to relaxation and mindfulness techniques, wherein controlled breathing shifts focus away from stressors and helps regulate emotional states [43, 44]. Together, these mechanisms align with established theories of distraction and emotional regulation, providing a plausible basis for the observed anxiety reduction [45].

These findings align with existing literature on non-pharmacological interventions for preoperative anxiety [46–50]. Similar results have been reported in studies utilizing bubble blowing, ball squeezing, puzzles, painting, storytelling, and other distraction techniques, which rely on sensory engagement and focused activities to mitigate anxiety. For instance, bubble blowing has been shown to reduce anxiety during venipuncture by combining deep breathing with play [27, 51, 52]. Also, a study on reducing pain and fear during phlebotomy procedures found that soap bubble blowing and ball squeezing were effective active distraction methods, significantly lowering pain and fear scores compared to a control group

[53]. The mechanisms observed in bubble-blowing, such as deep breathing combined with play, closely parallel those of BB in this study. Additionally, bubble blowing was more effective than ball squeezing in reducing fear, highlighting the nuanced benefits of specific distraction techniques [53]. Furthermore, a study investigating the effects of play dough on anxiety associated with oral premedication demonstrated similar anxiolytic benefits. Children who played with play dough in the preoperative holding area exhibited significantly lower m-YPAS scores than those who did not. While anxiety levels increased over time in the control group, children in the play dough group maintained consistently lower anxiety levels [54]. These findings further validate the use of PD as a practical, simple, and economical method for reducing preoperative anxiety in children, particularly in settings where oral premedication is necessary. By offering a creative and gender-neutral distraction, PD provides children with a sense of control and engagement during a potentially stressful experience [54].

Compared to more complex interventions such as virtual reality (VR) [55] or multimedia educational tools [4], PD and BB offer a more straightforward, cost-effective alternative that is easily integrated into clinical workflows. While VR and multimedia approaches provide immersive distraction, their reliance on technological infrastructure may limit accessibility, particularly in resource-constrained settings [4, 55]. Conversely, PD and BB leverage universally understood play behaviors, making them broadly applicable across diverse pediatric populations.

Unlike pharmacological treatments, which carry the risk of side effects and may not address the psychological dimensions of anxiety, PD and BB emphasize holistic, child-centered care. These interventions align with recommendations for age-appropriate, non-invasive anxiety management, as highlighted in systematic reviews and meta-analyses [14, 19, 56]. Furthermore, this study expands the evidence base by demonstrating that these interventions are effective during critical moments of preoperative care, including anesthesia induction.

Based on the results of this study, we predict that integrating PD and BB into standard preoperative protocols could significantly improve anxiety management in pediatric surgical settings. These simple, engaging techniques may serve as effective first-line non-pharmacological interventions that align with child-centered care approaches. Future studies are encouraged to explore long-term outcomes to determine whether reduced preoperative anxiety translates to improved postoperative recovery. In addition, investigating combination strategies—such as pairing PD or BB with parental presence or guided imagery—could help enhance their effectiveness. It is also worth examining whether these methods are effective in older children or those with developmental differences. Lastly, conducting cost-benefit analyses comparing PD and BB to other distraction techniques would offer insights into their practicality and scalability. Given their affordability, ease of implementation, and minimal need for training, we recommend that healthcare providers adopt PD and BB as part of routine, child-friendly preoperative care.

Study limitations

This study has several limitations that should be considered when interpreting the results. First, the study was conducted at a single hospital, which may limit the generalizability of the findings to other healthcare settings with different cultural or demographic characteristics. Second, while the sample size was increased to account for potential attrition, the study's power might still have been affected by unmeasured confounding variables, such as variations in parental anxiety or differing levels of pediatric familiarity with the hospital environment. Third, the lack of blinding for participants and evaluators could have introduced bias during the intervention and data collection processes, as expectations might have influenced the observed outcomes. Although blinding data analysts mitigates some concerns, future studies with double-masked designs could enhance the reliability of the findings. Additionally, while the m-YPAS is a widely validated tool for assessing anxiety, it is primarily observational and may not capture subtle, subjective nuances of a child's emotional state. Incorporating additional qualitative methods, such as interviews or self-reports from older children, could provide a more comprehensive understanding of the interventions' impact. Finally, the study did not examine long-term outcomes, such as post-operative recovery, behavioral changes, or anxiety in subsequent medical visits.

Conclusion

This study highlights the effectiveness of non-pharmacological interventions, specifically PD activities and BB, in reducing preoperative anxiety in pediatric patients undergoing surgery. Among these, PD demonstrated a slight advantage in alleviating anxiety, suggesting it may be the preferred option when feasible. These findings support using creative, child-friendly techniques that are both cost-effective and free from the side effects commonly associated with pharmacological treatments. By offering pediatric patients a sense of control and distraction, these interventions can play a crucial role in enhancing the preoperative experience, potentially improving surgical outcomes, and contributing to emotional well-being.

Abbreviations

PD	Play Dough
BB	Balloon Blowing
ASA	American Society of Anesthesiologists
m-YPAS	Modified Yale Preoperative Anxiety Scale
VAS-A	Visual Analog Scale for Anxiety
IV	Intravenous
IRCT	Iranian Registry of Clinical Trials
VR	Virtual Reality

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Author contributions
PR and RV wrote the main manuscript textMM prepared figures and tablesRF and YS ConceptionPR Initial draft.

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Data availability
The datasets used and/or analyzed during the current study available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
This clinical trial was conducted in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments. The study was reviewed and approved by the Ethics Committee of Kermanshah University of Medical Sciences (ID: IR.KUMS.REC.1402.177) and was registered on the Iranian Registry of Clinical Trials (IRCT20230514058183N1). Written informed consent was obtained from the parents or legal guardians of all participating children aged 4–8 years after providing a clear explanation of the study's objectives, procedures, and potential benefits. All data were anonymized, stored securely, and were only accessible to authorized members of the research team. This study adheres to the CONSORT guidelines for the reporting of randomized clinical trials.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

Phone
+989186855038.

Author details
[1]Department of Operating Room, School of paramedical, Kermanshah University of Medical Sciences, Kermanshah, Iran
[2]Instructor of Operating Room School of Paramedicial Sciences, Arak University of Medical Sciences, Arak, Iran
[3]Research Center for Environmental Determinants of Health, School of Public Health, Kermanshah University of Medical Sciences, Kermanshah, Iran
[4]Department of Operating Room, School of Allied Medicine, Shahroud University of Medical Sciences, Shahroud, Iran

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