


# Comparative efficacy of pharmacological and non-pharmacological interventions for mitigating pain and anxiety associated with venipuncture: a randomised controlled trial

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## ABSTRACT

**Background** Venipuncture is one of the most commonly performed medical procedures in paediatric care, but it can also be one of the most painful and distressing experiences for patients. Finding effective strategies to manage pain and fear associated with venipuncture is crucial for improving the paediatric patient experience and promoting positive health outcomes. This study aimed to evaluate the efficacy of a combined approach using a topical analgesic cream (TKTX cream) and a distraction technique (Trace Image and Colouring for Kids-Book, TICK-B) in reducing pain intensity and fear levels in children undergoing venipuncture procedures.

**Methods** We conducted this randomised controlled trial among 176 children aged 6–12 years undergoing venipuncture. Participants were randomly assigned to four groups: TICK-B, TKTX cream, TICK-B+TKTX cream and a control group. Pain and fear were measured using the Wong-Baker FACES Pain Rating Scale and Children's Fear Scale. The study was carried out from 20 February 2024 to 1 June 2024 at the emergency unit of Heevi paediatric teaching hospital in the Kurdistan region of Iraq. In the intervention groups, TICK-B was applied for 2–3 min before needle insertion, and TKTX cream was applied 20 min before the venipuncture procedure. All outcome measures were evaluated 2–3 min after the completion of the venipuncture procedure.

**Results** The combined TICK-B (colouring book) and TKTX cream (topical anaesthetic) intervention was the most effective in reducing both pain intensity (mean score 2.80 vs 7.24 in the control,  $p<0.001$ ) and fear levels (mean score 0.93 vs 2.83 in the control,  $p<0.001$ ) during and after venipuncture procedures compared with individual interventions and control.

**Conclusions** The combined TICK-B distraction and TKTX cream topical anaesthetic intervention was the most effective in reducing pain intensity and fear during and after venipuncture in children, providing a practical strategy for healthcare providers to optimise needle procedure management.

## WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Venipuncture is a frequently performed medical procedure in paediatric care that often causes significant pain and distress in paediatric patients.
- ⇒ Previous research has explored various pharmacological and non-pharmacological interventions to mitigate pain and anxiety associated with venipuncture, but their comparative efficacy remains unclear.

## WHAT THIS STUDY ADDS

- ⇒ This randomised controlled trial provides evidence that a combined intervention using TKTX cream (a topical analgesic) and TICK-B (Trace Image and Colouring for Kids-Book, a distraction technique) significantly reduces pain intensity and fear levels in children aged 6–12 years undergoing venipuncture procedures.
- ⇒ The study quantifies the efficacy of individual and combined interventions using validated scales (Wong-Baker FACES Pain Rating Scale and Children's Fear Scale), demonstrating superior outcomes for the combined approach.

## HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ These findings may inform evidence-based guidelines for paediatric venipuncture procedures, encouraging the implementation of multimodal pain management strategies.
- ⇒ The study's results warrant further investigation into the synergistic effects of pharmacological and non-pharmacological interventions in various paediatric procedures and age groups.
- ⇒ Healthcare institutions may consider incorporating combined topical anaesthetic and distraction techniques as standard practice for paediatric venipuncture, potentially improving patient experience and procedural outcomes.

Trial registration number [NCT06326125](https://www.clinicaltrials.gov/ct2/show/study/NCT06326125).

## INTRODUCTION

Many children often undergo painful clinical procedures such as venipuncture and cannulation in paediatric departments. Paediatric patients often experience pain and fear during these invasive procedures.<sup>1</sup> According to previous studies, venipuncture can induce severe pain in the absence of intervention. Dalvandi *et al*<sup>2,3</sup> reported that analgesic interventions are not administered during venipuncture.<sup>2,3</sup> Children who are not managed as effectively as possible may suffer from anxiety at follow-up appointments and may develop significant needle phobias, which can persist into adulthood if untreated.<sup>4</sup> Traumatic needle use in childhood can have long-term psychological impacts, and the avoidance of healthcare services and health in all aspects is the consequence of this negative influence.

In general, there are two types of pain management interventions: pharmacological and non-pharmacological. In needle-related pain management, local anaesthetics are among the primary pharmacological interventions that penetrate the cuticle and epidermal layer of intact skin, penetrate the dermis, where nerve endings are located, and provide pain relief.<sup>5</sup> Researchers have studied a eutectic mixture of a local anaesthetic (EMLA) emulsion containing 25 mg of lidocaine and 25 mg of prilocaine per gram to treat pain associated with venipuncture in paediatric settings since it is both effective and less invasive.<sup>6</sup> The EMLA significantly reduced pain perception in 85% of patients according to a meta-analysis of 20 studies conducted to determine the effectiveness of this cream.<sup>7</sup>

Nevertheless, EMLA cream requires a 60 min application period at least before the start of the blood draw process, and it can still cause moderate pain.<sup>8</sup> However, some anaesthetics, such as TKTX cream, have been suggested to require shorter application periods than EMLA.<sup>9</sup> TKTX cream is a topical anaesthetic formulation comprising 5.0% lidocaine, 5.0% prilocaine and 1.0% epinephrine (epinephrine). In comparison, EMLA cream typically contains 2.5% lidocaine and 2.5% prilocaine, without epinephrine. The TKTX cream is notable for its quick onset of action, usually becoming evident within approximately 20 min.<sup>9</sup> This faster onset may be attributed to its higher concentration of active ingredients and the addition of epinephrine, which can enhance local absorption and prolong the anaesthetic effect.

Several non-pharmacological approaches, such as distraction techniques, cognitive and behavioural therapy, hypnosis and altered memory, have been studied for the treatment of needle procedures in children.<sup>10</sup> Distraction is the most straightforward of these interventions, can be applied immediately and requires little before training.<sup>10</sup> Based on a systematic review of the literature, distraction has been shown to be an effective method of reducing pain from needle-related operations.<sup>11</sup> Evidence shows that art-based interventions decrease pain very effectively

as distraction methods and are inexpensive.<sup>12–14</sup> Additionally, there have been limited studies examining the combination of these two forms of management (pharmacology and non-pharmacology).

Pharmacological approaches can efficiently alleviate pain; however, they do not address the psychological factors of fear and anxiety associated with needles in a comprehensive manner. In addition, non-pharmacological approaches, such as distraction, cognitive-behavioural therapy, hypnosis and filled memory formation, have been taken into account.<sup>10</sup> Specifically, art-based distractions such as colouring/drawing decreased pain affordably.<sup>12,13</sup>

Limited data are available regarding the use of pharmacological and non-pharmacological interventions in combination to compensate for the insufficiencies of each.<sup>15,16</sup> Therefore, the purpose of this study was to evaluate the effectiveness of combining topical anaesthesia and distraction techniques in comparison with a single intervention. We hypothesise that combining these pharmacological and non-pharmacological methods will be more effective in reducing paediatric patients' pain and fear than either approach used separately.

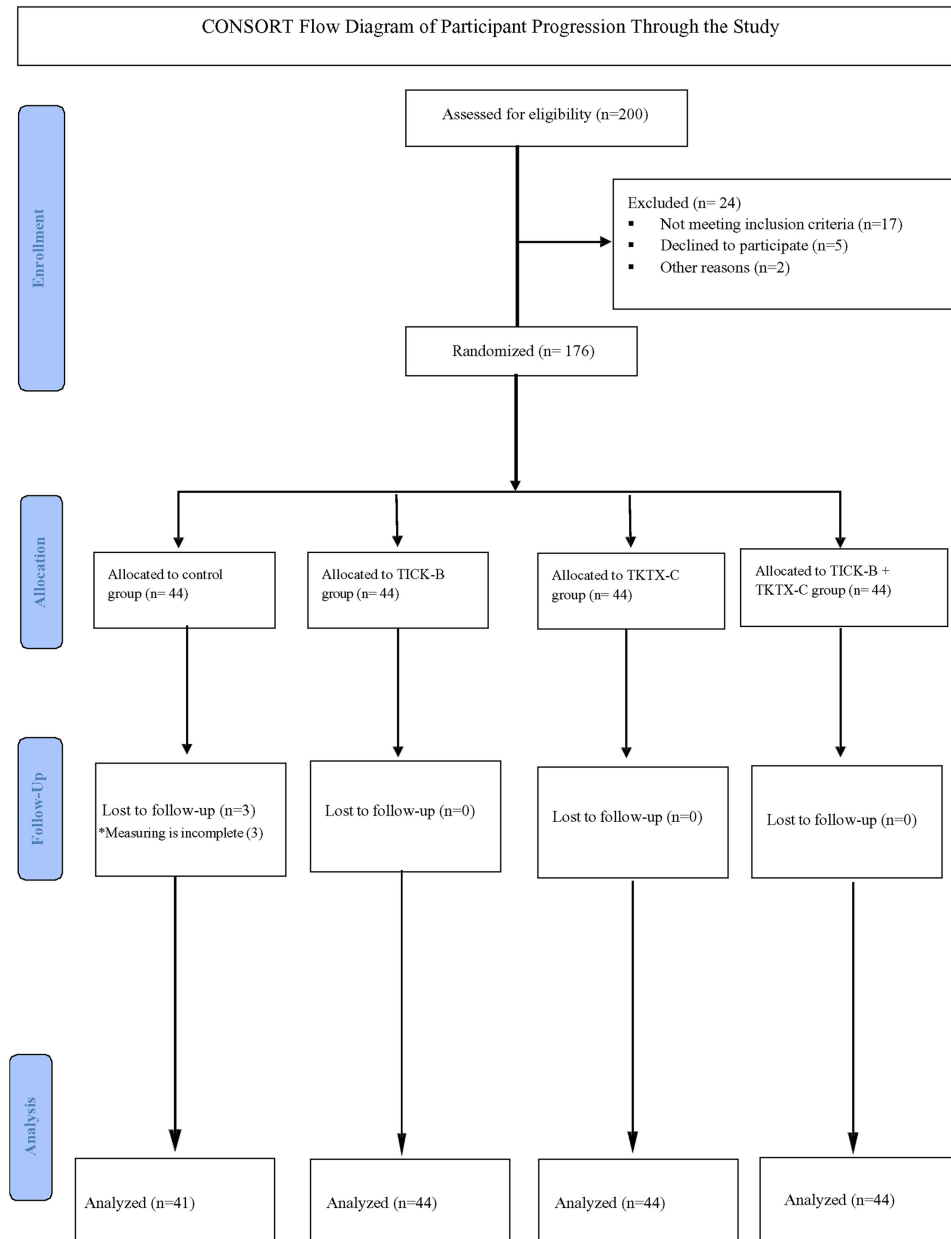
## METHODS

### Design and settings

The present study was conducted at Heevi Paediatric Teaching Hospital in Duhok City from February 2024 to the end of May 2024 as a prospective, randomised clinical trial (RCT). Moreover, the study followed the Consolidated Standards of Reporting Trial guidelines for pharmacological and non-pharmacological interventions (figure 1). In this experimental study, 176 6- to 12-year-old students were randomly selected and divided into four groups based on their level of venipuncture requirements (TICK-B group, TKTX cream group, TICK-B+TKTX cream group and control group). This research was conducted in a double-blinded manner on paediatric patients requiring venipuncture. The study sample included 176 paediatric patients requiring venipuncture who met the eligibility criteria and were randomly assigned to four groups. The patient eligibility criteria included being 6 to 12 years of age and requiring venipuncture. The study excluded children with delayed neurological development, difficulties with oral expression, hearing and visual impairments or who had recently been prescribed analgesic medications or who were allergic. Children who had recently been administered topical anaesthesia were also excluded.

### Study sample

The sample size of the study was determined by performing a power analysis. Previous research<sup>12,13</sup> indicated that the control group participants had an SD of 2.0, while the experimental group participants had an SD of 1.5. To achieve a power of 0.80 with a type I error rate of 0.05, 40 participants were required for each group. In



**Figure 1** The flow of participants through each stage of our randomised controlled trial, as per the Consolidated Standards of Reporting Trial guidelines. This flow diagram provides a clear overview of participant recruitment, allocation, follow-up and analysis, ensuring transparency in our research methodology and allowing for accurate interpretation of the study results.

these previous studies, participants were not lost during painful procedures because children are attracted to these activities. With a 10% loss rate included in the study group, the final sample size will be approximately 44 participants.

### Randomisation

A pre-designed form was used to fill out the names of the paediatric patients who needed venipuncture. To ensure blindness and randomisation, this study was conducted with simple random sampling. The computer-generated sequences were used to randomly allocate eligible participants to four groups. The opaque and sealed envelopes were sequentially numbered. The envelope contains specific information categorising paediatric patients into

one of four groups. Each child was instructed to pick an envelope from this set. The 176 paediatric patients who agreed to participate were randomly assigned to one of four groups. In each group, 44 patients were included. Among the 44 children, each child was randomly assigned to one of four groups: the TICK-B group, the TKTX cream group, the TICK-B+TKTX cream group or the control group. Three children from the control group were unable to provide samples due to being hurried, while in other groups, there were no children lost during venipuncture. Therefore, 41 children were included in the control group, and 44 were included in the TICK-B, TKTX cream and TICK-B+TKTX cream groups (figure 1).

The ward nurse, unaware of the study details, distributed randomisation envelopes for each intervention. Each family and child were informed of which group they were assigned to. Nurses, parents and children were blinded to the groupings via opaque sealed envelopes. To conceal the allocation, one child was randomly assigned to each study group in each emergency room. This special place contains facilities for children to undergo the venipuncture procedure of being blinded by other children.

We collaborated with the emergency room's head nurse to ensure that no one entered the room and disrupted the procedure. It is important to note that the children and the observer nurse were not aware of the main objective of the study, and the parents were advised not to disclose the purpose to their children or interventions that were performed during venipuncture procedures on the patients. In addition, they were not informed that they were compared with children participating in other interventions. Interventions were performed during the venipuncture process. The observer is a senior paediatric nurse who has been trained by the second author in pain and fear assessment but has not been involved in the design of the study or statistical analysis and does not have any knowledge of the procedures that were performed.

### Measurements

For randomisation purposes, each child who participated in the study completed a sociodemographic questionnaire. The observer nurse provided information on the Wong–Baker Pain Rating Scale (W-B FACES) and the Child Fear Scale (CFS) to the parents of the children. Face-to-face interviews were performed based on self-reports.

A predesigned questionnaire was used to assess the patient characteristics, including their age, sex, number of attempts, hospitalisation period, fear of previous procedures and pain experienced during the last painful procedure, based on the Children's Fear Scale and WB-FACES.

#### Wong–Baker faces (Wb-FACES) pain rating scale

According to their self-reports, the Wong–Baker FACES scale was used to measure the intensity of children's pain levels. The scale ranges from 0 to 10. It consisted of six illustrations depicting varying emotions, ranging from smiles (0, a very happy emotion, with no pain) to crying (10, a very painful emotion).<sup>17</sup>

#### Children's Fear Scale (CSF)

During cannulation procedures, children's fear levels were assessed through their facial expressions, graded on a scale from 0 to 4. This scale encompasses five facial expressions, each corresponding to a specific score. Pictures of children exhibiting no fear (0 points) indicate the absence of fright, while pictures showing highly fearful expressions (four points) denote a strong sense of fear in the child.<sup>18</sup>

#### Visual Analog Scale (VAS)

The pain and fear experienced by the children were assessed by both parents and an observing nurse through

the use of a VAS. This particular scale measures the intensity of pain and fear on a continuum ranging from 0 (indicating no pain or fear) to 10 (representing the most severe or intense pain or fear). Following venipuncture procedures, the nurses and parents evaluated the children's levels of fear and pain, using a scale that ranged from 'No fear' to 'Most fear' and 'No pain' to 'Worst pain', respectively. Additionally, the degree of discomfort experienced by the children after the blood draws was documented, using a scale that ranged from 'No discomfort' to 'Worst discomfort'. It is important to note that this VAS is widely acknowledged as a reputable and dependable instrument for the assessment of pain and anxiety in children aged 8 to 18 years.<sup>19</sup>

### Interventions

In this study, the first author applied all pharmacological and non-pharmacological methods (TICK-B, TICK-B+TKTX cream and TKTX cream). For both the children and the observing nurse, the study's primary objective was to remain secret, and parents were requested not to disclose it to their children. To minimise potential bias, children and the observing nurse were not informed about the specific hypotheses being tested. Parents were instructed not to discuss the study details with their children.

Pre-venipuncture pharmacological intervention was applied 20 min before the procedure according to the manufacturer's instructions. The non-pharmacological intervention was conducted for approximately 2–3 min before the procedure.

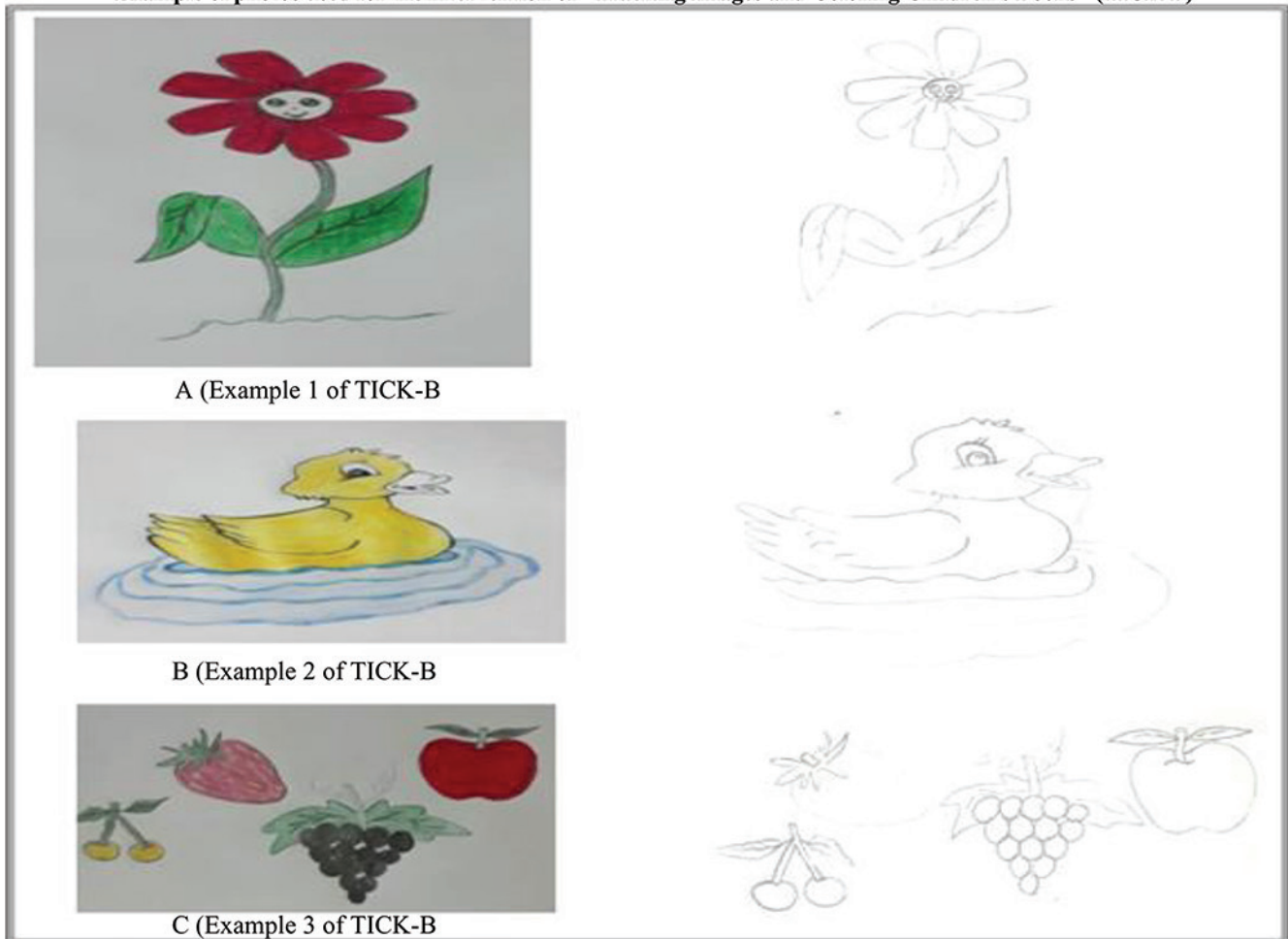
#### TICK-B

The colouring book for kids, known as the Trace Image Colour for Kids-Book (TICK-B), consists of illustrated pictures of colour. Before cannulation, participants were given TICK-B (figure 2). While undergoing the procedure, they were directed to either draw or colour an image, highlighting the image's use, and were asked to keep their nondominant hand steady.

#### TKTX cream group

Tattoo creams such as KTX cream are currently available in cosmetic clinics. We consulted two pharmacologists about its use and side effects. The pharmacologist provided some insights into the mechanism of action of TKTX. They advised us that this cream's formulation was effective, safe and free of side effects. Despite the Food Drug Association's acceptance of this cream, they advised us to conduct a pilot study of approximately 10–20 children to determine its safety and side effects. A pilot study was conducted with 20 patients from our hospital before the current study was initiated within 3 months. The aim of the pilot study was to be sure about the safety of the cream in terms of the allergy and other immunological reactions. The patients were administered TKTX cream 20 min before the procedure. TKTX cream is a topical anaesthetic formulation that includes lidocaine,

## Example of photos used for the intervention of "Tracking Images and Coloring Children's Books" (TICK-B)



**Figure 2** Representative samples of visual stimuli used in the 'Tracking Images and Colouring Children's Books' (TICK-B) intervention. These age-appropriate illustrations, designed to engage paediatric patients during medical procedures, encourage children to visually track and colour. The TICK-B intervention was implemented either alone or in combination with TKTX cream, as part of examining non-pharmacological strategies for managing pain and fear in paediatric patients. Figure (A) severity of pain Figure (B) levels of fear.

prilocaine and epinephrine (epinephrine). Due to its prompt onset of action, the effects typically occur within approximately 20 min. Based on expert pharmacologists' advice and a pilot practice study, this cream was applied. The TKTX cream was provided before the procedure, and the children were allowed to proceed until the venipuncture procedure was completed.

#### TICK-B plus TKTX cream

TKTX cream was applied 20 min before the venipuncture procedures, and TICK-B was applied as a distraction method 2 min before the procedure began. The children in this group received both pharmacological and non-pharmacological interventions as combined interventions.

#### Control group

Children in this group were permitted to stay alongside their families. Furthermore, they were instructed not to use any other form of distraction with their children.

#### Study procedure

To conduct the study, we enlisted the participation of an experienced nurse with over 15 years of clinical paediatric experience, particularly in the administration of painful medical procedures. The decision regarding venipuncture was made by physicians. The second author provided training to an observer nurse, who had more than 5 years of experience in paediatric nursing, on the measurement tools used in this study. The observer nurse provided parents and children with a standardised description of pain and fear assessment tools, and both parties expressed satisfaction with the instructions provided. Patient demographic information was collected through a self-report form. The VAS was used for the observational measures, while self-report measures were employed to determine the levels of pain and fear experienced during and after the procedure. Fear levels were assessed using the CFS on a 0–4 scale, while pain levels were assessed using the Wong–Baker FACES Pain Rating Scale on a 0–10 scale. A



clinical nurse performed the venipuncture procedure on all the children using their nondominant hand.

The 176 children were randomly assigned to four groups, each comprising 44 children. The samples were provided with opaque sealed envelopes. Once assigned to their respective groups, the parents and children proceeded to the venipuncture unit for the procedure. In all groups, parents were permitted to accompany their children during the venipuncture procedure. The first author, who had over 10 years of experience as a paediatric nurse, implemented all interventions for children without being aware of their group allocation. Parents or caregivers were allowed to be present in the room during the procedure but were instructed not to interfere with administering interventions. Their role was limited to providing emotional support to the child if needed. The TICK-B intervention was administered for 2–3 min before and during the venipuncture procedure. Meanwhile, TKTIX cream was applied, and the tube was left on for 20 min. The interventions included activities such as colouring a picture book, application of a local anaesthesia cream (TKTX cream) or a combination of both methods. The participants were instructed to continue with the intervention until the completion of the procedure. After the procedure, the nurse observer, parents and children were requested to report their respective levels of pain and fear after 2–3 min.

The nurses who participated in the study were not informed about its primary objective, which involved the assessment and comparison of participant outcomes. Following venipuncture, the observer nurse assessed the children's pain and fear, and the parents and their children were instructed to provide self-reports regarding their pain and fear levels without being aware of their assigned group. Furthermore, both parents and the

clinical nurse were given instructions not to divulge the purpose of the intervention to the children. Consequently, the children remained uninformed about the objective of the intervention.

### Statistical analyses of the data

In the present study, the Statistical Package for the Social Sciences version 28.0 (SPSS Inc., Chicago, IL, USA) was used for all statistical analyses. Descriptive data were examined using means, SD, frequencies and percentages. The normality of the data was verified through a histogram to confirm a normal distribution of scores on the scale. Group similarities in demographic and clinical characteristics were assessed using the X<sup>2</sup> test and Levine's one-way analysis of variance (ANOVA) for homogeneity. Parametric data, including children's pain levels and fear intensity, were compared using a statistical ANOVA. A significance level of 0.05 was set, and a post hoc Bonferroni correction was conducted.

### Patient and public involvement in the study

Patients and the public were not involved in the design, conduct, reporting or dissemination of this research project.

## RESULTS

### Participant characteristics

General characteristics across participant groups were essentially similar; distributions by sex, age, number of attempts, body mass index, days of hospitalisation, fear before venipuncture and previous pain levels were all set at  $p > 0.05$  [table 1], meaning that differences in pain intensity and fear scores between the groups were due to the interventions and not to substantive differences.

**Table 1** A comparison of baseline characteristics and previous procedural fear and pain scores among the study groups

Child's characteristics	Study groups				P value (two-sided)
	Control group (n=41)	TICK-B group (n=44)	TKTX cream group (n=44)	TICK-B+TKTXC group (n=44)	
No. (%)					
Gender					0.745*
Male	21 (51.2%)	21 (47.7%)	25 (56.8%)	20 (45.5%)	
Female	20 (48.8%)	23 (52.3%)	19 (43.2%)	24 (54.5%)	
Mean (SD)					
Age	8.49 (1.705)	8.11 (1.351)	8.95 (1.751)	8.84 (1.413)	0.207†
Attempts	1.41 (0.499)	1.43 (0.501)	1.45 (0.504)	1.39 (0.493)	0.634†
BMI	17.4 (0.93)	16.74 (0.85)	17.17 (0.95)	18.7 (1.00)	0.701†
Hospitalisation days	3.73 (0.807)	3.68 (0.909)	3.52 (1.045)	3.66 (0.888)	0.119†
Pre-venipuncture fear	2.61 (0.891)	2.32 (0.883)	2.45 (0.875)	2.48 (0.876)	0.970†
Previous pain	6.85 (1.667)	6.84 (1.462)	6.20 (1.837)	6.77 (1.683)	0.599†

The data are presented as a percentage or as a mean  $\pm$  standard deviation, as appropriate.

\*Chi-square test.

†One-way analysis of variance.

### Pain intensity

The analysis of the pain intensity scores (table 2) revealed significant differences between the groups. The mean pain score during the procedure in the TICK-B+TKTX cream group was 2.80, which was significantly lower than that in the control group (7.24,  $p<0.001$ ), TICK-B group (5.09,  $p<0.001$ ) and TKTX cream group (5.43,  $p<0.001$ ). Similarly, after the procedures, the lowest mean pain score (2.34) was found in the TICK-B+TKTX cream group, which was significantly lower than that in the control group (7.32,  $p<0.001$ ), TICK-B group (4.30,  $p<0.001$ ) and TKTX cream group (4.09,  $p<0.001$ ). The results clearly indicate that compared with all the other interventions, the combined TICK-B+TKTX cream intervention was the most effective in reducing the intensity of pain during and after the procedures.

### Fear levels

By analysing the fear scores (table 3), we found that there were considerable differences between the groups. The TICK-B group had the lowest mean fear score (1.82), which was significantly lower than that of the control group (3.27,  $p<0.001$ ), TKTX cream group (2.41,  $p<0.007$ ) and TICK-B+TKTX cream group (1.14,  $p<0.05$ ). The TICK-B+TKTX cream group had the lowest mean fear score (0.93), which was significantly lower than that of the other groups, namely, the control group (2.83,  $p<0.001$ ), TICK-B group (1.57,  $p<0.018$ ) and TKTX cream group ( $p=2.14$ ). This study revealed that the TICK-B intervention was best at managing fear associated with the procedures, while the TICK-B+TKTX cream intervention was the best at managing fear after the procedures.

In general, the lines depicted in figure 3 demonstrate the superiority of the complex intervention TICK-B+TKTX cream in reducing the pain intensity and the fear of patients during the procedures and after them in comparison with the control group and individual interventions.

In summary, the combined TICK-B+TKTX cream intervention was most effective in reducing both pain intensity and fear levels during and after the procedures compared with the control group and individual interventions. The TICK-B intervention alone was also effective in reducing fear levels, particularly during the procedures. These findings are further supported by the consistency of results across different reporters (child self-report, parent report and observer report) as shown in table 4, which demonstrates the robustness of the intervention effects across multiple perspectives (table 4).

### DISCUSSION

The present study aimed to evaluate the effectiveness of combining pharmacological (TKTX cream) and non-pharmacological (TICK-B colouring book) interventions in reducing pain and fear levels during and after venipuncture procedures in paediatric patients aged 6–12 years. The findings revealed that the combined

**Table 2** Comparison pain intensity among the groups

Child's characteristics	Groups				F	P value (two-sided)			
	Control group (n=41)	TICK-B group (n=44)	TKTX cream group (n=44)	TICK-B+TKTXC group (n=44)		TICK-B vs control	TKTX cream vs control	TICK-B + TKTX cream vs control	TICK-B vs TICK-B+TKTXC group
Pain during procedures	M=SD 7.24=1.17	5.09=1.92	5.43=2.16	2.80=1.19	50.40	0.000	0.000	0.000	0.000
Pain after procedures	7.32=1.21	4.30=1.32	4.09=1.59	2.34=0.93	107.93	0.000	0.000	0.000	0.000

Wong-baker scale pain rating scale.  
Bonferroni test results.  
TICK-B, Trace Image and Colouring for Kids-Book; TKTX-C, TKTX cream.



**Table 3** Fear scores to compare between the groups

Child's characteristics	Groups				P value (two-sided)				
	Control group (n=41)	TICK-B group (n=44)	TKTX-C group (n=44)	TICK-B+TKTXC group (n=44)	TICK -B vs -B vs control	TKTX-C vs control	TICK-B+TKTXC vs Control	TICK-B vs TKTX-C group	TICK -B vs TICK -B+TKTXC vs TKTX-C group
	M=SD	M=SD	M=SD	M=SD	P value	P value	P value	P value	P value
Fear during procedures	3.27=0.59	1.82=0.97	2.41=0.92	1.14=0.82	0.000	0.00	0.000	0.007	0.000
Fear after procedures	2.83=0.83	1.57=0.84	2.14=1.13	0.93=0.66	0.000	0.002	0.000	0.018	0.006
					48.77	35.48			
Wong-baker scale pain rating scale. Bonferroni test results. TICK-B, Trace Image and Colouring for Kids-Book; TKTX-C, TKTX cream.									

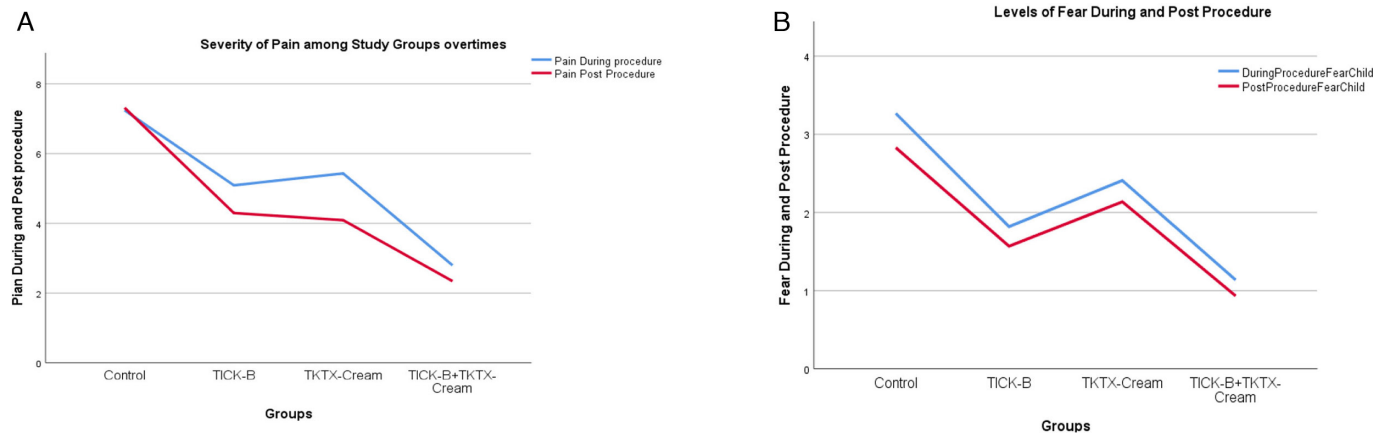
intervention (TICK-B+TKTX cream) was most effective in managing both pain intensity and fear levels compared with the control group and individual interventions.

Previous studies have shown that children are very sensitive to painful venipuncture when no pain relief is provided.<sup>2 3</sup> Numerous types of distraction have been shown to affect children's anxiety and pain perception by taking their mind during procedures. However, the problem was that most of the distractions that have been found to be effective require training, are expensive and are nonattractive to children during these procedures.

This study examined the effectiveness of psychological interventions, especially distraction methods such as the TICK-B, in helping children develop the ability to use coping mechanisms to address distress and pain. The TICK-B can be developed and implemented by non-psychologists; therefore, it is readily implemented. This act of focusing away from the source of pain has been shown to alleviate fear and anxiety in patients.<sup>20</sup> In the distraction condition of this study, children's attention was attracted by interacting with enjoyable things in a very relaxed environment. Pain is a subjective reality that is significantly shaped by environmental conditions.<sup>21</sup> Hence, the environment in which medical procedures take place is crucial, especially for children. Environments that seem to be familiar and comfortable can be vigilant and help reduce anxiety. Giving children an opportunity to select and participate in an activity that they like before venipuncture can make the procedure room more familiar and friendly. Distraction interventions have also been found to help reduce anxiety in parents and nurses viewing the procedure in a meta-analysis.<sup>10</sup>

The TKTX cream emulsion in the TKTX cream group was used to block the transmission of nerve impulses, thus relieving the pain of venipuncture. This method has proven effective in a previous study,<sup>9</sup> with a duration of 20 min considered as being sufficient for its application. Although several local anaesthetic cream preparations, such as EMLAs, tetracaine and amethocaine, were found to be effective at decreasing pain in children during painful nursing procedures, these preparations required a longer time of 40–60 min.<sup>22 23</sup> Moreover, some studies have revealed that some liquid sprays have a short onset time; sometimes, it takes only a few seconds before painful procedures are performed. Nevertheless, the effect of these sprays is not similar to that of EMLA cream. Furthermore, vapocoolant spray did not show any benefit in reducing pain associated with intravenous cannulation in children.<sup>2 24 25</sup> The shorter duration and greater effectiveness of TKTX cream make it practical and feasible for paediatric nurses to manage children's outcomes during painful procedures.

This study's results can be understood through the lens of the gate-control theory<sup>26</sup> of pain and the WHO's guidelines for pain management. The gate-control theory, proposed by Melzack and Wall,<sup>26</sup> suggests that pain perception is modulated by a 'gate control system' in the spinal cord, which can be influenced by both



**Figure 3** (A and B): This figure illustrates the variations in levels of pain and fear over time among different treatment groups. The graph compares four groups: TICK-B (Tracking Images and Colouring Children's Books), TKTX-C, TICK-B+TKTXC (combined intervention) and control.

sensory inputs and descending signals from the brain. Pharmacological interventions, such as topical anaesthetic creams such as TKTX cream, primarily act on the peripheral and spinal mechanisms of pain transmission, reducing nociceptive input and 'closing the gate' to pain perception.<sup>5,26</sup> The findings of the present study, in which the TKTX cream group demonstrated significantly lower pain scores during and after venipuncture than did the control group, align with this proposed mechanism of action.

However, the superiority of the combined intervention (TICK-B+TKTX cream) over the individual TKTX cream intervention highlights the importance of addressing the cognitive-evaluative and affective components of pain, as proposed by the gate-control theory.<sup>26</sup> Non-pharmacological interventions, such as the TICK-B colouring distraction technique, engage cognitive and attentional resources, modulating descending inhibitory pathways and 'closing the gate' to pain perception.<sup>12,27</sup> By actively involving children in their own care through engaging and age-appropriate interventions such as colouring books, they may experience a sense of control

and empowerment, which can further alleviate their fears and anxieties,<sup>12-14</sup> thereby influencing the affective-motivational component of pain.

The synergistic effect of the combined intervention aligns with the WHO's guidelines for pain management, which recommend a multimodal approach incorporating both pharmacological and non-pharmacological interventions (WHO, 2022). The WHO guidelines emphasise the importance of addressing the multidimensional nature of pain, including its physical, psychological and emotional aspects (WHO, 2022). By combining pharmacological interventions that target the physiological component of pain with nonpharmacological interventions that address the cognitive and affective dimensions, the present study's combined approach effectively addressed the multifaceted nature of pain and fear associated with needle procedures.

#### Implications for clinical practice

The findings of this study have significant implications for clinical practice in paediatric settings, as they align with the WHO's recommendations for a multimodal approach

**Table 4** Comparison of pain and anxiety of children among groups for different examiners after the procedure

Child's characteristics	Groups				F	P value (two-sided)
	Control group (n=41)	TICK-B group (n=44)	TKTX-C group (n=44)	TICK-B+TKTXC Group (n=44)		
Pain Mean=SD						
Self-report (Child)	7.32=1.21	4.30=1.32	4.09=1.59	2.34=0.93	<b>107.930</b>	<b>0.000</b>
Parent report	7.27=1.20	4.30=1.35	4.16=1.64	2.36=0.94	<b>100.928</b>	<b>0.000</b>
Observer report	7.20=1.14	4.39=1.35	4.11=1.57	2.43=1.02	<b>98.472</b>	<b>0.000</b>
Fear Mean=SD						
Self-report (Child)	2.83=0.83	1.57=0.84	2.14=1.13	0.93=0.66	<b>35.48</b>	<b>0.000</b>
Parent report	2.78=0.82	1.52=0.82	2.09=1.13	0.89=0.68	<b>35.50</b>	<b>0.000</b>
Observer report	2.83=0.83	1.57=0.84	2.14=1.13	0.93=0.66	<b>35.48</b>	<b>0.000</b>

The data are presented as a percentage or as a mean = standard deviation, as appropriate. One-way analysis of variance.



to pain management (WHO, 2022). Healthcare professionals should consider incorporating a combination of pharmacological and non-pharmacological interventions to optimise pain and fear management during needle procedures. The implementation of such combined approaches can lead to improved patient experiences, reduced long-term psychological impacts and increased adherence to future medical procedures.<sup>28</sup> However, it is important to address potential barriers to implementation, such as staff training, resource allocation and patient acceptance. Strategies such as interdisciplinary collaboration, ongoing staff education and patient/family engagement could facilitate the successful implementation of these interventions.<sup>29</sup>

### Strengths and limitations

A notable strength of this study is its randomised controlled design and double-blinding approach, which minimise potential biases and enhance the reliability and validity of the findings. Additionally, the standardised assessment tools used for measuring pain and fear levels increase the objectivity and validity of the results. However, this study has several limitations that should be acknowledged. First, the sample was drawn from a single paediatric hospital, which may limit the generalisability of the findings to other settings. Second, the study focused on a specific age range (6–12 years), and the effectiveness of the interventions may vary for younger or older age groups. Moreover, while the study assessed pain and fear levels immediately after the procedures, it did not investigate the long-term psychological impacts or the potential development of needle phobias.

### Implications for research and practice

The TICK-B+TKTX cream, which combines pharmacological and non-pharmacological interventions, offers a convenient option for nurses aiming to relieve pain in children undergoing venipuncture procedures. The TICK-B intervention was appealing to children because it was easy to administer and did not require training. We strongly recommend further research to examine the potential effectiveness of integrating these approaches, as well as their impact on pain and fear levels in children during various medical interventions. Future research should explore the applicability of these interventions across different age groups and diverse cultural contexts. Longitudinal studies are warranted to evaluate the sustained effects of combined interventions on children's attitudes and behaviours towards future medical procedures, as traumatic needle experiences in childhood can have lasting psychological impacts and contribute to the avoidance of healthcare services.

### CONCLUSIONS

In conclusion, both pharmacological topical anaesthetics and non-pharmacological distraction interventions were effective for managing venipuncture-related pain in

paediatric patients. While topical anaesthetics reduced procedural pain, distraction uniquely decreased pre-procedure fear and anxiety levels. The findings of this study provide compelling evidence for the benefits of combining pharmacological (TKTX cream) and non-pharmacological (TICK-B colouring book) interventions in managing pain and fear levels during and after venipuncture procedures in paediatric patients. For nurses, we recommend the combination of TICK-B+TKTX cream due to its ease of use, practicality and shorter waiting time.

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