



Clinical trial

Comparing the use of colored Trace Images in Kids' Books with passive distractions to decrease pain and fear during cannulation in children: A randomized clinical trial

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ARTICLE INFO

Keywords:

Cannulation

Pain

Fear

Music

Cartoon

TICK-B

Randomized controlled trial

ABSTRACT

Introduction: Cannulation can be frightening and a source of pain and fear for pediatric patients. The study evaluated the effectiveness of Trace Image and Coloring for Kids-Book (TICK-B) as active distraction with two passive distractions in reducing children's pain and fear during cannulation.

Methods: This study employed a prospective, controlled, randomized experiment conducted from January 2023 to April 2023 at Heevi Pediatric hospital in the Kurdistan region of Iraq. A total of 176 participants were randomly assigned to one of four study groups, with 44 participants assigned to each group. The interventions were administered 2–3 min before continued until the cannulation procedure finished. Data were collected through interviews conducted before and after the procedure. Children reported pain using Wong-Baker FACES® scale, and fear evaluated with the Child Fear Scale as an outcome after the cannulation procedure. Children's outcomes during and after procedure were measured 2–3 min after completed procedure.

Results: All distraction methods significantly reduced children's pain and fear compared to the control group. TICK-B showed large effects in reducing average pain (mean difference = -4.65, 95 % CI: -5.67 to -3.65) and fear (mean difference = -2.18, 95 % CI: -2.67 to -1.69) during cannulation. Post-procedure, TICK-B maintained large pain relief (mean difference = -4.10, 95 % CI: -4.98 to -3.22) and fear reduction (mean difference = -1.89, 95 % CI: -2.39 to -1.39) effects. Music listening and cartoon watching both showed improvements compared to the control group, with minimal differences between them in terms of pain and fear during the procedure. Also, the differences were the same after the procedure. No adverse events were reported.

Conclusion: All distraction techniques effectively and safely decreased children's pain and fear during cannulation. The TICK-B technique most effectively reduced children's pain and fear during cannulation procedures compared to music-listening and cartoon-watching techniques.

Trial registration: NCT04977323.

1. Introduction

Children undergoing medical procedures in the emergency room can experience great pain and fear [1]. According to research approximately 51 % of children aged 7–12 years who underwent painful procedures reported experiencing pain during or after the procedure [2,3].

Strikingly, only 10 % of these painful medical interventions integrate approaches for pain alleviation [4]. The inadequate management of pain and fear during needle procedures can precipitate cardiovascular and immune system implications, psychological effects [5], the development of needle-related phobias, delayed recovery, and prolonged hospital stays [5]. Therefore, managing the pain associated with needle therapy

Abbreviations: TICK-B, Trace Image and Coloring for Kids-Book; CFS, Child Fear Scale; WB FACE, Wong-Baker's FACES; RCT, Randomized Clinical Trial; music MLG, Music Listening Group; CWG, Cartoon Watching Group; M, Mean; SD, Standard Deviation; CI, Confidence Interval.

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<https://doi.org/10.1016/j.eujim.2024.102379>

Received 17 January 2024; Received in revised form 13 June 2024; Accepted 18 June 2024

Available online 21 June 2024

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procedures is a therapeutic priority [6,7].

To effectively assess and manage pain and fear in pediatric patients, nurses must be able to assess and manage both effectively [8]. Different pharmaceutical and non-pharmaceutical methods are utilized to reduce pain and fear in children undergoing procedures such as venipuncture and cannulation [8]. The predominant pharmacological approach employed to alleviate pain during medical procedures involves the use of topical anesthetic creams [9,10]. These cream-based anesthetics that induce localized anesthesia may necessitate a waiting period of 45–60 min [10]. Non-pharmacological approaches are very beneficial for decreasing the need for analgesics and improving the quality of life of pediatric patients [11].

Compelling evidence and robust recommendations endorse the utilization of distraction techniques during needle procedures [12]. These distraction methods can be categorized into two types: active and passive. Active methods engage the child's involvement in an activity, such as toys, digital games, virtual reality, and controlled breathing techniques [13–16]. In contrast, during passive distraction, the child is encouraged to maintain a calm and composed state during a medical procedure, which may include listening to music or watching television [17–19]. The mechanisms of passive distraction are still unclear [20].

Despite the potential benefits of these interventions, they are often not used by healthcare practitioners due to cost, time, or difficulty in implementation [21,22]. The Trace Image Coloring for Kids-Book approach, an art-based active distraction, has been found to be an effective technique for decreasing children's pain and fear during needle procedures [21,22]. The simplicity, time-savings, and child-friendliness of the TICK-B make it an effective distraction. This is the reason for comparing TICK-B with attractive passive distractions.

This study examined the effects of Trace Image and Coloring for Kids-Book (TICK-B), cartoon watching and music listening on pain and fear during cannulation procedures among school-aged children between the ages of 6 and 12. Researchers hypothesized that children who use the TICK-B during cannulation procedures would experience less pain and fear than children who passively watch cartoons and listen to music during the procedure.

2. Methods

2.1. Design and settings

The present study was a prospective, randomized clinical trial (RCT) with four arms, that was carried out at the emergency unit of Heevi Pediatric Teaching Hospital in the Kurdistan Region/Iraq from January 2023 to April 2023. This study was conducted in accordance with CONSORT guidelines [22]. This experimental research was conducted in a single-blinded manner on pediatric patients who required cannulation and comprised 176 school-children aged from 6 to 12 years who were randomly selected and divided into four groups: the Music listening Group (MLG), Cartoon Watching Group (CWG), TICK-B, and Control Group (CG).

2.2. Participants

The study sample consisted of 176 school aged children between 6 and 12 years old who required a cannula, and met the eligibility criteria. Eligible participants were randomly allocated into four groups: Music listening Group (MLG), Cartoon Watching Group (CWG), Trace Image Coloring for Kids-Book (TICK-B), and Control Group (CG).

The inclusion criteria were as follows aged between 6 and 12 years and requiring a cannula. Children with delayed neurological development, difficulty with verbal expression, hearing or visual impairments, who had recently taken analgesic medication, and who had received topical anesthesia were excluded from the study.

2.3. Sample size

The study's sample size was established using power analysis. Based on previous research [15,16], the control group was expected to have a standard deviation of 2.0, while the experimental groups would have a standard deviation of 1.5. To achieve a power of 0.80 with a Type I error rate of 0.05, each group required 40 participants. Accounting for a potential 10 % dropout rate, the final sample size was set at approximately 44 for each group.

2.4. Randomization

A predesigned form was used to fill out the names of the pediatric patients who needed cannulation. A simple random sampling approach was used for allocation concealment and randomization. Eligible participants were randomly assigned to one of four groups: trace image coloring for kids-book (TICK-B), cartoon-watching, music-listening, or control group. Computer-generated random sequences were used to allocate participants. Opaque, sealed, and sequentially numbered envelopes containing group assignments were prepared. Each participant picked an envelope to reveal their group allocation. This ensured concealment from participants, families, and healthcare providers. Initially, 44 participants were assigned to each group. However, during the study, some participants were lost. In the control group, 4 participants could not provide samples due to time restrictions. In the music-listening group, 3 participants could not provide samples for the same reason. In the cartoon-watching group, 2 participants refused to watch cartoons during cannulation. Consequently, the final sample sizes were: control group ($n = 40$), music-listening group ($n = 41$), cartoon-watching group ($n = 42$), and TICK-B group ($n = 44$, no dropouts).

To ensure blinding, randomization envelopes were distributed by a ward nurse unaware of study details. Only one participant per group was randomized within each emergency room setting. Cannulation procedures occurred in an isolated room to prevent observation by other children. Collaboration with the emergency room's head nurse prohibited unauthorized entry during procedures, avoiding disruptions. Participants (children) remained naive to the study's primary objective. Parents were instructed not to disclose the purpose or interventions performed during cannulation. Furthermore, children were unaware they were being compared to other intervention groups, but their parents had provided informed consent for this. Interventions were administered concurrently with cannulation. The observer nurses refrained from disclosing information about the intervention to participants.

2.5. Measurements

For randomization 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 conducted to collect self-reported data.

2.5.1. Child information form

A pre-designed questionnaire was used to assess the characteristics of the patients, including their age, gender, hospitalization period, "attempts" (number of tries) to perform cannulation on the participant, while "previous pain" refers to the intensity of pain experienced by participants during previous cannulation procedures, and "previous cannulation fear" refers to participants' level of fear experienced during previous cannulation procedures, as assessed by the Children's Fear Scale and WB-FACES. .

2.5.2. Wong-Baker FACES (WB-FACES) Pain Rating Scale

Using self-report, the Wong-Baker FACES scale (WB-FACES) was used to measure the intensity of children's pain levels. The scale ranged

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) [23]. This scale has sufficient psychometric properties, with a reliability of $\alpha = 0.90$, and has demonstrated validity, making it widely acceptable [24]. Additionally, in this study, the α was 0.75.

2.5.3. Children's Fear Scale (CSF)

During cannulation procedures, the 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 (4 points) denote a strong sense of fear in the child. This scale is a viable and reliable instrument for measuring procedural anxiety in school-aged children [25]. The Child Fear Scale has sufficient psychometric properties, with a reliability of $\alpha = 0.863$ [26]. Additionally, in this study, α was 0.85.

2.6. Intervention

This study implemented all distraction-based methods (musical, cartoon, and TICK-B) with no difficulties by the first author. Both the

children and the observing nurse were kept unaware of the primary study objective, and the parents were instructed not to disclose the main purpose to their children. The interventions were conducted on patients within 2–3 min preceding the start of the cannulation procedure. The SS was blinded to the study's measurement outcomes.

2.6.1. TICK-B

The coloring book for kids, known as the Trace Image and Coloring for Kids-Book (TICK-B), consists of illustrated pictures of color. Prior to cannulation, the participants were given TICK-C. While undergoing the procedure, they were directed to either draw or color an image, highlighting the image's use, and were asked to keep their nondominant hand steady continue the intervention until the procedure was completed (Fig. 2) (examples of TICK-B).

2.6.2. Music listening group

This particular group employed an iPad mini that incorporates an 8.3-inch diagonal LED-backlit multi-touch display, offering a resolution of 2266×1488 pixels and a pixel density of 326 pixels per inch. Additionally, it was equipped with an internet connection. The songs were chosen according to the children's wishes, and they were instructed that they would listen to music when the cannulation procedure started and continued until the procedure was completed.

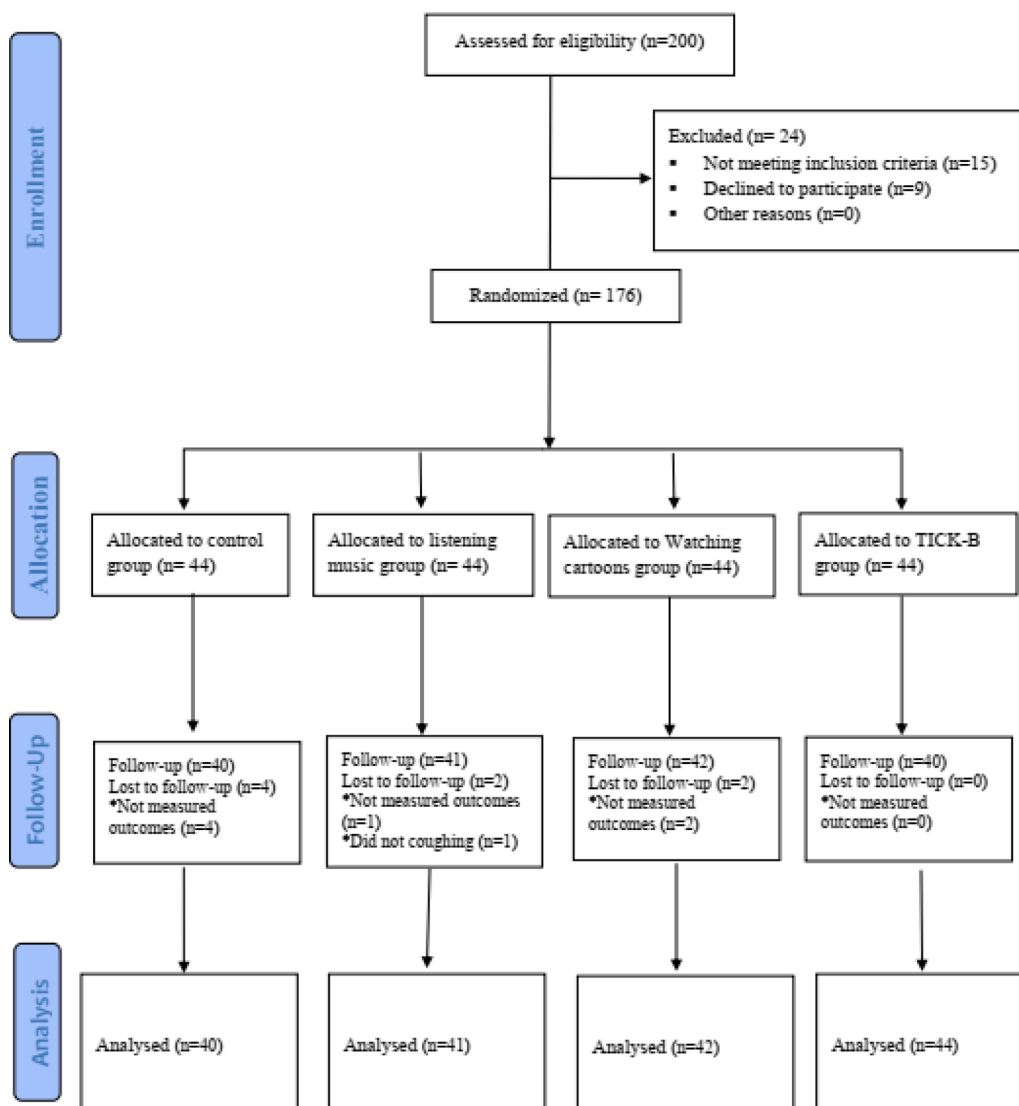


Fig. 1. Flow chart showing patient recruitment.

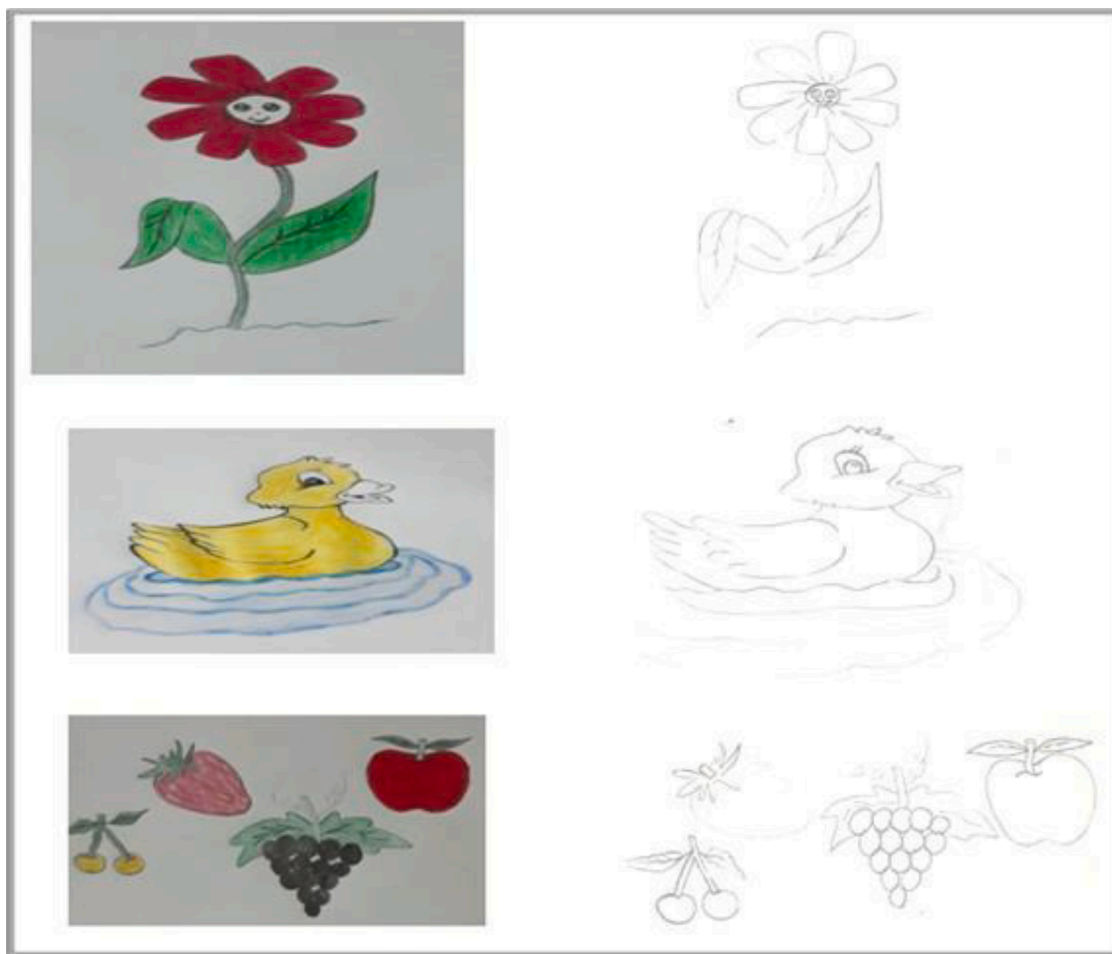


Fig. 2. Example of photos used for the intervention of "Tracking Images and Coloring Children's Books" (TICK-B).

2.6.3. Cartoon watching group

In this group, children watching cartoons used an iPad mini with an LED-backlit multi-touch display (8.3-inch diagonal), a resolution of 2266×1488 with a pixel intensity of 326 pixels per inch, and an internet connection. The cartoon was chosen according to the children's wishes, and the children were instructed that they would watch the cartoon when the cannulation procedure started until the procedure was completed.

2.6.4. Control group

The usual care at Heevi Pediatric Hospital does not involve use any distraction forms or pharmacological approaches. Children in this group were permitted to stay alongside their families. During this procedure, fluids and medications were administered.

2.7. Study procedure

To conduct the study, two nurses with more than 10 years of extensive experience in clinical pediatric settings, particularly in conducting painful medical procedures, were recruited. Nurses make clinical decisions regarding cannulation. Before randomization, the second author read a standardized description of tools to measure children's pain and fear to the parents and children, and both expressed satisfaction that they understood the instructions. Patient demographic information was collected using a self-report form. Self-reports were used to assess pain and fear during and after the procedure; the CFS 0–4 scale was used to measure fear, and the WB-FACES 0–10 scale was used to measure pain. In all children, the cannulation procedure was performed

by a second nurse using the nondominant hand of the child. A total of 176 children were randomly allocated into four groups of 44 children each and distributed in opaque sealed envelopes. Following the assignment of the children to their groups, the parents and children went to the cannulation unit. In all groups, the parents were allowed to remain with their children during the cannulation procedure.

Before cannulation, interventions were conducted for 2–3 min before and throughout the procedure. These interventions included coloring a picture book, watching cartoons, or listening to preferred music, and the participants were instructed to continue the intervention until the procedure was complete. The clinical nurse performed cannulation procedures for all children using the same needle size and in the nondominant hand. Children were requested to report their levels of pain and fear after 2–3 min of the following procedure.

The nurses involved were unaware of the study's primary goal, including all evaluations and comparisons of participant outcomes. The children were asked to report their pain and fear levels post-cannulation without knowledge of their group assignments. Instructions were given to parents and the clinical nurse to prevent them from discussing the intervention's purpose with the children. Consequently, the children remained uninformed about the intervention's objective (Fig. 1).

2.8. Considerations related to ethics

On June 1, 2021, this study was approved by the Scientific Research Department of the General Directorate of Health in Duhok (registered number 01062021-5-2) for granted publication rights to also receive administrative approval from Heevi Hospital. All patients' parents

provided written informed consent forms, as well as verbal consent from the children prior to the study, in accordance with the Declaration of Helsinki. This study did not include any harmful interventions.

2.9. Statistical analyses of the data

This study used the Statistical Package for the Social Sciences version 28.0 (SPSS Inc., Chicago, IL, USA) for all the statistical analyses. The descriptive data were evaluated using means, standard deviations, frequencies, and percentages. Data normality was assessed using a histogram, demonstrating a normal distribution of scores on the scale. The data are presented as the means, standard deviations, frequencies, and percentages. To examine similarities among groups concerning demographic and clinical characteristics, both the chi-square test and Levine's one-way ANOVA test for homogeneity were utilized. Statistical analysis of variance (ANOVA) was employed to compare parametric data, such as children's experienced pain levels and fear intensity. The significance level for this study was set at 0.05, and a post hoc Bonferroni correction was conducted.

3. Results

3.1. Baseline characteristics

The study sample comprised 167 participants [80 (51.00 %) females, 77 (49.00 %) males] aged 6 to 12 years (mean age 8.62 ± 1.61 years). Participants were randomly allocated to one of four intervention groups: control ($n = 40$), music-listening ($n = 41$), cartoon-watching ($n = 42$), and TICK-B ($n = 44$). As detailed in Table 1, the groups were well-balanced with respect to baseline characteristics, including number of prior procedure attempts, length of hospital stay, self-reported past pain experience, and procedural fear levels, with no statistically significant differences observed (all $p > 0.05$). However, sample attrition occurred in the control ($n = 4$) and music-listening ($n = 3$) groups due to

Table 1

A comparison of baseline characteristics and previous procedural fear and pain scores among the study groups.

Child's characteristics	Groups				P
	Control group (n = 40)	Music listening group (n = 41)	Cartoon-watching group (n = 42)	TICK-B group (n = 44)	
Gender					0.511 ^a
Male	19 (47.5)	19 (46.3)	25 (59.5)	19 (43.2)	
Female	21 (52.5)	22 (53.7)	17 (40.5)	25 (56.8)	
Age	8.45 (1.70)	8.17 (1.37)	9.05 (1.84)	8.80 (1.42)	0.131 ^b
Hospitalization days	3.53 (0.75)	3.66 (0.85)	3.38 (1.03)	3.86 (0.93)	0.151 ^b
Attempts	1.43 (0.50)	1.44 (0.50)	1.45 (0.50)	1.43 (0.50)	0.969 ^b
Previous pain	6.85 (1.68)	6.80 (1.40)	6.17 (1.86)	6.80 (1.69)	0.446 ^b
Previous cannulation fear	2.40 (0.81)	2.32 (0.91)	2.45 (0.89)	2.52 (0.88)	0.740 ^b

The data were presented as no (%) or as a mean (SD) as appropriate.

^a = Chi-square test ^b = One-way ANOVA.

Attempts refers to the numbers of cannulation procedure performed for the child.

Previous Pain refers to the severity of pain during cannulation procedure experienced in the past procedure.

Previous cannulation fear refers to the level of fear during cannulation procedure experienced in the past procedure.

participants' unwillingness or inability to provide data, while two participants in the cartoon-watching group refused to engage with the intervention. Conversely, the TICK-B group retained all 44 enrolled participants without any losses (Fig. 1). Similarities in these characteristics were observed across all groups. The self-reported levels of pain and fear were not significantly different among the groups ($P = 0.51$, $P = 0.13$, $P = 0.46$, $P = 0.96$, $P = 0.15$, $P = 0.44$, and $P = 0.98$, respectively) (Table 1).

3.2. Procedural pain scores

Compared to the control group, the TICK-B group demonstrated a significantly large reduction in pain during the procedure (mean difference = -4.65 , 95 % CI = -5.67 to -3.65) and after (mean difference = -4.10 , 95 % CI = -4.98 to -3.22). The CW group also showed large reductions versus the control group during (mean difference = -2.56 , 95 % CI = -3.58 to -1.53) and after the procedure (mean difference = -2.70 , 95 % CI = -3.59 to -1.82). The ML group had moderate-to-large pain reductions compared to the control group during the procedure (mean difference = -1.56 , 95 % CI = -2.60 to -0.54) and after (mean difference = -2.65 , 95 % CI = -3.55 to -1.76). The TICK-B intervention resulted in significantly larger reductions in procedural pain versus the ML group during the procedure (mean difference = -3.10 , 95 % CI = -4.10 to -2.08) and after (mean difference = -1.44 , 95 % CI = -2.31 to -0.58). Similarly, the TICK-B intervention resulted in significantly larger reductions in procedural pain versus the CW group during the procedure (mean difference = -2.10 , 95 % CI = -3.10 to -1.10) and after (mean difference = -1.39 , 95 % CI = -2.26 to -0.53), respectively (Table 2).

3.3. Procedural fear scores

For procedural fear, the TICK-B group again demonstrated significantly large reductions compared to the control group during the procedure (mean difference = -2.18 , 95 % CI = -2.67 to -1.69) and after (mean difference = -1.89 , 95 % CI = -2.39 to -1.39). Large reductions in

Table 2

Average scores on the Wong-Baker Faces (Wb-Faces) Pain Rating Scale across all the study groups.

Pain	Groups			
	Control group (n = 40)	ML group (n = 41)	CW group (n = 42)	TICK-B group (n = 44)
During procedure	7.25 (1.19)	5.68 (2.26)	4.69 (1.82)	2.59 (1.48)
Mean (SD)	6.87-7.63	4.97-6.40	4.12-5.26	2.14-3.04
95 % CI				
After procedure	6.85 (1.71)	4.20 (1.53)	4.14 (1.52)	2.75 (1.20)
Mean (SD)	6.30-7.40	3.71-4.68	3.67-4.62	2.38-3.12
95 % CI				
Pairwise comparisons	Pain during procedure		Pain after procedure	
	Mean diff (95 % CI)		Mean diff (95 % CI)	
ML vs. Control	-1.56 (-2.60 to -0.54)		-2.65 (-3.55 to -1.76)	
CW vs. Control	-2.56 (-3.58 to -1.53)		-2.70 (-3.59 to -1.82)	
TICK-B vs Control	-4.65 (-5.67 to -3.65)		-4.10 (-4.98 to -3.22)	
TICK-B vs. ML Group	-3.10 (-4.10 to -2.08)		-1.44 (-2.31 to -0.58)	
TICK-B vs. CW Group	-2.10 (-3.10 to -1.10)		-1.39 (-2.26 to -0.53)	
ML vs. CW Group	0.99 (-0.03 to 2.01)		0.05 (-0.83 to 0.93)	

ML: Music Listening, CW: Cartoon Watching, TICK-B: Trace Image and Coloring for Kids-Book.

Bonferroni correction test was performed for statistical analyses.

fear were also observed for the CW group compared to the control group during the procedure (mean difference = -1.41, 95 % CI = -1.91 to -0.92) and after (mean difference = -1.06, 95 % CI = -1.56 to -0.55). The ML group exhibited moderate-to-large fear reductions compared to the control group during the procedure (mean difference = -1.15, 95 % CI = -1.65 to -0.65) and after (mean difference = -1.06, 95 % CI = -1.57 to -0.56). Compared to the ML intervention, the TICK-B group had significantly larger reductions in procedural fear during the procedure (mean difference = -1.03, 95 % CI = -1.51 to -0.54) and after (mean difference = -0.82, 95 % CI = -1.32 to -0.33). Similarly, compared to the CW group, the TICK-B intervention resulted in greater fear reductions during the procedure (mean difference = -0.76, 95 % CI = -1.25 to -0.28) and after (mean difference = -0.83, 95 % CI = -1.32 to -0.33).

4. Discussion

The study showed that there is a significant difference between active and passive distractions because active distractions involve a child participating in the relevant technique interactively. Numerous studies have demonstrated that engaging in active distraction, in which the child actively interacts with the distracting stimulus, is more effective than engaging in passive distraction, in which the child passively observes the stimulus either visually or auditorily [27-29].

Psychological interventions with strong evidence for managing procedural pain include distraction. The proposed mechanism underlying distraction is neurocognitive pain modulation the top-down modulation of nociceptive processing through higher-order cognitive engagement. Distraction aims to engage attentional resources with an absorbing positive stimulus, thereby disrupting cognitive processing and subjective appraisal of nociceptive inputs [30]. This limits the attentional resources available for the capture of ascending pain signals, which underpins the analgesic effects of distraction [31]. Critically, for distraction to be effective, a positive experience must outcompete the salience of nociceptive stimuli.

Distraction as a pain management strategy involves engaging attentional resources with positive experiences to divert focus from nociceptive pain signals. Recent research highlights the efficacy of distraction, including in pediatric patients undergoing needle-related procedures, for alleviating pain and associated distress [32]. In conclusion, distraction interventions leverage neurocognitive pain modulation by engaging higher-order cognitive processes with positive stimuli to attenuate nociceptive transmission and reduce perceived pain intensity. These evidence-based non-pharmacological techniques show promise for procedural pain management, particularly among pediatric populations.

In the present study, all distraction techniques effectively reduced children's pain and fear during the cannulation procedure. Compared with all other techniques, the TICK-B technique was the most effective at reducing children's pain and fear levels compared to all other techniques during and after the procedure. This might be attributed to children's heightened motivation in crafting new shapes and basic forms [16]; in this way, their attention is directed towards a fun and exciting process rather than to factors that may be frightening [15,16]. Active distraction proved to be more efficacious than passive distraction. Several studies have evaluated the effectiveness of active versus passive distraction during painful medical procedures in emergency departments, as well as in other departments, with conflicting results. These studies indicate that active forms of distraction are more effective than passive methods in alleviating pain [33-35]. Others have found them to have similar effects [36,37]. In addition, some studies have examined only one of these approaches [38,39].

These findings suggest that TICK-B, an active distraction approach, was more effective than music-listening and cartoon-watching, two types of passive distraction approaches, in decreasing cannulation-induced pain in children aged between 6 and 12 years [15,16,39,40].

Although there has not been a direct study comparing TICK-B with music-listening or cartoon-watching, previous research has highlighted the effectiveness of TICK-B, music-listening, or cartoon-watching in reducing acute procedural pain in children [15,16,38,40]. For example, a music intervention reduced pain and anxiety in children who underwent lumbar punctures [41]. In another study, children distracted by cartoons exhibited significantly lower distress levels than those receiving conventional care during immunization [42]. Additionally, in a study conducted with children aged 7-14 years, listening to music was found to reduce postoperative pain and fear [43].

In the intervention and control groups, the children were similar in terms of age, gender, hospitalization period, trials, previous experience of pain, and fear of the cannulation procedure. These characteristics can influence children's pain and fears. This is why the similarity between these groups in terms of these variables (Table 1) played a significant role in determining the effectiveness of active and passive distractions during cannulation.

Painful procedures are usually used to manage or diagnose a variety of conditions [15,16]. However, if adequate pain control is not achieved, children may experience significant pain and fear, leading to psychological problems [44,45]. Therefore, pediatric nurses working in emergency units with children must know how to manage procedural pain to provide excellent care. In this study, all methods were found to decrease pain (Table 2), although active distraction was more effective than passive distraction. The children in active distraction will actively engage in an activity during cannulation, the purpose of which is to transition them from an unpleasant situation to a pleasant one. Moreover, multiple studies have demonstrated that engaging in active distractions is more effective than engaging in passive distractions in alleviating pain [33-35]. For instance, there have been published studies comparing various forms of virtual reality and video games with less interactive modes of distraction. These studies indicate that active distraction is likely to be more effective [8,46]. However, some studies have shown that passive distraction may be a more effective way to relieve pain [36,47]. These studies were not compared with appropriate active distraction interventions.

Two studies reported that active play with TICK-B reduces pain levels and distracts children during painful medical procedures by activating their attention with an engaging cognitive task [15,16]. Hence, the superior effectiveness of the TICK-B method in reducing cannulation pain might be ascribed to its engaging color-related activities and greater ease of application compared to other methods. The color tasks draw the attention of the children, who are required to actively concentrate on coloring throughout the process. It is an active distraction that stimulates the patient's cognitive and visual abilities and is beneficial for reducing the level of discomfort caused by the procedure.

The fear of medical procedures can increase if the patient is not provided adequate medical care during the procedure [44,45]. There may be a reduction in children's willingness to participate in healthcare procedures, a reduction in their ability to cover healthcare services in the event of illness, and a negative impact on the treatment process due to an increase in their fear behaviors [48,49]. Therefore, it is vital for pediatric patients to be free from fear during painful medical procedures. In this study, both methods were found to decrease the fear of children during cannulation (Table 3). Active distraction surpasses passive distraction in terms of effectiveness. In the literature, only a few studies have compared active and passive distractions in regard to decreasing fear during cannulation. It has been found that active distractions reduce pain better than passive distractions [36,47]. Others have found them to have similar effects [36,37]. In addition, some studies have examined only one of these approaches [38,39]. This study indicated that TICK-B reduces pain and fear during cannulation in children more effectively than usual care. The reason for this may be that children are more motivated to create new shapes and simple forms [16]; in this way, their attention is directed towards a fun and exciting process rather than to factors that may be frightening [15,16].

Table 3

Average scores on the Child Fear Scale (CFS) Pain Rating Scale across all the study groups.

Fear	Groups			
	Control group (n = 40)	ML group (n = 41)	CW group (n = 42)	TICK-B group (n = 44)
During procedure	3.27 (0.59)	2.12 (0.95)	1.85 (0.95)	1.09 (0.80)
Mean (SD)	3.08- 3.46	1.82- 2.42	1.56-2.15	0.84-1.33
95 % CI				
After procedure	2.85 (0.83)	1.78 (0.85)	1.74 (0.91)	0.93 (0.66)
Mean (SD)	2.58-3.11	1.51-2.046	1.47-2.091	0.73-1.17
95 % CI				
Pairwise comparisons	Fear during procedure		Fear after procedure	
	Mean diff (95 % CI)		Mean diff (95 % CI)	
ML vs. Control	-1.15 (-1.65 to -0.65)		-1.06 (-1.57 to -0.56)	
CW vs. Control	-1.41 (-1.91 to -0.92)		-1.06 (-1.56 to -0.55)	
TICK-B vs Control	-2.18 (-2.67 to -1.69)		-1.89 (-2.39 to -1.39)	
TICK-B vs. ML Group	-1.03 (-1.51 to -0.54)		-0.82 (-1.32 to -0.33)	
TICK-B vs. CW Group	-0.76 (-1.25 to -0.28)		-0.83 (-1.32 to -0.33)	
ML vs. CW Group	0.26 (-0.22 to 0.75)		-0.005 (-0.50 to 0.49)	

ML: Music Listening, CW: Cartoon Watching, TICK-B: Trace Image and Coloring for Kids-Book.

Bonferroni correction was performed for statistical analyses.

4.1. Study strengths and limitations

The present study was a randomized controlled trial and single-blinded, and the sample size was large, which enhanced the validity of the findings. The study involved 167 children, making it one of the most extensive studies ever conducted on distraction methods for reducing pain and fear during cannulation procedures. To ensure fairness in this study, children, nurses, and statisticians were blinded to the main objective of the study. No difficulties were encountered during the implementation of the experiments involving the children in this study. However, there are still some limitations to the generalization of our findings. First, all of the pediatric patients participating in this study were hospitalized at the same hospital. This study had a second limitation in that it was limited to schoolchildren between the ages of 6 and 12 years. In this regard, the results may not be representative of those in other hospitals. The use of passive distraction techniques in future studies is recommended for children who prefer passive distraction techniques, since drawing and coloring are pleasant, enjoyable, and simple activities for young children who enjoy them.

4.2. Implications for emergency nurses

Children's perceptions and responses to pain are influenced by various factors, including behavior, physiology, psychology, and development. Behavioral cues such as crying or immobility, physiological changes such as increased blood pressure or tears, and psychological manifestations such as fear and restlessness all contribute to this complex response. Additionally, environmental factors, individual pain perception, developmental stage, gender, and age further shape their experience of pain.

Healthcare professionals frequently have the chance to prepare hospitalized children for medical procedures. However, those who unexpectedly arrive in emergency departments do not possess this advantage [50]. The World Health Organization (WHO) and the International Association for the Study of Pain recommend

nonpharmacological methods, particularly distraction techniques, to help reduce pain and fear during these procedures. However, some techniques require extensive resources and training and may not be universally effective for engaging children.

To address these challenges, our study aimed to alleviate pain and fear among school-age children in the emergency department. We introduced a novel distraction technique called TICK-B, which was implemented by emergency nurses without the need for additional training. TICK-B is known for its ease of use, cost-effectiveness, and appeal to children, and it significantly reduces pain and fear during invasive procedures [15,16]. This intervention not only improved the comfort of children and their families in pediatric emergency units, but also enhanced the overall quality of nursing care.

Our study highlights the significant impact of fear and pain during IV insertions, emphasizing the importance of prioritizing pain reduction in pediatric emergency care. By using the TICK-B as a distraction technique during IV insertions, nurses can effectively alleviate pain and fear in children. Supported by strong evidence, TICK-B is a valuable strategy for reducing pain and fear in pediatric care units.

5. Conclusions

The use of distraction techniques during cannulation, such as the TICK-B method, music, and cartoons, can help reduce pain and fear in children. According to this study, TICK-B can reduce children's pain and fear during cannulation more effectively than can watching cartoons or listening to music. The contribution of this study to the literature on the use of nonpharmacological approaches to manage pain is noteworthy; however, it needs to be replicated in other settings. In nursing, it is essential to prevent patients from experiencing pain or fear during cannulation procedures and to handle them appropriately. We recommend conducting multiple studies in various settings with different age groups and diverse cultural backgrounds. Additionally, we recommend comparing the TICK-B as an effective tool with technologies used to reduce children's pain and fear during various painful procedures. In addition, we recommend that pediatric nurses utilize the TICK-B technique in standard care when managing painful procedures.

Financial support

The study did not receive financial support from external sources.

Data availability

Data are available on the Mendeley Data, DOI: 10.17632/d3c3d5nmm8.1.

On reasonable request, the corresponding author will be provided with the data supporting the conclusions of this article.

CRedit authorship contribution statement

Sherzad Khudeida Suleman: Writing – review & editing, Writing – original draft, Visualization, Validation, Methodology, Investigation, Formal analysis, Conceptualization. **Nizar BakirYahya:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Methodology, Investigation, Formal analysis, Conceptualization. **Stefan Nilsson:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Methodology, Formal analysis, Conceptualization. **Karin Enskär:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Software, Resources, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial

interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

The authors wish to express their gratitude to the staff of the Heevi Pediatric Teaching Hospital for their invaluable support. Special acknowledgment is extended to the clinical performance nurse and observing nurse for her kind cooperation, emphasizing that no financial associations were involved. Sincere thanks are also conveyed to the participating families and children for their crucial role in this research. Additionally, we would like to thank Mr. Deldar Morad, Assistant Professor at Duhok University, for reviewing our manuscript. The paper was part of a PhD project, each of which was independently collected according to the objectives of the project. This paper presents data that have not been published and that have been collected and analyzed independently.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at [doi:10.1016/j.eujim.2024.102379](https://doi.org/10.1016/j.eujim.2024.102379).

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