

# Effectiveness of the Buzzy Device in Managing Needle Pain in Children: A Systematic Review

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## Keywords

Procedural analgesia ; pain relief ; paediatric.

## Abstract

### Background:

Needle procedures often cause pain and anxiety in children, highlighting the necessity for effective pain management strategies. This systematic review aimed to evaluate the effectiveness of the Buzzy<sup>®</sup> device, a non-pharmacological intervention combining cold and vibration, in managing paediatric needle pain using a standardized pain assessment tool.

### Methods:

A systematic search was conducted in December 2024 using PubMed, CINAHL, Embase, and Google Scholar databases to identify randomized controlled trials. Inclusion criteria were studies involving children aged 2–18 years undergoing needle-related procedures, employing the Faces Pain Scale-Revised (FPS-R), and comparing the Buzzy<sup>®</sup> device against control groups or alternative interventions like topical anaesthetics, distraction techniques, or other non-pharmacological methods. Study quality was assessed using the Risk of Bias 2 (RoB 2) tool.

### Results:

8 RCTs comprising 1.569 paediatric participants were included. Studies consistently demonstrated significant pain reduction with Buzzy<sup>®</sup> compared to no intervention. Comparisons with topical anaesthetics showed mixed results: Buzzy<sup>®</sup> provided rapid analgesia advantageous in emergency settings but was commonly less effective in pain reduction than topical anaesthetics like EMLA cream. Buzzy<sup>®</sup> persistently outperformed other non-pharmacological methods, such as ShotBlocker<sup>®</sup> and DistrACTION<sup>®</sup> Cards, and was most effective when combined with distraction techniques. Risk of bias was moderate across studies, primarily due to the inability to blind participants and practitioners.

### Conclusion:

Our work provides nuanced support for the claim that the Buzzy<sup>®</sup> effectively reduces needle-related procedural pain in children, particularly in acute clinical settings where a rapid onset of analgesia is required. Further research employing standardised methodologies is recommended to strengthen the evidence base for multimodal paediatric pain management strategies.

## What is already known on this topic

Children often undergo painful procedures when they visit or stay in a paediatric hospital.

## What this study adds

Procedural analgesia using a Buzzy device significantly relieves pain sensation in children who undergo a needle procedure.

## Introduction

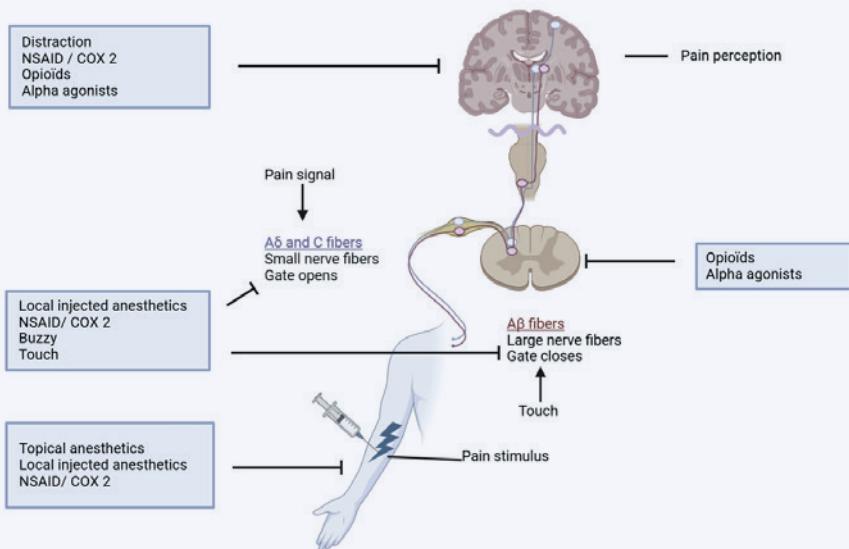
Children are frequently exposed to various needle-related procedures, including routine vaccinations, peripheral catheterisation and venipunctures. These procedures, commonly performed during emergency department visits, outpatient clinics or hospital admissions, can induce considerable distress in paediatric patients (1–3). Despite the existence of evidence-based pain management strategies, their implementation in clinical practice remains insuffi-

cient (4). Needle pain and injection fear are highly prevalent among children. Effective pain management techniques can improve procedure outcomes and reduce the need for repeated attempts (5,6).

Pain modulation in the spinal cord occurs through interactions between C-, A $\delta$ -, and A $\beta$ -fibres, as described by the Gate Control Theory (7). When a painful stimulus occurs, the signal travels through C- and A $\delta$ -fibres (small fibres), which open the pain gate by transmitting nociceptive input to second-order neurons in the dorsal horn. In contrast, A $\beta$ -fibres (large fibres), responsible

**FIGURE 1:** Pain mechanism.

Overview of pharmacological and non-pharmacological strategies targeting pain perception in paediatric patients. Various interventions—ranging from topical and locally injected anesthetics, NSAIDs/COX-2 inhibitors, opioids, and alpha agonists to non-pharmacological techniques such as distraction, tactile stimulation, and the use of devices like Buzzy®—act at different levels to modulate the child’s pain experience. Several of these strategies influence the transmission of nociceptive signals via A-delta and C fibers, either by inhibiting signal conduction or by modulating central pain processing



for touch and vibration, help close the gate and reduce pain perception. This explains why non-pharmacological interventions, such as vibration and cold therapy, can effectively relieve pain by stimulating Aβ-fibers. Additionally, topical anaesthetics reduce pain signals transmitted by (Aδ and C-fibers and simultaneously stimulate Aβ-fibers through touch or massage, enhancing pain relief (8,9).

Evidence-based multimodal strategies, including pharmacological and non-pharmacological approaches, are essential for effective paediatric pain management, particularly during needle-related procedures (10). Currently, various pain management strategies are employed in paediatric care to minimize discomfort and distress during medical procedures. These methods include non-pharmacological techniques like distraction cards and virtual reality, which divert attention from pain, and pharmacological options both local and systemic (e.g. vapo-coolant sprays, topical anaesthetics, sucrose solutions and analgetic drugs). Their effectiveness and tolerability in children make them valuable tools, with selection based on the procedure, age, and clinical context (11–13). An overview of the pain pathways and the possible pain relief approaches are given in Figure 1.

Non-pharmacological interventions can be categorized into three main groups: behavioural methods, supportive methods, and physical methods. Behavioural methods include techniques such as relaxation and distraction, which focus on modifying the patient’s pain perception and response. Supportive methods encompass interventions like the presence of a family member, watching videos, or listening to music, providing emotional comfort and reassurance to the patient. Lastly, physical methods involve sensory-based approaches such as deep touch, vibration, and thermal stimulation through the application of cold or heat, all of which act by altering pain perception through the gate control principle (14,15).

Among the pharmacological options available for pain reduction during needle-related procedures, Eutectic Mixture of Local

Anaesthetics (EMLA) composed of 2.5% lidocaine and 2.5% prilocaine, is considered the gold standard (16,17). Topical aesthetic creams, such as EMLA, are commonly used to reduce pain during needle procedures but require 30 to 60 minutes to achieve analgesic effect (18,19). This delayed onset makes them impractical for use in acute settings, such as the emergency department, where rapid pain management is often required.

The Buzzy® device (MMJ Labs, Atlanta, Ga) is a compact medical device consisting of a cold pack designed as wings and a central component that produces vibration. Developed by paediatrician Amy Baxter, it uniquely combines cold application with tactile vibration, effectively reducing procedural pain through dual sensory stimulation. It represents one of the more recent developments in non-pharmacological pain management techniques (20,21). The proposed mechanism behind its analgesic effect is based on the Gate Control Theory of pain, which describes how simultaneous stimulation of sensory nerves (e.g., through vibration and cold) will reduce pain perception as mentioned above (21).

Compared to traditional methods (topical anaesthetics), vibration and cold therapy may provide faster analgesic effects and is

associated with fewer side effects, making it particularly suitable for use in acute clinical settings, such as emergency departments, where rapid pain relief is essential (19).

There is a need for a new systematic review on the effectiveness of the vibration and cold therapy, as a substantial amount of new literature has emerged in recent years. While several recent systematic reviews have been published (20,22,23), they often compare studies that use different pain measurement tools or lack a non-active control group, limiting the comparability and overall conclusions.

Our systematic review provides a meaningful contribution to the current literature as it exclusively includes randomized controlled trials (RCTs) that use a consistent pain assessment tool across all studies. Furthermore, each included RCT compares the Buzzy® device to either a non-active comparator or a control group receiving the standard of care, ensuring a more robust and clinically relevant evaluation of its effectiveness.

The aim of the study is to evaluate the evidence on the efficacy of the Buzzy® device, which combines cold and vibration, in managing needle-related procedural pain and associated outcomes in the paediatric population up to 18 years old, using a well-validated and standardized assessment tool.

## Materials and methods

### Protocol

This systematic review was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (24). To clearly define the research question, the PICO (Population, Intervention, Comparison, Outcome) framework was utilized. Specifically, the review focused on evaluating the effectiveness of the Buzzy® device among children undergoing needle-related procedures. The effectiveness was assessed by comparing observed pain levels, measured with

the Faces Pain Scale-Revised (FPS-R), between the intervention group and a control group receiving either standard care or no intervention.

### Faces pain scale-revised

The Faces Pain Scale – Revised (FPS-R) is a self-report instrument designed to assess pain intensity in children. It consists of six facial expressions ranging from no pain (score 0) to severe pain (score 10). The FPS-R is a validated and widely used pain assessment tool, demonstrating strong reliability and validity across paediatric populations. Research suggests that it is most effective for children aged 4 to 12 years, as it aligns well with their cognitive and emotional development, allowing for an accurate representation of their pain experience (24,25). We chose the use of FPS-R over the Wong-Baker Faces Pain Scale because the latter may confound pain with emotions, as it features a smiling face for no pain and a crying face for severe pain. In contrast, the FPS-R uses neutral expressions, making it a more objective and reliable tool for paediatric pain assessment (24).

### Eligibility criteria

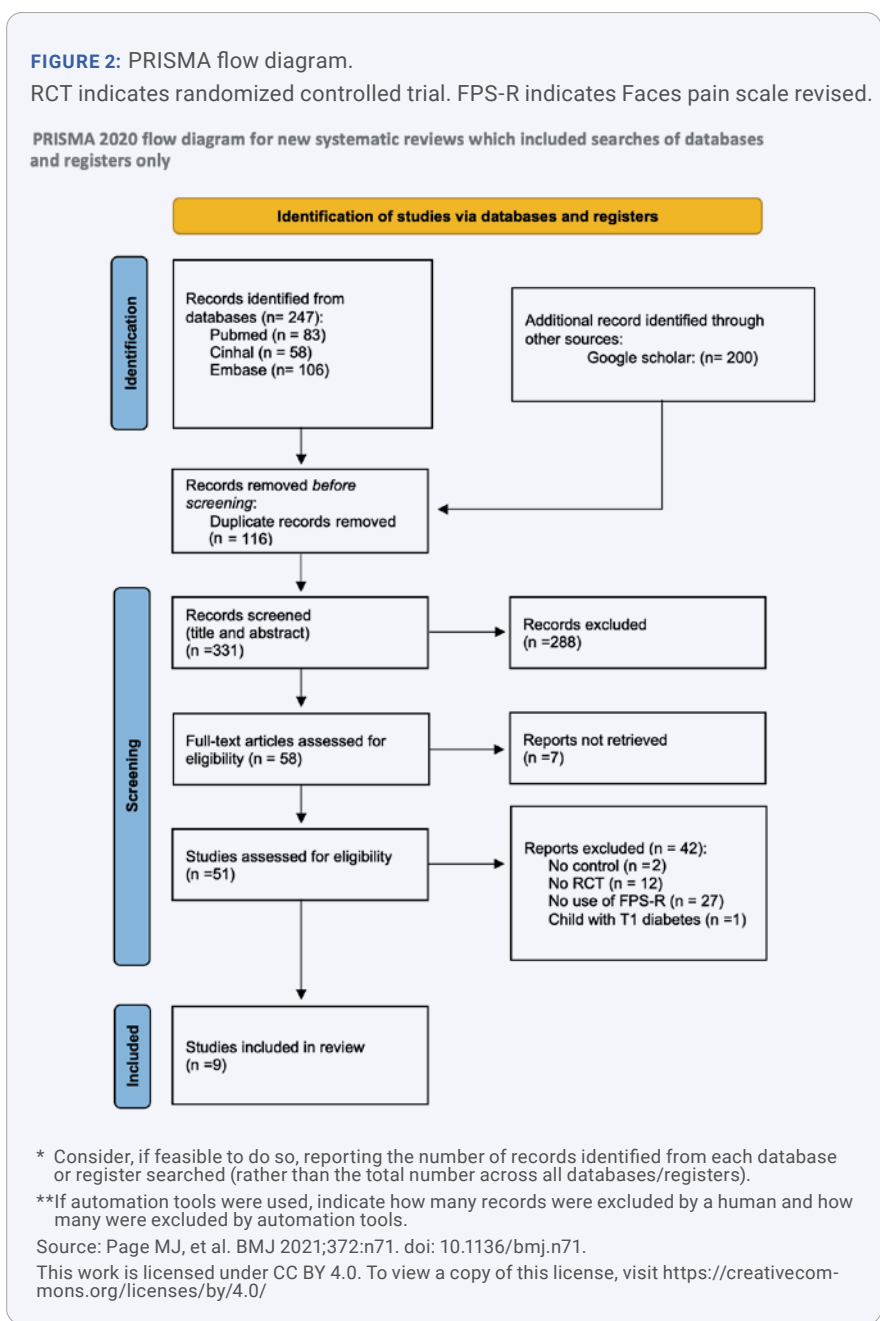
This systematic review included only randomized controlled trials (RCTs). Articles were deemed eligible for inclusion if they met the following criteria: participants aged 2–18 years, study design classified as an RCT, use of the Faces Pain Scale – Revised (FPS-R), involvement of needle-related procedures (e.g., single injections, intravenous therapy, vaccinations, or blood sampling), compared the experimental group to control subjects receiving either no intervention or standard of care, and publication in English or Dutch. Studies were excluded if they focused on dental procedures, involved children with cognitive impairments, or included participants with conditions that could affect sensitivity to cold.

### Search strategy and study selection

Searches were conducted between December 14 and December 18, 2024 using several databases, including PubMed, CINAHL, and Embase. Search terms consisted of a combination of relevant keywords and search terms. The search strategy was customized for each database. The complete study selection is detailed in figure 2. The initial screening was based on titles and abstracts. Each study was assessed for its eligibility based on the inclusion criteria. If studies appeared to meet the eligibility criteria, their full texts were analysed.

### Data extraction

Data extraction was performed manually by the researchers. The following information was collected from the included studies: pop-



**TABLE 1:** Risk of bias assessment of the included studies.

Study	Risk of bias domains					Overall
	D1	D2	D3	D4	D5	
Nasser A. Haidar et al. (2024)	+	-	+	-	+	-
Sivri B. B., Feng. Y. S. et al. (2023)	+	-	+	-	+	-
Sivri B. B., Balci S. et al. (2023)	+	-	+	-	-	-
Lescop, K et al. (2021)	+	X	+	-	+	-
Inal, S. et al. (2020)	+	-	+	-	+	-
Sivri B. B., Balci S. et al. (2019)	+	-	+	-	-	-
Potts, D et al. (2019)	-	-	+	-	-	X
Inal, S et al. (2012)	+	-	+	-	+	-

Domains:  
D1: Bias arising from the randomization process.  
D2: Bias due to deviations from intended intervention.  
D3: Bias due to missing outcome data.  
D4: Bias in measurement of the outcome.  
D5: Bias in selection of the reported result.

Judgement  
X High  
- Some concerns  
+ Low

**TABLE 2:** Studies that compare Buzzy® versus topical anaesthetics.

Title	Author(s)	Year	Journal	Mean age/ Sex	Number of participants	Comparison/ Control
<i>Efficacy of Buzzy Device Versus EMLA Cream for Reducing Pain During Needle-Related Procedures in Children: A Randomized Controlled Trial(21)</i>	Nasser A. Haidar et al.	2024	Pediatric Emergency Care	<p><u>Mean age:</u> 6.5 ± 3.1 years</p> <p><u>Sex distribution:</u> 49% male: -EMLA: 49.4 % -BUZZY®: 48.6 %</p>	N= 300 154: Buzzy® group 146: EMLA group	Buzzy® device vs EMLA cream (control)
<i>A Vibrating Cold Device to Reduce Pain in the Pediatric Emergency Department: A Randomized Clinical Trial(29)</i>	Potts, D et al.	2019	Pediatric Emergency Care	<p><u>Mean age:</u> 8.17 years (IQR: 6.2–11.9)</p> <p><u>Sex distribution:</u> -119 males (53.1%) - 105 females (46.9%)</p>	N= 224 114: Buzzy® (VCD) group 110: Topical Lidocaine (TL) group	VCD group (Buzzy® device) vs TL group (4% topical lidocaine cream = standard of care)
<i>The effectiveness of the Buzzy® device to reduce or prevent pain in children undergoing needle-related procedures: The results from a prospective, open-label, randomized, non-inferiority study(28)</i>	Lescop, K et al.	2021	International Journal of Nursing Studies	<p><u>Mean age:</u> 9 + 3.15 years</p> <p><u>Sex distribution:</u> -113 (52.6%) female -106 male (47.4%)</p>	N= 219 randomized 215 included 108: Buzzy® 107: Lidocaine patch)	Buzzy® vs Control group: Lidocaine patch applied 1 hour before procedure

**TABLE 3:** Studies that compare Buzzy® versus DistrACTION® cards (DC).

Title	Author(s)	Year	Journal	Mean age/ Sex	Number of participants	Comparison/ Control
<i>The Effect of External Thermomechanical Stimulation and Distraction on Reducing Pain Experienced by Children during Blood Drawing(31)</i>	Inal, S. et al.	2020	Pediatric Emergency Care	<p><u>Mean age:</u> Control: 9.3 ± 2.1 years -Buzzy®: 9.1 ± 2.0 years Distraction Cards: 9.5 ± 1.8 years Combi: 9.2 ± 1.7 years</p> <p><u>Sex distribution:</u> -108 female (49.5%) -110 male (50.5%)</p>	N= 218: 56: control, no intervention 55: Buzzy® 55:distraction Cards 52: Buzzy® + DistrACTION Cards	Group 1 (control): No intervention vs Group 2: Buzzy® vs Group 3: DistrACTION Cards vs Group 4: Combination of both methods
<i>The effect of Buzzy® and DistrACTION® cards on reducing pediatric pain and fear during blood collection in the rheumatology polyclinic: A randomized controlled trial(30)</i>	B. B. Sivri et al.	2023	Journal of Pediatric Nursing	<p><u>Mean age:</u> 9.21 ± 2.15 years</p> <p><u>Sex distribution:</u> - 45 male (46.9%): - Buzzy®: 53.1% - DC: 59.4% - Control: 53.1%</p>	N= 224 114: Buzzy® (VCD) group 110: Topical Lidocaine (TL) group	Buzzy® device vs DistrACTION® Cards vs Control: no intervention

ulation characteristics (e.g., mean age, gender distribution, and sample size), details of the intervention, reported outcomes, and key findings. The extracted data were summarized and structured according to the intervention used for comparison with the Buzzy® Device.

**Risk of Bias assessment**

All included studies were systematically assessed for their risk of bias. To evaluate the methodological quality of the randomized controlled trials (RCTs), the Risk of Bias 2 (ROB-2) tool was used (26). This tool allows for a structured assessment of potential biases that could influence study outcomes. The risk of bias assessment for all included articles can be found in Table 1. For each included study, the risk of bias was assessed for deviations

from intended interventions (performance bias), missing outcome data (attrition bias), the measurement of the outcome (detection bias), the selection of the reported result (reporting bias), and the randomization process (allocation bias), after which an overall risk of bias was calculated for each study.

**Primary outcome**

The primary outcome of this systematic review was to evaluate the efficacy of the Buzzy® device in reducing pain during needle-related procedures in the paediatric population compared to a control group receiving either no intervention or standard of care. The outcome parameter specifically assessed was the pain experienced by the child during or immediately after the

	Outcome	Key findings
	Pain, anxiety	EMLA cream = more effective in reducing pain and anxiety for needle procedures with observer assessment (not with self-assessment) Buzzy® device offers rapid action (valuable in emergency departments) <i>Needle Procedure:</i> Venipuncture and intravenous (IV) cannulation
	Pain, anxiety	Pain scores = similar between Buzzy® and TL. IV procedure time = significantly shorter with VCD (3.0 min vs. 40.5 min, p < 0.0001) <i>Intervention:</i> Intravenous (IV) catheter insertion
	Pain	Buzzy® did not meet non-inferiority criteria for pain relief. 43% of children removed the cold wings due to discomfort. Buzzy® is a cheaper but less effective alternative. <i>Interventions:</i> Vaccinations (93.5%) and venipuncture (6.5%)

	Outcome	Key findings
	Pain, anxiety	All intervention groups = significantly lower pain than control (p < 0.001). The Buzzy® + DistrACTION combination = most effective Buzzy® outperformed distraction alone. <i>Intervention:</i> Venipuncture
	Pain, anxiety	Buzzy® = most effective for reducing pain and fear during venipuncture DistrACTION® Cards : less effective than Buzzy®. <i>Intervention :</i> Venipuncture

intervention. This outcome was assessed through a descriptive comparative analysis. The efficacy of the device was determined by measuring pain using the Faces Pain Scale-Revised (FPS-R), a validated assessment tool.

## Results

### Study selection

The initial search across the three databases ( including PubMed, CINAHL, and Embase) yielded a total of 247 articles. In addition to the primary search strategy, Google Scholar provided an additional source to identify relevant articles. A total of 560 results were

retrieved using general search terms. Due to feasibility constraints, only the first 200 articles were screened for potential inclusion. The procedures for article selection within these databases are outlined in the PRISMA flowchart (Figure 2) (27). After applying the inclusion criteria and assessing the quality of the studies, a total of 8 articles met the eligibility requirements and were included in this systematic review. These studies collectively involved 1569 participants. The selection process ensured that only studies of the desired methodological quality were incorporated.

### Characteristics of the studies

A total of eight studies were included in this review, comprising a total of 1569 children. All studies were conducted between 2010 and 2022. Each study utilized the Faces Pain Scale - Revised to assess pain outcomes. All included studies incorporated a control group for comparison. The control condition consisted of either no intervention or the application of topical anaesthesia, using lidocaine or EMLA cream. The mean age of participants across studies ranged from 6.5 to 10.45 years, with relatively balanced sex distributions. The studies investigated the effectiveness of the Buzzy® device in various needle-related procedures, including venipuncture, intravenous (IV) cannulation, blood specimen collection, and intramuscular injections. Comparators included topical anaesthetics (e.g., EMLA cream, lidocaine patch, see Table 2), distraction techniques (e.g., DistrACTION® Cards, see Table 3), other non-pharmacologic pain mitigation strategies (e.g., ShotBlocker®, see Table 4), and negative controls (see Table 5). Of the 8 included studies, three focused on comparing Buzzy® with topical anaesthetics, two evaluated Buzzy® against distraction-based methods, two examined its efficacy relative to other non-pharmacologic pain relief techniques and one compared the Buzzy® device with no intervention. These studies collectively provide insights into the effectiveness and limitations of Buzzy® across different procedural contexts.

### Risk of Bias assessment

The risk of bias in the included RCTs was assessed using the Cochrane Risk of Bias 2.0 (RoB 2) tool. As shown in Table 1, most studies presented “some concerns” in several domains, particularly in deviations from intended interventions (D2) and measurement of the outcome (D4). The concerns in D2 were mainly due to the lack of blinding across all studies, which could have influenced participants’ or personnel’s behaviour and, consequently, the study outcomes. One study was rated as having a high risk of bias in the domain D2 (deviations from intended interventions) as participants could remove refrigerated wings, potentially affecting the efficacy of the intervention (28). Additionally, the study by Potts et al. was judged to have a high overall risk of bias due to concerns across multiple domains (29). These findings reflect moderate methodological quality across studies and should be considered when interpreting the overall results.

### Buzzy® vs. Topical Anaesthetics

Three studies evaluated the comparative effectiveness of the Buzzy® device against topical anaesthetics such as EMLA cream and lidocaine patches. Haidar et al assessed 300 paediatric patients undergoing venipuncture or IV cannulation (19). Observer-assessed pain and anxiety scores indicated superior efficacy of EMLA cream compared to Buzzy®, although self-reported pain scores showed no statistically significant differences. The rapid onset of Buzzy® was highlighted as a clinically relevant advantage in high-acuity settings. Similarly, Potts et al found that while pain scores between Buzzy® and 4% topical lidocaine cream were comparable, the procedural duration was significantly shorter with Buzzy® (3.0 min vs. 40.5 min, p < 0.0001), underscoring its practicality in time-sensitive environments (28). However, Lescop et al reported that Buzzy® failed to meet non-inferiority criteria relative to lidocaine patches for pain relief, with 43% of children requesting removal of the cold wings due to discomfort, indicating potential limitations in tolerability (29) .

**TABLE 4:** Studies that compare Buzzy® versus Shotblocker®.

Title	Author(s)	Year	Journal	Mean age/ Sex	Number of participants	Comparison/ Control
<i>The Effect of 3 Methods (Buzzy, ShotBlocker, and DistrACTION Cards) Used While Taking Blood Samples From Children with Pain and Anxiety: A Randomized Controlled Trial(32)</i>	B. B. Sivri et al.	2023	Pediatric Emergency Care	<p><u>Mean age:</u> 9 –12 years</p> <p>-ShotBlock: 10.34 ± 1.45 years</p> <p>-Buzzy®: 10.45 ± 1.55 years</p> <p>-Distraction Cards: 10.45 ± 1.32 years</p> <p>-Control: 10.38 ± 1.28 years</p> <p><u>Sex distribution:</u> -131 female (54.1%) - 111 male (45.9%)</p>	<p>N=242</p> <p>60: Buzzy®</p> <p>61: ShotBlocker</p> <p>60: Distraction Cards</p> <p>61: No intervention</p>	<p>Buzzy® vs ShotBlocker vs DistrACTION Cards vs Control group: No intervention</p>
<i>The Effect on Pain of Buzzy® and ShotBlocker® during the Administration of Intramuscular Injections to Children: A Randomized Controlled Trial(33)</i>	B.B. Sivri et al.	2019	Journal of Korean Academy of Nursing	<p>Mean age: 8.92 ± 1.87 years</p> <p>Sex distribution: -69 female (46%) -81 male (54%)</p>	<p>N= 150</p> <p>50: Control group</p> <p>50: Buzzy® group</p> <p>50: ShotBlocker</p>	<p>Control: no intervention vs ShotBlocker® vs Buzzy®</p>

**TABLE 5:** Studies that compare Buzzy® versus control (no intervention).

Title	Author(s)	Year	Journal	Mean age/ Sex	Number of participants	Comparison/ Control
<i>Relief of pain during blood specimen collection in pediatric patients(34)</i>	Inal, S et al.	2012	MCN (Maternal Child Nursing)	<p>Mean age: 9.3 +- 2.02 years</p> <p>Sex distribution: -56.7% male -43.3% female</p>	<p>N= 120</p> <p>60: Buzzy®</p> <p>60: Control no intervention</p>	<p>Buzzy® vs Control group: no intervention</p>

### Buzzy® vs. Distraction Methods

Two studies compared the Buzzy® device with distraction techniques such as DistrACTION® Cards. Inal et al and Sivri et al both examined the impact of Buzzy® and DistrACTION® Cards on procedural pain and anxiety (30) (31). Inal et al. found that all intervention groups had significantly lower pain levels than controls ( $p < 0.001$ ), with the combination of Buzzy® and DistrACTION® Cards being the most effective. Similarly, Sivri et al. demonstrated that Buzzy® alone resulted in the lowest procedural pain and fear scores across all evaluative measures, including self-report, parental assessment, and researcher evaluation. Both studies conclude that while Buzzy® is effective as a standalone intervention, its pain and anxiety-reducing effects are enhanced when combined with distraction techniques.

### Buzzy® vs. Other Pain-Relief Devices

Two studies compared the Buzzy® device with alternative non-pharmacologic pain relief methods. Sivri et al and Sivri and Balci both found that Buzzy® was more effective than ShotBlocker® in reducing procedural pain during venous blood collection and intramuscular injections, respectively (32) (31). Additionally, Sivri et al. showed that Buzzy® and DistrACTION® Cards provided comparable pain relief, both outperforming ShotBlocker®. These findings indicate that Buzzy® is a superior non-pharmacological intervention for pain management in paediatric needle-related procedures, particularly when compared to ShotBlocker®.

### Buzzy® vs. Control (no intervention)

Inal and Kelleci investigated the effect of Buzzy® on blood specimen collection in 120 children, finding significantly lower pain and anxiety levels in the Buzzy® group compared to controls ( $p < 0.001$ ) (33).

### Anxiety Outcomes

Several studies also examined the impact of Buzzy® on procedural anxiety. While pain relief was the primary focus, anxiety reduction was frequently assessed as a secondary outcome. Studies comparing Buzzy® with topical anaesthetics found that EMLA cream generally led to greater anxiety reduction, particularly in observer-assessed measures. However, Buzzy® demonstrated significant advantages in settings requiring rapid intervention, where prolonged preparation time for topical anaesthetics was not feasible. In comparisons with distraction techniques, Buzzy® was often found to be more effective at reducing both pain and anxiety, with the combination of Buzzy® and DistrACTION® Cards yielding the lowest anxiety scores.

### Discussion

Poorly managed pain in children can result in significant psychological effects, including increased anxiety and, in some cases, the development of needle phobia (34). Pain experienced by children during medical procedures can significantly influence their subsequent healthcare behaviours, potentially leading to avoidance of medical care or decreased compliance with future treatments (35) (36). Consequently, effective pain management in paediatric care is crucial not only to address immediate physical comfort but also to mitigate long-term psychological effects and reduce the risk of developing procedure-specific anxieties.

The aim of this study was to evaluate the evidence regarding the effectiveness of the cold and vibrations device in managing needle-related procedural pain in children utilizing a well-validated and standardized assessment instrument. This review synthesizes

	Outcome	Key findings
	Pain, anxiety	<p>Buzzy, ShotBlocker, and DistrACTION Cards significantly reduced pain and anxiety.</p> <p>Buzzy and DistrACTION Cards were the most effective.</p> <p>ShotBlocker was less effective but better than no intervention.</p> <p>The control group experienced the most pain and anxiety.</p> <p><i>Intervention:</i> Venipuncture</p>
	Pain	<p>Control group = significantly higher pain than the ShotBlocker® and Buzzy® groups.</p> <p>Buzzy® group = significantly less pain than the both the ShotBlocker® and control groups (p&lt;.001)</p> <p><i>Intervention:</i> IM injections with procaine penicillin</p>

	Outcome	Key findings
	Pain, anxiety	<p>Buzzy® = significantly lower pain and anxiety levels (p&lt;0.001)</p> <p>No significant effect on venipuncture success</p> <p><i>Intervention:</i> Venipuncture</p>

findings from 8 RCTs assessing the efficacy of the Buzzy® device in reducing pain in children undergoing needle-related procedures compared to alternative methods, such as topical anaesthetics and distraction techniques, as well as to no intervention. The primary findings from the reviewed RCTs indicated variable efficacy of the Buzzy® device. While some studies demonstrated equivalence or superiority of Buzzy® in comparison to distraction techniques alone or no intervention, other studies concluded inferior or equivalent efficacy compared to topical anaesthetics. Specifically, EMLA cream consistently outperformed Buzzy® in observer-rated pain scores, though self-reported scores were sometimes comparable between groups. Notably, Buzzy® provided faster analgesic action, an important advantage in settings such as emergency departments where waiting times are critical. Buzzy® outperformed distraction techniques and other non-pharmacologic devices (e.g., ShotBlocker®) in reducing procedural pain. Its effectiveness in anxiety reduction was notably enhanced when combined with distraction methods.

### Effectiveness of Buzzy® Versus Alternative Interventions

The findings of this review largely confirm previous literature which highlighted mixed results regarding Buzzy®'s effectiveness. Similar to prior studies the current systematic review found that topical anaesthetics generally offer superior pain reduction compared to cold and vibration therapy in paediatric needle-related procedures (37,38). However, topical anaesthetics have a slower onset of action and additional practical barriers, such as longer application time, whereas cold and vibration therapy provides benefits like rapid application and ease of use. The present systematic review demonstrates that combined cold and vibration therapy

significantly reduces pain during needle-related procedures compared to no intervention. Multiple RCTs -using other pain scales such as the Wong-Baker Face Pain Scale- consistently support this finding. For example, Redfern et al. showed reduced pain scores with cold and vibration during paediatric vaccinations (mean pain score 3.56 vs. 5.92, p=0.015) (39). Similarly, Canbulat et al. found significant pain and anxiety reduction during paediatric immunizations and intravenous cannulation (14). Additionally, Simoncini et al confirmed these results in venipuncture procedures (mean pain scores 2.5 vs. 4.7, p<0.001) (40). The consistency of these results highlights cold and vibration therapy as an effective and practical non-pharmacological approach for managing procedural pain in clinical settings.

However, it should be noted that not all studies confirm these findings. A recent RCT by Yilmaz et al. reported no significant difference in pain and anxiety levels with the use of cold and vibration therapy (Buzzy® device) compared to no intervention during peripheral intravenous cannulation in children (mean pain score 1.36 vs. 1.33, p>0.05) (41). The lack of a significant effect of the Buzzy® device in this study may be partially explained by the relatively higher mean age of the participants (12.8 ± 3.0 years). Previous studies that reported a significant reduction in pain and anxiety often included younger children, who may be more receptive to the Buzzy® due to its visual appeal and distracting features. In older children and adolescents, these sensory stimuli may be less engaging, thereby reducing the device's effectiveness. Furthermore, the sample size in this study (n = 60) was relatively small compared to other trials, which may have limited the statistical power to detect subtle differences in pain and anxiety levels between groups. Together, these factors could explain the discrepancy between the findings of the Yilmaz study and the previous ones. This discrepancy indicates that, while generally effective, the benefits of cold and vibration therapy may vary depending on the clinical context or specific patient characteristics. Further research is needed to assess these variations in more detail.

Additionally, a recent RCT by Erdogan and Ozdemir compared the Buzzy® device with distraction cards and virtual reality in children undergoing venipuncture (42). The Buzzy® device showed a higher effectiveness, achieving the lowest mean pain and anxiety scores compared to the other methods. These findings further support the efficacy of combined cold and vibration therapy, highlighting its advantage over alternative distraction methods in paediatric clinical practice. On top of that, in our systematic review, the ShotBlocker device appeared to be less effective than the Buzzy® in reducing procedural pain in children. However, there is currently a limited number of studies directly comparing these two interventions. Another systematic review that included four studies on this topic reported mixed results, suggesting that the relative effectiveness of these methods may vary depending on the clinical context (23). Interestingly, the study by Canbulat Sahiner et al. found that ShotBlocker was more effective than Buzzy® in reducing pain during insulin injections in children with type 1 diabetes (43). This discrepancy may be attributed to differences in procedure type (repetitive insulin injections versus single venipuncture), which can alter pain perception over time (44). Overall, Buzzy® is effective in managing paediatric procedural pain and anxiety, particularly when integrated with complementary distraction strategies. At present there are no trials available that directly compare Buzzy® to nitrous oxide, a common and effective analgesic and anxiolytic.

### Strengths and Limitations

A strength of this systematic review is that all included randomized controlled trials (RCTs) featured a control group and employed the same validated instrument for assessing pain. Although several recent systematic reviews have evaluated the effectiveness of Buzzy® in reducing pain during needle-related procedures, this is, to our knowledge, the first review specifically focused on pain outcomes assessed using a consistent measurement tool.

However, this review also has several limitations. Firstly, considerable heterogeneity existed among the interventions evaluated in the included studies. Additionally, none of the included RCTs employed blinding, primarily due to the inherent nature of the intervention, making participant and practitioner blinding impractical. Another limitation is the absence of a meta-analysis, mainly due to the insufficient number of comparable studies evaluating similar intervention strategies. Therefore, the conclusions of this review are based solely on qualitative assessments, potentially limiting the robustness and generalizability of the findings.

## Clinical implementation

Clinically, the results suggest that while Buzzy® may not universally outperform established topical anaesthetics, it holds substantial value in specific contexts, particularly where rapid pain relief is required, such as emergency or outpatient settings. The immediate onset of analgesic effects and ease of use make it an attractive option for healthcare providers, especially in environments demanding swift procedural actions, like emergency departments. However, clinicians should balance the convenience of Buzzy® against the superior analgesic efficacy of topical anaesthetics in settings where procedural delay is feasible. Currently, pain management techniques are still underutilized in clinical practice,

indicating a clear need for greater integration of effective pain relief strategies into standard care. Therefore, although Buzzy® presents clear advantages for reducing procedural pain, its application should be carefully considered depending on the specific clinical circumstances.

## Conclusion

In conclusion, the review provides nuanced support for the Buzzy® device as a practical, although sometimes less effective, alternative to topical anaesthetics in managing paediatric needle-related procedural pain. Buzzy® offers notable advantages such as rapid onset, ease of use, and superior performance compared to distraction alone or other non-pharmacologic devices like ShotBlocker®. The clinical decision to use Buzzy® should consider the specific context, urgency, and procedural environment. Recommendations for practice include utilizing multimodal approaches combining Buzzy® with distraction techniques to optimize pain and anxiety relief outcomes.

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