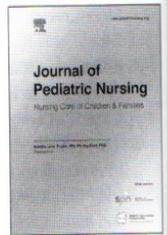




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Virtual reality vs. buzzy®. efficacy in pain and anxiety management during pediatric venipuncture. Systematic review and meta-analysis

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ABSTRACT

Problem: Non-pharmacological distraction methods are novel alternatives that can help to alleviate pain and anxiety generated by venipuncture in the pediatric population. The aim is to determine the effectiveness of virtual reality, compared to cold and vibration devices (Buzzy® device), as a distraction method used during venipuncture in the management of pain and anxiety in children.

Eligibility criteria: Clinical trials, cohort and quasi-experimental studies, published between 2017 and 2022, in Spanish or English and pediatric age, found in Medline, the Cochrane Library, Scopus, Web Of Science, CINAHL and Embase databases.

Sample: Twenty-one studies were included and ten met the criteria for meta-analysis.

Results: Fifty-seven percent of the studies evaluate virtual reality, 33.3% the Buzzy® device and 9.5% both comparatively. The effectiveness of virtual reality in reducing pain (66.6%, $n = 14$) and anxiety (47.6%, $n = 10$) compared to standard care (control group), 95% CI = 1.53 [0.91–2.16], $p < 0.001$, $I^2 = 78%$ and 95% CI = 1.53 [1.16–1.90], $p < 0.001$, $I^2 = 77%$ respectively is demonstrated. Similarly, the effectiveness of Buzzy® in reducing pain (42.9%, $n = 9$) and anxiety (23.8%, $n = 5$), 95% CI = 1.62 [0.90–2.34], $p < 0.001$, $I^2 = 94%$ and 95% CI = 1.40 [0.06–2.20], $p < 0.001$, $I^2 = 91%$ respectively is demonstrated. Comparatively, there is no significant difference between both methods 95% CI = 0.29 [–0.19–0.78], $p = 0.24$, $I^2 = 81%$.

Conclusions: The methods studied are effective in relieving pain and anxiety during venipuncture. Further research is needed on the level of satisfaction, adverse effects and cost-benefit.

Implications: This study provides evidence of novel tools in daily practice to provide more humane, holistic and quality care.

Introduction

Venous punctures or venipunctures constitute a nursing, diagnostic and frequently used technique to extract blood samples for various types of analytical controls (González, 2021). They are simple and generally not painful for adults, although children perceive them as one of the most feared invasive procedures, causing anxiety and pain (Friedrichsdorf et al., 2015; Zunino et al., 2018). In addition, children's sensation of impotence for not being able to avoid the procedure may

make children may perceive venipuncture as a traumatic event with negative repercussions in the future (Lerwick, 2016).

It is estimated that 78% of the hospitalized pediatric patients are subjected to at least one painful procedure during their hospitalization (venipunctures, intravenous cannulations, diagnostic/therapeutic procedures, etc.), reaching a mean of 6 or more procedures per child (Leyva et al., 2019). Internationally renowned bodies advocate children's right to enjoy good health, well-being, access to adequate health services and pain management without any type of discrimination (IASP, 2011).

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Although venipunctures represent a slightly painful technique for any person, children have a tendency to overestimate this pain (Orenius et al., 2018). The pain intensity and the anxiety experienced by children can be related to previous experiences regarding such situation and to the behaviour of the personnel performing it (Mahoney et al., 2010; Noel et al., 2010; Thompson et al., 2016). Nurses should assume responsibility for observing children's rights, especially pain and anxiety management in pediatric patients. On the other hand, there are studies indicating that 22% of children are not offered any type of intervention for pain or anxiety management (Leyva et al., 2019).

There are several ways to treat strategies to address pain and anxiety during venipunctures in paediatrics, which can be broadly classified into pharmacological and non-pharmacological interventions (Castro & Sánchez, 2016; García et al., 2017; Orenius et al., 2018). Among the pharmacological options are the following: using topical treatments with local action such as the EMLA® anaesthetic cream (25 mg/g lidocaine +25 mg/g prilocaine) or the *Cloretilo Chemirosa®* spray (Ethyl Chloride 100 g). The most common non-pharmacological strategies are the following: parents' presence during the procedure, a quiet and suitable environment and/or nurses' calm and patient behaviour. Distraction techniques adapted to each child's age also stand out, such as breathing techniques, music, toys, anti-stress balls, imagination games, bubble makers, kaleidoscopes, books or short stories, cards, films or videos and video games, among others (Ramírez & Mesa, 2014; Sampson & Allbright, 2019). The most innovative ones correspond to using Virtual Reality (VR) devices as a distraction method (Chan et al., 2018; Eijlers et al., 2019; Kipping et al., 2012; Ryu et al., 2018) and devices that combine cold and vibration, of which Buzzy® is currently the most popular, to help alleviate pain and anxiety while performing the technique (Castro & Sánchez, 2016; García et al., 2017; IASP, 2011; WHO, 1959; Sampson & Allbright, 2019).

VR has been used in Science and in Medicine since the 1990s, evolving and becoming an increasingly affordable, immersive, flexible and portable technology since then (Ioannou et al., 2020). It is a device capable of creating an interactive tridimensional environment projected by means of a helmet or a pair of glasses, which allows real-time interaction, feeling and listening stimuli associated to a visual image while giving out responses and interacting with the virtual environment (Das et al., 2005; Eijlers et al., 2019; Ioannou et al., 2020;). VR allows patients to divert their attention from symptoms such as depression, fatigue, pain and anxiety, thus showing its high efficacy because it helps to relieve them or perceive them to a lesser degree (Eijlers et al., 2019; Kipping et al., 2012; Ryu et al., 2018). Some studies highlight the important role of distraction in venipunctures (Chan et al., 2018; Eijlers et al., 2019), the high success rates in adults and its great appeal among preschool children to adolescents (Eijlers et al., 2019; Kipping et al., 2012).

The Buzzy® device is a bee-shaped instrument containing a vibration generating engine that works on a battery, with an ice bag below. It is simple to use: it only needs to be placed some 5 cm above the puncture site and a couple of minutes before the procedure (Baxter et al., 2011; Castro & Sánchez, 2016). The device gives off cold that acts on the A-Delta fibres and small vibrations acting on the C-fibres, helping to alleviate pain while performing the technique (Baxter et al., 2011). Its appearance contributes to the distraction and in reducing the anxiety experienced by the venipuncture (Baxter et al., 2011; Schreiber et al., 2016; Yilmaz et al., 2017). Effectiveness has been demonstrated in adults, and especially among children aged between 6 and 12 years old (Castro & Sánchez, 2016).

It is worth noting that it is not only children that suffer during venipunctures but that also nurses frequently experience stress when children show resistance which generates discomfort both for children and for the professionals themselves (García et al., 2017; Ives & Melrose, 2010; Orenius et al., 2018). Given the above, and to help children undergo the experience in a non-traumatic way and with effective management of their emotions (Baxter et al., 2011; Chan et al., 2018; Eijlers

et al., 2019; Schreiber et al., 2016; Yilmaz et al., 2017), research support is provided and training in advanced techniques for the management of perceived pain and anxiety. In addition, the recommendations set forth by the American Society for Pain Management Nursing (ASPMN) would be complied. Since 2011, it advised on the use of non-pharmacological interventions confirming their effectiveness while performing pediatric venipunctures (Czarnecki et al., 2011).

This review and meta-analysis are pertinent because of the high prevalence of venipuncture pain in this population, as well as its repercussions. In addition, due to the rise of new technologies in the clinical field, such as virtual reality. For these reasons, this study focuses the attention on the innovative techniques of VR and cold/vibration devices for pain and anxiety management in children during venipunctures, comparing both non-pharmacological interventions to determine which one presents better results, as no similar comparative studies have been found. At the same time, the children's, parents' and nurses' perceptions and satisfaction levels are measurable results to compare how both tools are employed and determine if they are useful and easy to apply, in addition to whether they improve how the everyday nursing practice is developed.

The general objective of this systematic review and meta-analysis is to determine the effectiveness of VR when compared to cold and vibration devices (Buzzy®) as distraction methods employed during venipunctures in terms of pain and anxiety management in the pediatric population; in addition to determining the effectiveness of VR for pain and anxiety, as well as the efficacy of Buzzy® and of both tools in a comparative way; and knowing the satisfaction levels of the health personnel and of the participants' parents, the adverse events arising from the use of any of the devices and the cost-benefit ratio when compared to the usual venipuncture technique.

Material and methods

Design

This is a systematic review and meta-analysis reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Rethlefsen et al., 2021) and the PRISMA literature search extension (Page et al., 2021).

The population/intervention/comparison/outcomes (PICO) format was used to prepare the research question:

Population: pediatric patients (age: 2–18 years old).

Intervention: virtual reality (VR) devices.

Comparison: cold and vibration devices (Buzzy®).

Outcome: efficacy in pain management during venipuncture.

Secondary outcome measures: anxiety during venipuncture.

The review protocol was registered in the Prospective International Register of Systematic Reviews (PROSPERO) with number CRD42022322366.

Information sources

To identify relevant studies, a search was made from February to April 2022 in following databases: Medline (PubMed) via Ovid, The Cochrane Library via Wiley, Scopus, Web Of Science (WOS) via Thomson Reuters, Cumulative Index to Nursing and Allied Health Literature (CINAHL) via EBSCO and Embase. Grey literature was retrieved through Google Scholar and a reverse search was conducted of the analysed articles. The search terms used for the databases were a combination of keywords extracted from the Medical Subject Headings (MeSH) (MeSH Browser, 2021). The search strategy employed was: "(Pain OR Anxiety) AND ('Virtual Reality' OR Buzzy OR 'Buzzy device' OR 'Cold- vibration device') AND ('Child, Preschool' OR Child OR Adolescent) AND (Venipuncture OR Phlebotomy OR 'Blood Drawing') AND ('Pediatric Nursing' OR 'Nurses, Pediatric' OR Nursing OR Nurses OR Parents OR 'Cost-Benefit Analysis' OR Satisfaction OR Duration OR 'Injection Site

Reaction' OR Complications OR 'Adverse Effects') NOT (Vaccination OR 'Intravenous cannulation' OR 'Venous port access')". Table 1 shows the search strategy, filters and descriptors according to each database used.

Selection criteria

The articles included in the review were Randomized Clinical Trials (RCTs), cohort and quasi-experimental studies (these last two as long as they had an Experimental Group and a Control Group), both for the quantitative and qualitative analysis. The studies included were those published in the last 5 years (2017–2022), in English or Spanish, conducted with human populations and with individuals of pediatric age (from 2 to 18 years old, encompassing the following life stages: Pre-school, 2–5 years old; Elementary School, 6–12 years old; and High School, 13–18 years old). The studies excluded were those whose research was in a preliminary phase, with incomplete results, lacking comparisons between the VR and Buzzy® interventions, and with objectives other than the ones of this study. To determine the biases of the studies, the ROB2 tool was used (Sterne et al., 2019).

As eligibility criteria to enter the meta-analysis, it was considered that the measurements were taken with the same measurement scale or, failing that, comparable, in addition to obtaining data with statistical similarities (percentage of events in discontinuous variables or average and standard deviation in continuous variables).

Selection process

Two authors conducted the search. Potentially identified studies from the six bibliographic databases ($N = 176$) were imported into the Mendeley Software reference manager (London, UK) and duplicates were removed ($n = 98$). The search in the grey literature did not provide

Table 1
Search strategy and results in different databases.

Database	Search strategy	Filters	Results
Medline (PubMed)	"(Pain OR Anxiety) AND ('Virtual Reality' OR Buzzy OR 'Buzzy device' OR 'Cold-vibration device') AND ('Child, Preschool' OR Child OR Adolescent) AND (Venipuncture OR Phlebotomy OR 'Blood Drawing') AND ('Pediatric Nursing' OR 'Nurses, Pediatric' OR Nursing OR Nurses OR Parents OR 'Cost-Benefit Analysis' OR Satisfaction OR Duration OR 'Injection Site Reaction' OR Complications OR 'Adverse Effects') NOT (Vaccination OR 'Intravenous cannulation' OR 'Venous port access')"	Year of publication: 2017–2022(Sajeev et al., 2021) Language: Spanish/English Age: Preschool (2–5 years), Child (6–12 years), Adolescent (13–18 years)	24
The Cochrane Library		Year of publication: 2017–2022	37
Scopus		Year of publication: 2017–2022 Language: Spanish/English	17
Web of Science (WOS)		Year of publication: 2017–2022 Language: Spanish/English	23
CINAHL		Year of publication: 2017–2022 Language: Spanish/English Age: Preschool (2–5 years), Child (6–12 years), Adolescent (13–18 years)	10
Embase		Year of publication: 2017–2022 Language: Spanish/English Age: Preschool (2–5 years), Child (6–12 years), Adolescent (13–18 years)	26

relevant results. The selection of studies was conducted based on titles and abstracts to determine their relevance and 18 were eliminated due to exclusion criteria. The full texts of the remaining studies were read to determine their eligibility, and those that met the inclusion criteria were maintained. Once the eligibility process was over, two authors assessed the methodological quality and the biases of studies. This allowed improving the screening of the results to obtain more complete and relevant information, thus enhancing the quality of the study. The agreement degree between the two researchers in terms of evaluating the eligibility of the study was assessed using Kappa's statistical test, obtaining a high result regarding agreement (Kappa statistics = 0.91). Supplementary material 1 shows the flowchart (PRISMA) with the search, screening, and articles selection.

Data extraction

A narrative data analysis and a meta-analysis was performed. We extracted the following information from the articles: author, publication year, study design, level of evidence, general objective of the study, methodology used and study sample, scales used to assess pain and anxiety, and main results. The studies were organized in a table based on the type of analysis performed (quantitative and/or qualitative), grouping them according to the type of device employed as intervention and sorted out in alphabetical order (Table 2).

The results were analysed in two complementary ways because not all studies presented their data using the same statistical concepts: quantitatively, if their results were expressed as mean and standard deviation (σ ; SD), or qualitatively, if they were expressed as frequencies or proportions. A subgroup analysis was performed according to the scale used (pain and anxiety) and the intervention evaluated (VR vs control, Buzzy vs control and VR vs Buzzy).

The results were represented by means of a forest plot where each study can be observed with its confidence intervals and the weight they contribute to the analysis. The asymmetry of this last graphic was assessed by means of the funnel representation, which indicates evidence of publication bias (Supplementary material 2). The funnel diagrams show certain symmetry, indicating that publication bias is low.

The continuous data that were introduced into Review Manager were assessed using the Random Effects model when they presented high heterogeneity ($I^2 \geq 50\%$) across the studies and resorting to the Fixed Effects model when heterogeneity was low ($I^2 \leq 50\%$) and, to the contrary, the articles were homogeneous between each other.

Methodological quality assessment and risk of bias

The risk of bias assessment corresponding to the articles that comprise this review was performed in the Review Manager computer software, version 5.4, proposed by The Cochrane Collaboration in its "Cochrane Handbook for Systematic Reviews of Interventions" (Higgins et al., 2022). A graph was generated with three colours, each one representing a different risk of bias level (Supplementary material 3). The green colour indicates low risk of bias, yellow denotes uncertainty regarding the risk of bias due to lack of information and, finally, red means high risk of bias. Likewise, the risk of bias level of the articles was recorded by author in the graph (Risk of Bias Summary) (Supplementary material 4).

Results

The studies included in the systematic review were $n = 21$, of which 81% ($n = 17$) were RCTs, 14.3% ($n = 3$) were quasi-experimental studies and 4.7% ($n = 1$) corresponded to cohort studies. Most of them were published between 2018 and 2020 (76.2%, $n = 16$) and in the English language (85.7%, $n = 18$). All the articles compared one of the two non-pharmacological methods to a Control Group to assess its efficacy in reducing pain and anxiety. 57.2% ($n = 12$) of the studies evaluated VR,

Table 2
Studies included in the meta-analysis.

Author, year Design and evidence level	Objectives	Methodology and sample Population age	Scales	Results
Atzori et al. (2022) ECA (1++)	To assess the effectiveness of VR as a method of analgesia among pediatric patients with kidney disease undergoing venipuncture.	The sample was randomly into 2 groups: control (non-medical conservation with the nurse) and experimental (use of VR). N = 82; Control (n = 41) Experimental (n = 41)	Numeric Rating Scale (NRS), scored from 0 to 10. Pain was assessed in terms of its cognitive (time spent thinking about pain), affective (unpleasant) and perceptual (worst pain) components.	There are significant differences regarding the perceptive and affective component (lower levels in the experimental group, $p < 0.05$). There are no significant differences in the cognitive component of pain ($p > 0.05$); although the levels were higher in the control group).
Aydın and Özyazıcıoğlu, 2019ECA (1+)	To determine the effect of VR in reducing pain during venipuncture in children.	Sample randomly divided into control and experimental group (VR) Age: 9–12 years Sample (N = 120) Control (n = 60) Experimental (n = 60)	Wong-Baker FACES Pain Rating Scale (WBFPS) score from 0 to 10. Visual Analog Scale (VAS), score 0–10	Significant differences were found between both groups, with the level of pain being higher in the control group (according to VAS, $p < 0.05$; according to WBFPS $p < 0.01$)
Dumoulin et al. (2019) ECA (1+)	To test the efficacy and satisfaction of the use of VR as a pain and anxiety distraction technique for children during medical procedures.	The sample was randomly divided into three groups: minimal distraction (television TV, standard care (child life program, CL) and VR. Age: 8–17 years. Sample (N = 59); TV (n = 24); CL (n = 15); VR (n = 20)	VAS scale, from 0 to 100, to assess the pain caused by the procedure and the fear of pain (anxiety).	The level of fear of pain (anxiety) was significantly less in the VR group ($p < 0.05$). However, there were no significant differences between the groups regarding pain intensity.
Inal and Kelleci, 2020ECA (1++)	To examine the efficacy of different devices for viewing pictures during venipuncture in children.	Sample randomly divided into three groups: control, virtual reality (VR) and Tablet. Age: 7–12 years. Sample (N = 120) Control (n = 40) VR (n = 40) Tablet (n = 40)	WBFPS scale, with a score of 0–10, to measure pain. Scale “Children’s Fear Scale” (CFS), scored from 0 to 4, to measure the level of anxiety.	There are significant differences between the groups, experiencing less pain and anxiety in the VR group ($p < 0.001$).
Koç Özkan and Polat, 2020ECA (1+)	To determine the effect of VR and the kaleidoscope on children’s perception of pain and anxiety during venipuncture.	The sample was randomly divided into three groups: control, kaleidoscope, and VR. Age: 4–10 years. Sample (N = 135) Control (n = 43) Kaleidoscope (n = 46) VR (n = 46)	VAS and WBFPS scales, with a score of 0–10, to measure pain. CFS scale, scored 0–4, to measure anxiety level.	There were significant differences between the groups regarding pain, being lower in the VR group ($p < 0.05$). Significant differences were also found in anxiety, with a lower score in the VR group ($p < 0.05$).
Özalp-Gerçeker, Ayar, Özdemir, and Bektaş, 2020ECA (1++)	To evaluate the effect of two types of VR on the levels of pain, fear and anxiety in children during the extraction of blood samples.	Sample randomly into 3 groups: control (no distraction), VR-Roller coaster and VR-Ocean tour. Age: 5–12 years. Sample (N = 136) Control (n = 46); VR-Roller coaster (n = 45); RV-Ocean Tour (n = 45).	WBFPS scale, with a score of 0–10, to measure pain. CFS scale, scored from 0 to 4, to measure anxiety level. The Children’s Anxiety Meter (CAM), from 0 to 10, was also used for the same purpose.	The pain scores was lower in the VR-Roller coaster and VR-Ocean tour groups, with no statistical superiority between them ($p < 0.05$).
Piskorz and Czub, 2018Quasi-experimental (2+)	To determine the effectiveness of VR in reducing pain during venipuncture in pediatric patients.	The sample was divided into 2 groups: control and experimental (RV) Age: 7–17 years. Sample (N = 38); Control (n = 19); Experimental (n = 19).	VAS scale, scored from 0 to 10, to assess the intensity of pain and anxiety.	There are significant differences in the level of pain (lower in the RV group, $p < 0.02$). Similar results were obtained in anxiety level (lower in the VR group, $p < 0.01$).
Bergomi et al. (2018) ECA (1-)	To assess the efficacy of analgesia using a cold and vibration device (Buzzy®) and cartoons, in terms of pain and anxiety during venipuncture in children.	The sample was divided into four groups: control, Buzzy®, cartoons, Buzzy® + cartoons. Age: 5–12 years. Sample (N = 150) Control (n = 39) Buzzy® (n = 36) Cartoons (n = 37) Buzzy® + cartoon (n = 38)	WBFPS scale, with a score of 0–10, to measure pain (used by children). WBFPS and Children’s Emotional Manifestation Scale (CEMS) scales to measure children’s pain and anxiety, respectively (completed by parents or nurses).	Significant differences in pain reduction were obtained in the cartoon group ($p = 0.02$) according to the children. The Buzzy® device was shown to be highly effective in children under 9 years of age ($p = 0.04$). The level of anxiety was significantly lower in the Buzzy® ($p = 0.03$, according to the nurses; $p = 0.03$ according to the mothers) and + Buzzy® cartoons ($p = 0.02$, according to the nurses) groups.
Inal and Kelleci (2020) ECA (1+)	To investigate the effects of the Buzzy® cold plus vibration device and distraction in relieving pain from venipuncture in children.	Sample randomly divided into four groups: control (no intervention), Buzzy®, distraction cards, Buzzy® + distraction cards. Age: 6–12 years.	WBFPS scale, with values from 0 to 10, to measure pain. CFS scale, from 0 to 5, to measure anxiety prior to the process.	Anxiety prior to the procedure was not different between the groups ($p > 0.05$). There were significant differences in pain levels, being lower in the groups in which

(continued on next page)

Table 2 (continued)

Author, year Design and evidence level	Objectives	Methodology and sample Population age	Scales	Results
Küçük and Yaman, 2019ECA (1+)	To investigate the effects of the Buzzy® device, lidocaine, bubble blower, and inhalation aromatherapy (lavender) on pain, stress, and fear caused by venipuncture in children.	Sample (N = 218) Control (n = 56) Buzzy® (n = 55) Cards (n = 55) Buzzy® + cards (n = 52) Sample randomly divided into five groups. Age: 5–10 years. Sample (N = 195) Control (n = 39) Buzzy® (n = 39) Lidocaine (n = 39) Bubbles (n = 39) Aromatherapy (n = 39)	Scales to measure pain and fear: “Oucher Pain Scale” (from 0 to 10) and CFS (from 0 to 4), respectively.	performed some intervention (p < 0.001). The lowest pain score was obtained in the group that combined Buzzy® and distraction cards. There were significant differences between the intervention groups and the control group in terms of pain level during and after venipuncture, in favor of the Buzzy® group (p < 0.05). The same occurred in terms of fear level, again in favor of the Buzzy® group (p < 0.05).
Susam et al. (2018) ECA (1++)	To verify the efficacy of the Buzzy® device in reducing pain during venipuncture in children.	The sample was randomly divided into two groups: control and experimental (Buzzy® + distraction cards). Age: 3–10 years. Sample (N = 64); Control (n = 34); Experimental (n = 30)	VAS, WBFPS and NRS scales, with a score of 0–10, to measure pain.	Significant differences were found between the level of pain experienced in the two groups, being lower in the experimental group (p = 0.039).
Tork, 2017ECA (1+)	To investigate the efficacy of the Buzzy® device, distraction cards, and inflating a balloon as distraction methods in reducing pain and anxiety during pediatric venipuncture	Sample randomly divided into four groups: control (standard care), Buzzy®, distraction cards, and inflating a balloon. Age: 7–12 years. Sample (N = 180) Control (n = 45) Buzzy® (n = 45) Cards (n = 45) Balloon (n = 45)	Scales to assess pain and anxiety: WBFPS (from 0 to 10) and CFS (from 0 to 4), respectively.	Significantly lower levels of pain were observed with the use of the Buzzy® device (children, p = 0.012; nurses, p = 0.036; parents, p = 0.014). There were no significant differences between the groups regarding the level of anxiety (nurses, p = 0.13; parents, p = 0.42), although the lowest values were obtained in the Buzzy® group.
Erdogan and Aytekin Ozdemir, 2021ECA (1+)	To determine the effect of the Buzzy® device, virtual reality and distraction cards as methods of distraction and pain and anxiety relief in pediatric venipuncture.	The sample was randomly divided into four groups: control, Buzzy®, virtual reality, and distraction cards. Age: 7–12 years. Sample (N = 142) Control (n = 34) Buzzy® (n = 36); Virtual reality (n = 37); Letters (n = 35)	VAS scales (0–10), WBFPS (0–10), to measure pain, and CFS (0–4), to assess fear.	There were significant differences between the groups regarding the level of pain (p < 0.05), whose lowest score was in the Buzzy® group. The same results were obtained at the level of anxiety (p < 0.05, highlighting the Buzzy® group). The results between the Buzzy® group and the RV group were similar, with no significant differences in pain and anxiety between them (p > 0.05).
Özalp-Gerçeker, Ayar, Özdemir, and Bektaş, 2020ECA (1+)	To compare the efficacy of VR and the Buzzy® device in reducing pain during venipuncture in children.	Sample divided into three groups: control, RV and Buzzy®. Age: 7–12 years. Sample (N = 121) Control (n = 40) Virtual reality (n = 40) Buzzy® (n = 41)	WBFPS scale, with a score of 0–10, to measure pain (according to children, parents and nurses).	Significant differences were found in the level of pain reported by children, parents and nurses between the 3 groups (p < 0.05), being lower in the Buzzy® group and RV group, compared to the control group. There were no significant differences between the Buzzy® group and the RV group (p > 0.05).
Atzori et al. (2018) ECA (1+)	To explore the effectiveness of VR as a distraction technique for pain management in pediatric patients undergoing venepuncture. Promote the use of VR analgesia in clinical settings	Sample randomly divided into two groups: control (non-medical conversation with the nurse), and experimental (VR). Age: 7–17 years. Sample – Nephrology Service (N = 24) Control (n = 12) Experimental (n = 12) Sample – Oncohematology Service (N = 11) Control (n = 11) Experimental (n = 11)	Italian version of a self-report questionnaire based on the “Graphic Rating Scale” (GRS), from 0 to 10. Pain was assessed in terms of its cognitive component (time spent thinking about pain), affective component (unpleasant), and perceptual component (worst pain).	Nephrology Department: There are significant differences regarding the cognitive and affective component (lower levels in the experimental group, p < 0.05). There are no significant differences in the perceptual component of pain. Oncohematology Service: There are significant differences regarding the cognitive and affective component (lower levels in the experimental group, p < 0.05).
Chan et al. (2019) ECA (1++)	To assess the efficacy (in reducing pain and anxiety) and safety of VR distraction in needle procedures in pediatric patients.	The sample was randomly divided into two groups: control (standard care) and experimental (VR). Age: 4–11 years. Sample – Emergency	WBFPS scale, scored from 0 to 10 to measure pain. VAS scale (analog visual thermometer), from 0 to 10, to rate anxiety.	There are significant differences, observing better results in pain reduction in the experimental group, both in the Emergency Service (p = 0.018) and in the Ambulatory Pathology (p = 0.034).

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Table 2 (continued)

Author, year Design and evidence level	Objectives	Methodology and sample Population age	Scales	Results
Osmanliu et al. (2021) ECA (1+)	To determine the feasibility and acceptability of distraction via VR during needle-related procedures in the management of pain and anxiety.	Department (N = 123) Control (n = 59) Experimental (n = 64) Sample – Ambulatory Pathology (N = 129) Control (n = 66) Experimental (n = 63) The sample was randomly divided into two groups: control (standard care) and experimental (VR). Age: 7–17 years. Sample (N = 63) Control (n = 31) Experimental (n = 31)	NRS scale, from 0 to 10, to assess pain. CFS scale, scored from 0 to 4, to measure the level of anxiety	Significant differences were found in the reduction of anxiety (the experimental group achieved better results) in both services (Emergency Services $p = 0.011$; Ambulatory Pathology $p = 0.016$). The level of pain was not statistically significant between the groups ($p = 0.75$). Differences were found in the level of anxiety, being lower in the experimental group (VR).
Tejada-Muñoz et al., 2020 Quasi-experimental (2+)	To verify the effect of VR in the reduction of pain and anxiety in children during venous puncture.	Sample randomly divided into two groups: control and experimental, the latter subjected to VR. Age: 6–10 years. Sample (N = 50) Control (n = 25) Experimental (n = 25)	WBFPSS scale, with a score of 0–10, to measure pain. “Groninger Discale” scale, valued from 0 to 5, to measure anxiety.	There were significant differences between both groups in the values obtained for pain and anxiety, being lower in the experimental group (VR) ($p < 0.05$).
Toledo et al., 2019 Cohort (2+)	To assess whether the use of VR (associated or not with lidocaine/prilocaine cream) reduces pain and anxiety during invasive procedures in pediatric patients without producing relevant adverse effects.	The sample was divided into three groups: control, RV group without coadjuvant and RV group + analgesic cream. Age: 4–15 years. Sample (N = 56) Control (n = 18) RV group without adjuvant (n = 16) RV group + analgesic cream (n = 22)	Pain and anxiety scales completed by children: VAS (0–10), WBFPSS (0–10) and CFS (0–4). NRS (0–10) and CFS (0–4) scales, completed by adults.	Significant differences were found in the VR groups with respect to the control, obtaining lower levels of pain and anxiety ($p < 0.001$). The VR + analgesic cream group obtained lower scores for pain (children, $p = 0.02$; parents, $p = 0.03$; health personnel, $p = 0.001$) and anxiety (health personnel, $p = 0.03$; non-significant values in children and parents).
García-Aracil et al., 2018 Cuasiexperimental (2-)	To compare the effectiveness of the use of the Buzzy® device vs. game through a tablet in the relief of pain related to venipuncture in the pediatric population.	Sample randomly divided into two groups: Buzzy® group and tablet group. Age: 4–12 years. Sample (N = 200) Buzzy® (n = 100) Tablet (n = 100)	WBFPSS scale (from 0 to 10), to measure pain (applied in children from 4 to 7 years). NRS scale (from 0 to 10), to measure pain (applied to children aged 8–12, parents and nurses).	No significant differences in pain relief were found between the Buzzy® group and the tablet group (children, $p = 0.72$; parents, $p = 0.47$; nurses, $p = 0.50$).

33.3% ($n = 7$) did so with the Buzzy® device, and 9.5% ($n = 2$) made a comparative assessment of both with a total sample of 2504 patients aged between 2 and 18 years old. 47.6% ($n = 10$) of the studies added an additional group to the control group employing other distraction techniques to reduce pain and/or anxiety (distraction cards, electronic tablet, TV set, kaleidoscope, and bubble maker). The Wong-Baker FACES® Pain Rating Scale (WBFPSS), the Analogue Visual Scale (AVS) and the Numeric Rating Scale (NRS) were mostly employed to assess pain (95.2%, $n = 20$; 38.1%, $n = 8$; and 57.1%, $n = 12$, respectively), where it was possible to compare their scores as they measure absence of pain with 0 points and maximum pain with 10 or 12 points, which are comparable formats. The Children's Fear Scale (CFS) was mostly employed (52.4%, $n = 11$) to assess anxiety, to detriment of other minority scales such as the Groninger Distress Scale (GDS), the Children's Anxiety Meter (CAM) and the Children's Emotional Manifestation Scale (CEM). On the other hand, the analysis was assessed according to the sex of the participants and age. None of the studies assessed their main objectives according to gender. Regarding age ranges, only three studies performed an analysis by age, however the age ranges were not the same and did not meet any criteria for using such ranges (Atzori et al., 2018: 7–11 years versus 12–17 years; Aydın & Özyazıcıoğlu, 2019: disaggregates age from 9 to 12 years and Erdogan & Aytekin Ozdemir, 2021: 7–9 years versus 10–12 years).

VR effectiveness against pain and anxiety

Fourteen studies were found analysing the effectiveness of VR in reducing pain and anxiety during venipunctures in children, from which it was possible to include nine in the meta-analysis (Atzori et al., 2018;

Erdogan & Aytekin Ozdemir, 2021; Dumoulin et al., 2019; Erdogan & Aytekin Ozdemir, 2021; Piskorz & Czub, 2018; İnangil et al., 2020; Özalp, Binay, Bilsin, Kahraman, & Yilmaz, 2018; Özalp-Gerçeker et al., 2020; Koç Özkan & Polat, 2020). The other five studies (Atzori et al., 2018; Chan et al., 2019; Osmanliu et al., 2021; Tejada-Muñoz et al., 2020; Toledo et al., 2019) were analysed qualitatively. All studies investigated pain and ten of them address anxiety (Chan et al., 2019; Dumoulin et al., 2019; Erdogan & Aytekin Ozdemir, 2021; İnangil et al., 2020; Koç Özkan & Polat, 2020; Osmanliu et al., 2021; Özalp-Gerçeker et al., 2020; Piskorz & Czub, 2018; Tejada-Muñoz et al., 2020; Toledo et al., 2019).

Regarding pain, all the studies found significant differences when they compared the experimental and control groups, with lower pain levels and reducing the unpleasant sensation in the group using VR, always with $p < 0.05$. Through the tree diagram (Fig. 1), the meta-analysis confirms the following results: 95% CI = 1.53 [0.91–2.16], $p < 0.001$, $I^2 = 78\%$. H_0 is rejected and, therefore, the Experimental Group presents pain reduction during venipunctures when compared to the Control Group, with high heterogeneity across the studies. The data continued to show improvements in the experimental group in sensitivity analyses despite the removal of biased studies (Supplementary material 5).

All the studies that evaluated anxiety showed lower levels in the experimental group that used VR compared to the control group. With the diamond displaced to the right (Experimental Group) of the null effect line, the meta-analysis shows that H_0 is rejected with 95% CI = 1.53 [1.16–1.90], $p < 0.001$, $I^2 = 77\%$ (Fig. 2).

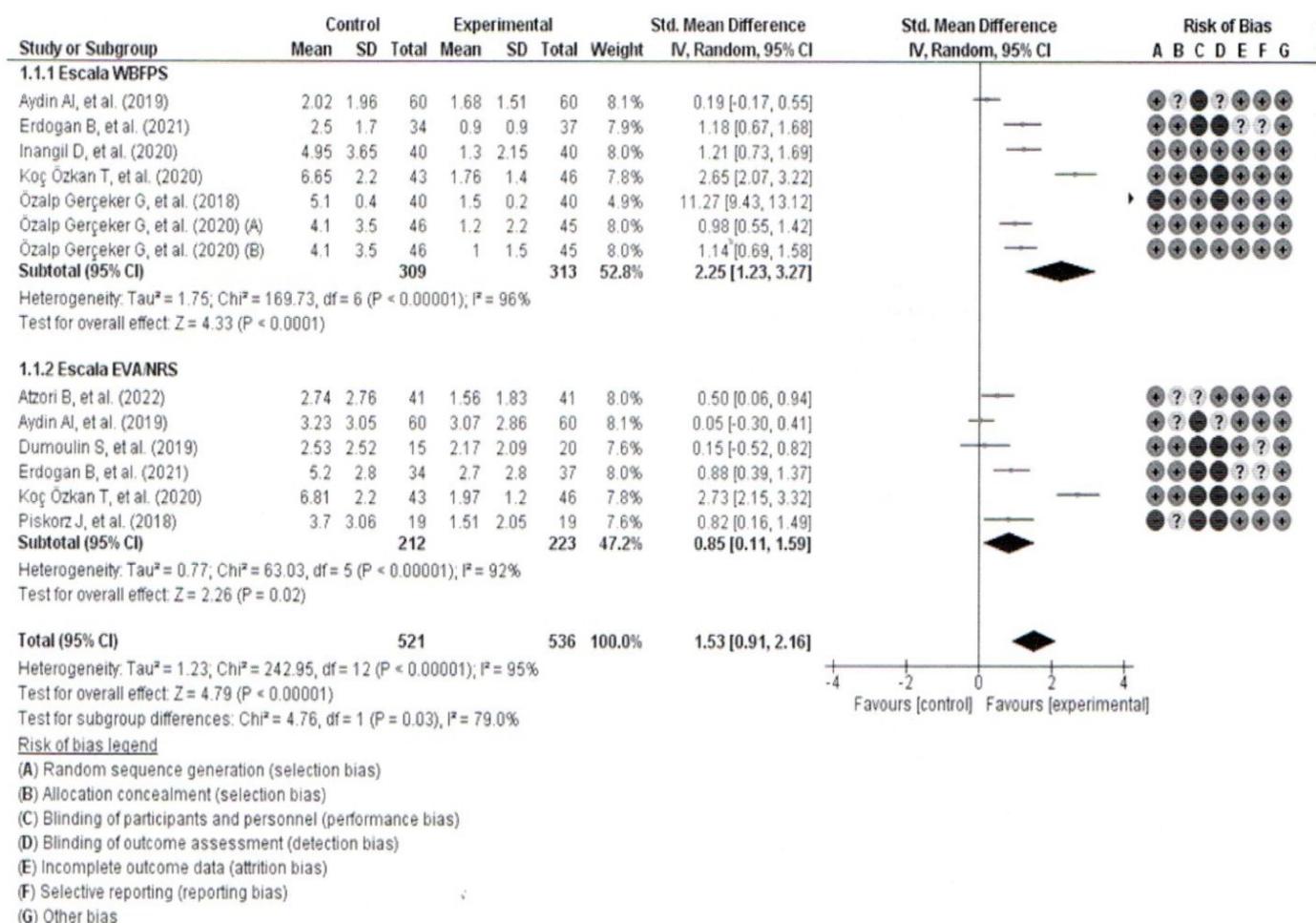


Fig. 1. Tree diagram: efficacy of VR in pain management during venipuncture pediatric. Made with RevMan 5.4 (Forest plot).

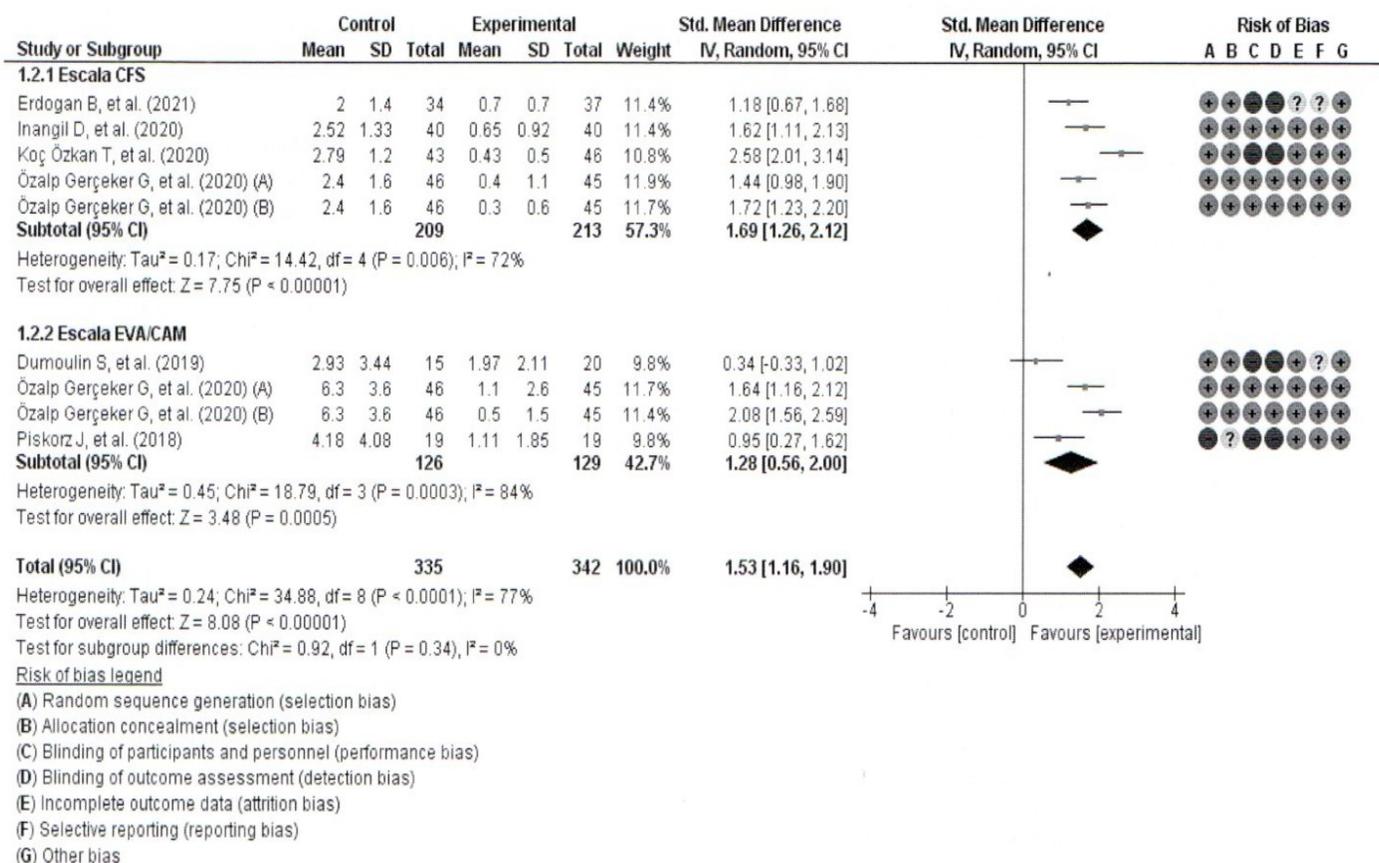


Fig. 2. Tree diagram: Efficacy of VR in reducing anxiety during pediatric venipuncture. Made with RevMan 5.4 (Forest plot).

Effectiveness of the Buzzy® cold and vibration device against pain and anxiety

Nine studies were found that investigated the efficacy of the Buzzy®

device in reducing pain and anxiety during venipunctures in children. Seven of them (Bergomi et al., 2018; Erdogan & Aytekin Ozdemir, 2021; Özalp et al., 2018; Inal & Kelleci, 2020; Küçük & Yaman, 2019; Susam et al., 2018; Tork, 2017) were included in the meta-analysis, and two

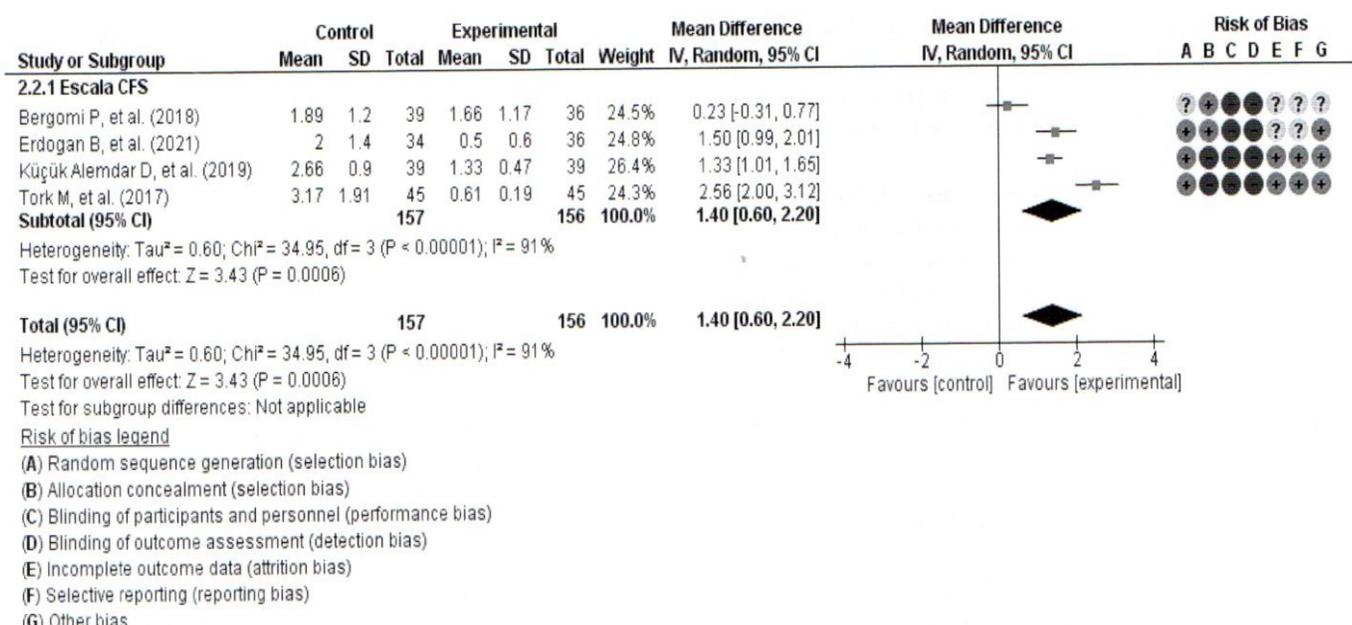


Fig. 4. Efficacy of Buzzy® in reducing anxiety during pediatric venipuncture. Made with RevMan 5.4.

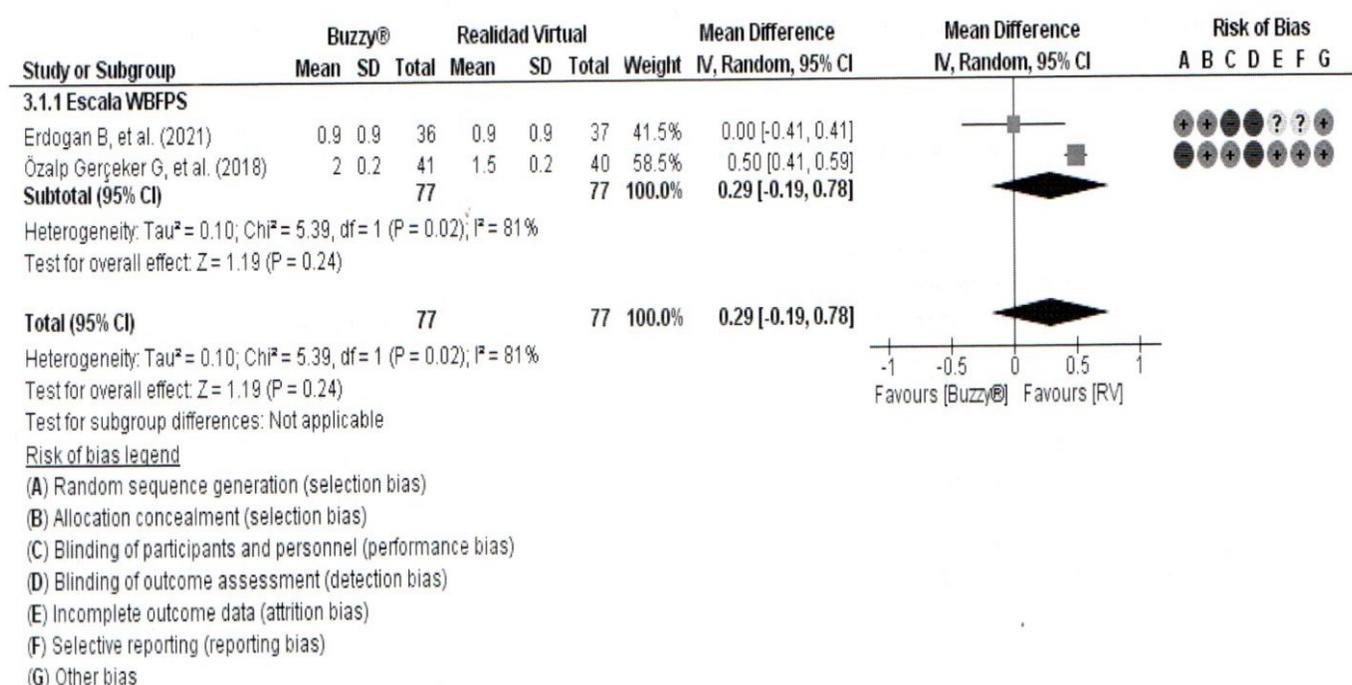


Fig. 5. VR Efficacy vs Buzzy® in pain management during pediatric venipuncture. Made with RevMan 5.4.

Adverse effects arising from the use of RV and/or the Buzzy® device

Three studies reported no adverse effects, whether nausea or discomfort, among the participants that used VR during the venipunctures (Atzori et al., 2018; Piskorz & Czub, 2018; Toledo et al., 2019). Those that pointed out adverse effects indicated that were unusual, that they represented a minority and that they were of low severity. Nausea (Chan et al., 2019; Dumoulin et al., 2019; Osmanlliu et al., 2021), cephalgia (Chan et al., 2019; Osmanlliu et al., 2021) and dizziness (Osmanlliu et al., 2021) were reported, although their levels were not significant for any of the study groups (p > 0.05; Control Group = 0.83 [σ = 3.74]; VR Group = 0.35 [σ = 0.99]) as they were below 1 in a scale from 0 to 10 (Atzori et al., 2022). Only one study reported possible adverse effects produced because of using cold and vibration devices (Bergomi et al., 2018), with no subsequent complications.

Cost-benefit ratio corresponding to the use of VR and/or the Buzzy® device

It was not possible to find enough information about the cost-benefit

ratio of both devices. However, the following stand out as advantages regarding VR use: its cost-effectiveness ratio and easy access (Erdogan & Aytekin Ozdemir, 2021); the high percentage of successful procedures in the first attempt (Erdogan & Aytekin-Ozdemir, 2021; Osmanlliu et al., 2021; Özalp-Gerçekler et al., 2020); uneventful procedures (İnangil et al., 2020); and unchanged duration of the procedure (Chan et al., 2019). Regarding the advantages of the Buzzy® device: its cost-effectiveness ratio (Cozzi et al., 2021; Tork, 2017) and the fact that it is easy to employ and reusable (Erdogan & Aytekin Ozdemir, 2021); on the other hand, its disadvantage corresponded to the replacement of some of its parts (Cozzi et al., 2021; Tork, 2017), such as the battery and the ice bags, which can increase its cost and requires time and money investments (Erdogan & Aytekin Ozdemir, 2021).

Discussion

This systematic review gathers the evidence from 21 published studies that show the effectiveness of both VR and Buzzy® on pain and anxiety, with significant differences when the experimental and control groups were compared. The different meta-analyses applied have

confirmed H_1 in all the cases, with high significance values. It was only in the comparison of both methods to verify the effectiveness of one against the other that the results and meta-analysis did not represent a considerable difference, therefore H_0 is confirmed: there is no significant difference between VR and Buzzy®.

In relation to VR and regarding pain, all the studies found significant differences when they compared the experimental and control groups, with lower pain levels and reducing the unpleasant sensation in the VR group, always with $p < 0.05$. This is line with the study by Sajeev et al. (2021), who obtained a significant reduction in anxiety [95% CI = $-0.61 (-0.88-(-0.34))$, $p < 0.001$ ($p < 0.05$)] and in pain [95% CI = $-0.43 (-0.67-(-0.20))$, $p < 0.001$ ($p < 0.05$)] in several procedures including venipunctures; with the study by Saliba et al. (2022), who also verified effectiveness against pain ([95% CI = $2.54 (0.14-4.93)$, $p = 0.038$ ($p < 0.05$)] and against fear or anxiety [95% CI = $0.89 (0.16-1.63)$, $p = 0.017$ ($p < 0.05$)] in children aged between 4 and 12 years old in the vascular access context; and with the study by Gates et al. (2020), where digital distraction enabled a modest but clinically important reduction in self-reported pain (Standardized Means Difference [SMD] of -0.48 ; 95% Confidence Interval [CI]: from -0.66 to -0.29 ; and 46 randomized controlled trials [RCTs]; $n = 3200$). Likewise, in the review by Birnie et al. (2018), it was shown that distraction does work; however, no data were found about what type of distraction is the most suitable for children based on their age, developmental stage or clinical environment.

On the other hand, regarding the cold and vibration devices, multiple studies have been conducted after the Buzzy® device was created in 2009, showing their effectiveness in pediatric venipunctures (Baxter et al., 2011) with significant results in reducing pain [95% CI = $-1.11 (-1.52-(-0.70))$, $p < 0.0001$ ($p < 0.05$)] and anxiety [95% CI = $-3.03 (-3.38-(-2.68))$, $p < 0.0001$ ($p < 0.05$)] in procedures involving needles (Ballard et al., 2019). This is also the case during peripheral intravenous cannulation in children aged from 7 to 12 years old (Canbulat et al., 2015) and in those with cognitive impairment (Schreiber et al., 2016). Finally, the systematic review published in 2021 corroborates favourable results in pain reduction [95% CI = $-1.3 (-1.9-(-0.7))$, $p < 0.00001$ ($p < 0.05$)] in children over the age of 2, although with the limitation of heterogeneity and scarcity of records about pediatric venipunctures (Su et al., 2021), where the results of all these studies were similar to the findings of this review (Erdogan & Ayttekin Ozdemir, 2021; Özalp, 2018).

In the same line of the systematic review, Lambert et al. (2020) found limited data about the adverse effects and other secondary results, which were either non-existent or showed very low incidence, without short and medium-term complications, and not significant when compared to the control group.

Likewise, in the current study it is made evident that there are high satisfaction levels with these techniques in the nursing personnel, in the parents participants and even in the children subjected to venipunctures, results that are similar to those found in the study by Ryu et al. (2022), where the parents' satisfaction with the process was higher in the VR group than in the control group ($p = 0.029$). In addition, the procedural difficulty degree was lower in the VR group when compared to the control group ($p = 0.026$) (Ryu et al., 2022), which is similar to the findings of this study, where nursing professionals indicate willingness to use the device again, thus easing performance of the venipunctures and also perceiving lower pain and anxiety levels in the children, in line with other recently published studies (Ali et al., 2022; Wong & Choi, 2023).

Likewise, although insufficient, the results in relation to the cost-benefit ratio both in the VR technique and in Buzzy® were encouraging in the studies found, showing the high percentage of successful first venipuncture attempts, easy use of the devices and unchanged duration of the procedure, in line with the study by Rezai et al. (2017), which showed that distraction was an effective and low-cost strategy with few side effects, affordable and appealing for pediatric patients

subjected to venipunctures. Other studies also suggest that the active forms of distraction (such as video games and Virtual Reality) might be more effective than passive distraction (such as cartoons and films), although this is not yet definitely established (Birnie et al., 2018; Sajeev et al., 2021), reason why it would be necessary to include this dimension in future studies.

Limitations

The studies included in the review present limitations. In the first place, non-blinding among participants, health personnel and evaluators. Secondly, the sample size is small; therefore, precautions should be taken when generalizing the results. The selection, publication and researcher biases associated with the review and meta-analysis itself are also acknowledged; for example, variability in the methodological quality or the level of evidence when selecting RCT, quasi-experimental and cohort studies. The high heterogeneity of the studies submitted to analysis ($I^2 > 75\%$ in all the comparisons made) can be due to disparity in the sample sizes. The fact that different scales were used to assess pain and anxiety, some of them different in terms of their application, measurement and scoring, which precluded their inclusion in the meta-analysis. No differentiation of the sample by sex was made, making it impossible to assess whether this variable has an influence.

Finally, the VR and Buzzy® devices are relatively recent, reason why there are few scientific publications, which limits the comparison between both techniques. Despite that, a systematic and in-depth search has been conducted, collecting the evidence to address the objectives set.

Implication for the clinical practice

This study brings together the latest available scientific evidence comparing new virtual reality techniques and cold/vibration devices during venipuncture. Integrating also, the perception and satisfaction of children, parents and nurses to determine if they are useful, easy methods that improve the daily nursing practice.

This study shows the effectiveness of the VR and Buzzy® devices for pain and anxiety in pediatric patients during venipunctures. Therefore, nurses (especially those specialized in Paediatrics) are encouraged to employ one of these two non-pharmacological and distraction methods. This might improve therapeutic rapport, in addition to offering humanized, good quality, optimum, safe, effective and affordable care, which would not only be able to relieve the symptoms during the procedure but also to reduce the previous, perceived and real stress levels, thus mitigating the long-term consequences such as fear or phobia to the puncture and invasive procedures performed by nurses. Likewise, employing and consolidating these novel tools may increase nurses' satisfaction levels at work, developing an innovative practice based on current scientific evidence. In addition, it might also increase the satisfaction levels in the patients subjected to the procedure and in their family members.

Likewise, researchers are encouraged to continue in this line of work to enhance knowledge about the VR and cold/vibration devices, especially in terms of the nurses' and parents' satisfaction levels, the adverse events and the cost-benefit ratio, in order to achieve extrapolatable results with greater scientific relevance.

Conclusion

It can be asserted that VR and the Buzzy® device are effective distraction methods for pain and anxiety relief during pediatric venous punctures. They do not only achieve adequate management of these symptoms but also favor proper development of the technique, they are cost-effective, do not produce any adverse effects, and pediatric patients, their parents and nursing professionals alike present high satisfaction levels with their use. However, more research is needed to further

substantiate the implementation of both devices. In addition, it would be of interest to assess differences by age range and sex.

CRedit authorship contribution statement

Carolina Merino-Lobato: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Resources, Software. **Isabel Rodríguez-Gallego:** Investigation, Methodology, Resources, Software. **Manuel Pabón-Carrasco:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Resources, Software. **Rocío Romero-Castillo:** Writing – review & editing. **Nerea Jiménez-Picón:** Supervision, Validation, Visualization, Writing – original draft.

Declaration of Competing Interest

The authors of this manuscript declare that they have no conflict of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.pedn.2023.08.014>.

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