Journal of Pediatric Nursing 58 (2021) e54–e62

Contents lists available at ScienceDirect

Journal of Pediatric Nursing

journal homepage: www.pediatricnursing.org

The Effect of Three Different Methods on Venipuncture Pain and Anxiety in Children: Distraction Cards, Virtual Reality, and Buzzy® (Randomized Controlled Trial)

Birgül Erdogan, MSc [a], Aynur Aytekin Ozdemir, PhD [b,*]

[a] Gazi University, Department of Nursing, Faculty of Health Sciences, Turkey
[b] Istanbul Medeniyet University, Department of Nursing, Turkey

ARTICLE INFO

Article history:
Received 6 May 2020
Revised 1 January 2021
Accepted 1 January 2021

Keywords:
Anxiety
Children
Nursing
Procedural pain

ABSTRACT

Purpose: The aim of this study was to determine the effect of the distraction cards, virtual reality and Buzzy® methods on venipuncture pain and anxiety in children aged 7–12 years.
Design and methods: This was a randomized controlled trial with parallel groups conducted between November 16, 2017 and August 14, 2018 at the pediatric venipuncture unit of a university hospital in Western Turkey. The sample consisted of 142 children who met the inclusion criteria. The experimental group consisted of 108 children divided into three groups: Distraction Cards (DC; $n = 35$), Virtual Reality (VR; $n = 37$), and Buzzy® ($n = 36$). The control group ($n = 34$) received no intervention during venipuncture. Data were collected using a descriptive characteristics form, and the Visual Analog Scale (VAS), Wong-Baker FACES, and Children's Fear Scale (CFS). The participants themselves and their parents and the researcher scored venipuncture pain and anxiety levels. The study was approved by the Ethics Committee. Permission was obtained from related institutions. Informed consent was obtained from parents. Verbal consent was obtained from children prior to participation.
Results: Buzzy® group had the lowest mean VAS score (2.2 ± 2.0), followed by the VR (2.7 ± 2.8), DC (3.4 ± 2.4), and control (5.2 ± 2.8) groups ($p < 0.05$). According to all raters (child, parent, and researcher), the Buzzy® group had the lowest mean Wong Baker FACES score, followed by the VR, DC, and control groups ($p < 0.05$). According to all raters, the Buzzy® group had the lowest mean CFS score, followed by the VR, DC, and control groups ($p < 0.05$).
Conclusions: The DC, VR, and Buzzy® methods were effective in reducing venipuncture pain and anxiety in children.
Practice implications: Nurses can use the DC, VR, and Buzzy® methods to help reduce venipuncture pain and anxiety in children.
The clinical trial registration number is NCT04421430. (https://clinicaltrials.gov/ct2/show/study/NCT04421430).

Introduction

Pediatric patients often undergo invasive procedures (intravenous catheterization, venipuncture, and immunization) that cause pain, anxiety, stress, and fear during diagnosis and treatment (Ali, McGrath, & Drendel, 2016; Babl et al., 2009; ENA Clinical Practice Guideline Committee, 2019; Farion, Splinter, Newhook, Gaboury, & Splinter, 2008). Pain has numerous physiological, mental, and emotional effects, and therefore, pain management during such procedures is of paramount importance (Ballard, Khadra, Adler, Trottier, & Le May, 2019; Brennan, Carr, & Cousins, 2007). The International Guide to Pediatric Anesthesia (Good Practice in Postoperative and Procedural Pain) recommends pharmacological and nonpharmacological methods for the effective management and prevention of acute procedural pain in children (Association of Pediatric Anesthesia (APA), 2012). For pain management, nonpharmacological methods are easy to use and cost- and time-effective with no side effects (Canbulat, Ayhan, & Inal, 2015). Studies have evaluated a large number of pharmacological and nonpharmacological interventions for procedural pain management in children. However, most of those interventions are not used by healthcare professionals because they are expensive, time-consuming, or hard to use (Ballard, Khadra, Adler, Doyon-Trottier, & Le May, 2018; Fein, Zempsky, & Cravero, 2012; Leahy et al., 2008). Therefore, easy-to-use, practical, non-invasive, cost-effective, and reusable nonpharmacological methods, such as distraction cards (DC), virtual reality (VR), and Buzzy®, can be used, especially in acute settings.

Distraction is considered a simple and effective method that can be used to distract children's attention from pain during medical

* Corresponding author.
E-mail addresses: b.erdogan@outlook.com (B. Erdogan), aynur.ozdemir@medeniyet.edu.tr (A. Aytekin Ozdemir).

https://doi.org/10.1016/j.pedn.2021.01.001
0882-5963/

procedures (Koller & Goldman, 2012). Distraction cards contain various hidden pictures and patterns (Flippits®, MMJ Labs, Atlanta; GA, USA) and are effective in phlebotomy pain management (Canbulat et al., 2015; Canbulat, Inal, & Sönmezer, 2014; Inal & Kelleci, 2012a; Sahiner & Bal, 2016). It was reported that DC with visual stimuli resulted in distraction from medical procedures and helped reduce perceived pain in children aged 6–12 years (Inal & Kelleci, 2012a). One study investigated the effect of DC on intramuscular injection pain and anxiety in children 6–11 years of age and reported that the DC group had lower pain and anxiety scores than controls (Canbulat Şahiner & Türkmen, 2019). Aydin and Sahiner (2017) looked into the effect of music therapy and DC on phlebotomy pain and anxiety in children aged 7–12 but found no significant difference in procedural pain and anxiety levels between the experimental and control groups.

Virtual reality (VR) is a safe and cost-effective distraction method used in painful procedures in children. VR is a computer-based 3D virtual environment (Arane, Behboudi, & Goldman, 2017). Conventional VR systems include a head-mounted device with 3D-enabled goggles, sensory input devices, headphones, or body tracking sensors, allowing for a multisensory experience (Li et al., 2017; Pourmand, Davis, Marchak, Whiteside, & Sikka, 2018). It appeals to different age groups and can be adapted to mobile phones, and therefore, can be used easily in pediatric care units (Arane et al., 2017; Gerçeker, Ayar, Özdemir, & Bektaş, 2020; Gupta, Scott, & Dukewich, 2018). It reduces pain and anxiety during medical procedures in children, thereby ensuring better adaptation and treatment adherence (Mahrer, 2018). To date, only a handful of randomized controlled trials (RCTs) have investigated the effect of VR on venipuncture/phlebotomy pain management and reported that it helps reduce pain and/or anxiety during venipuncture/phlebotomy procedures (Aminabadi, Erfanparast, Sohrabi, Oskouei, & Naghili, 2012; Chan et al., 2019; Dunn et al., 2019; Gerçeker et al., 2020; Gerçeker, Binay, Bilsin, Kahraman, & Yılmaz, 2018; Mahrer, 2018). According to a systematic review and meta-analysis of the effect of VR on pain and anxiety, although some studies address the effectiveness of VR on pain, there are very few studies examining its effect on anxiety, hence, calling for further research (Eijlers et al., 2019).

Buzzy® (MMJ Labs, Atlanta, GE, ABD) is an easy-to-use, reusable, and fast device designed to reduce injection pain in children. It is a bee-shaped device consisting of a body and wings. The body part vibrates, while the wings apply concentrated cold at the injection site before the shot (Ballard et al., 2019). Research in the last decade has focused on Buzzy® and reported that it is effective in injection pain and anxiety management in children (Baxter, Leong, & Mathew, 2009; Canbulat et al., 2015; Gerçeker, Binay, et al., 2018; Inal & Kelleci, 2012a; Moadad, Kozman, Shahine, Ohanian, & Badr, 2016; Potts, Davis, Elci, & Fein, 2019; Redfern, Chen, & Sibrel, 2018; Schreiber et al., 2016; Whelan, Kunselman, Thomas, Moore, & Tamburro, 2014). A systematic review shows that Buzzy® can easily be used for injection pain management in clinical practice, but that more RCTs are needed to gain more insight into the effectiveness of Buzzy® due to limited quality evidence in the literature (Ballard et al., 2019).

Pain and anxiety management requires a multidisciplinary team, of which nurses are a crucial part. The American Society for Pain Management Nursing (ASPMN) stipulates that nurses are responsible for using pharmacological and nonpharmacological methods for pain management before, during, and after painful procedures (Czarnecki et al., 2011). Therefore, this study aimed to determine the effect of three different methods (DC, VR, and Buzzy®) on venipuncture pain and anxiety in children aged 7–12 years.

Research hypotheses

The hypotheses were as follows:

H_1. The DC group will have less venipuncture pain than the control group.

H_2. The DC group will have less venipuncture anxiety than the control group.

H_3. The VR group will have less venipuncture pain than the control group.

H_4. The VR group will have less venipuncture anxiety than the control group.

H_5. The Buzzy® group will have less venipuncture pain than the control group.

H_6. The Buzzy® group will have less venipuncture anxiety than the control group.

H_7. The DC, VR, and Buzzy® methods will affect venipuncture pain in children at varying levels.

H_8. The DC, VR, and Buzzy® methods will affect venipuncture anxiety in children at varying levels.

Methods

Design and setting

This was an RCT with parallel groups conducted between November 16, 2017 and August 14, 2018 at the pediatric venipuncture unit of a university hospital in Western Turkey (ClinicalTrials.gov registration). The study adhered to the CONSORT guidelines (Schulz, Altman, Moher, & CONSORT Group, 2010). Using a block randomization method, 160 children aged 7–12 years were randomized into four groups; Distraction Cards (DC; $n = 35$), Virtual Reality (VR; $n = 37$), Buzzy® ($n = 36$), and control ($n = 34$). It was the age group of choice because children of that age group are open to co-operation and are curious about technology.

Sample size and randomization

Power analysis was performed using G*Power to ascertain whether the number of samples would be sufficient to detect significant differences. The power analysis revealed a power of 98% with an effect size of 0.40 (large) at a significance level of 0.05 (Faul, 2014), indicating that a sample size of 160 would be sufficient to detect significant differences. Six children from the control group, five from the DC group, three from the VR group, and four from the Buzzy® group were excluded from the study either because venipuncture could not be completed at the first attempt or because children or their parents withdrew from the study. Therefore, the final sample consisted of 142 children. Fig. 1 shows the flow diagram of sampling.

Research shows that age, gender, and fear affect procedural pain and anxiety in children (Ball, Bindler, & Cowen, 2010; Twycross, 2009). Therefore, the variables of age (7–9 and 10–12 years), gender (girls and boys), and fear of procedure (yes and no) were used for block randomization. The blocks were repeated five times in each group, and 40 participants were assigned to each. A 2X2X2X5 blocked randomization list was developed using an online randomization tool (Sealed Envelope Ltd., 2018). The researcher was not blinded to the group allocation because she performed the randomization herself.

Participants

The inclusion criteria were (1) being between the ages of 7 to 12 years, (2) literate, and (3) requiring blood tests. The exclusion

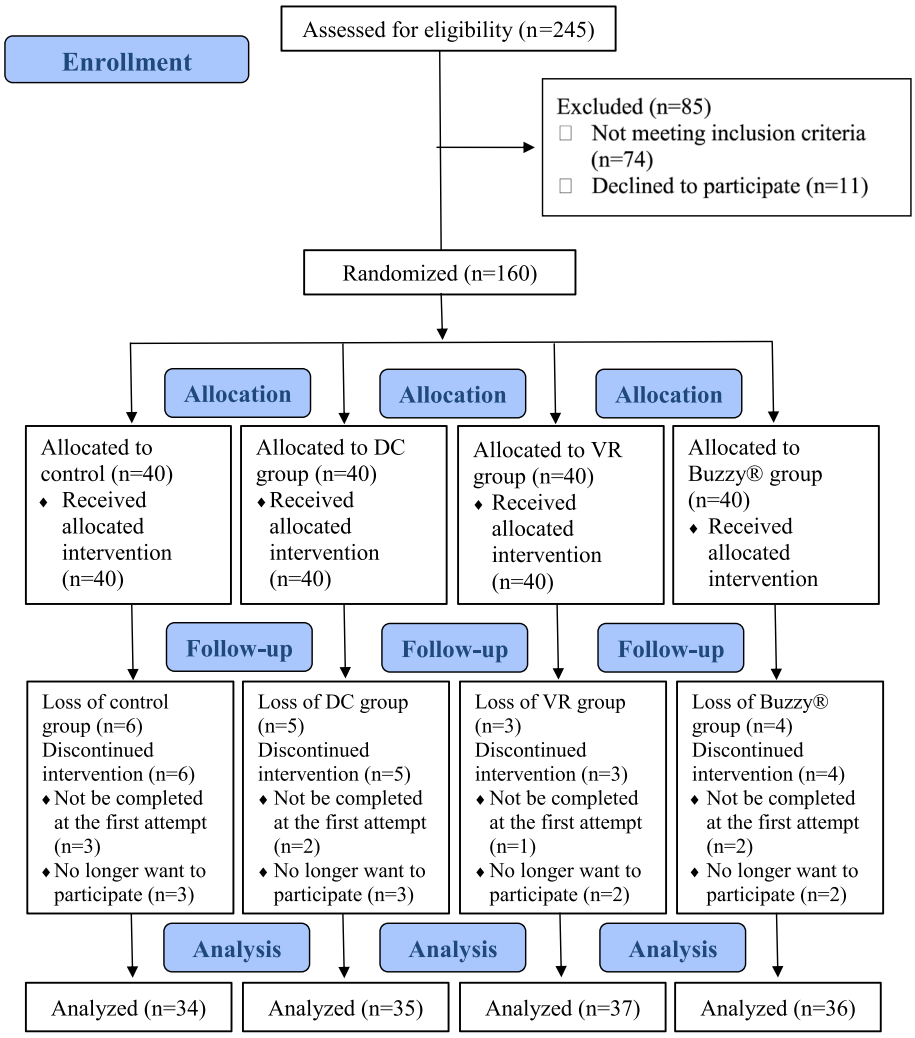

Fig. 1. Flow of study.

criteria were (1) having chronic diseases, (2) hospital stay for treatment, (3) visual, audio, or speech impairments, (4) mental disorders, (5) history of sedative, analgesic, or narcotic use within 24 h before admission, and (6) inflammatory disease during admission (Fig. 1).

Ethical considerations

The study was approved by the Ethics Committee. Permission was obtained from the institution. Participants were informed about the purpose and procedure of the study prior to participation and that they could withdraw from the study at any time without explanation. Informed consent was obtained from parents. Verbal consent was obtained from children prior to participation.

Data collection tools

Data were collected by the researchers using a descriptive characteristics form, and the Visual Analog Scale, the Wong-Baker FACES Pain Rating Scale, and the Children's Fear Scale. The descriptive characteristics form was based on a literature review to elicit information on children's and their parents' descriptive characteristics (Aydin, Şahiner, & Ciftci, 2016; Canbulat et al., 2015; Redfern et al., 2018).

Visual analog scale (VAS)

The Visual Analog Scale (VAS) developed by Hayes and Patterson (1921) is used to measure and monitor pain intensity. It is a 10 cm or 100 mm long horizontal or vertical line with anchor statements “no pain or pain at its least” at the left-most end and “unbearable pain or worst pain imaginable” at the right-most end. The participant is asked to mark a point on the line that best represents their pain level. The VAS score is determined by measuring (in cm) the distance of the mark from the left end of the line. VAS is an easy-to-understand and easy-to-measure scale for children aged seven or older (Wewers & Lowe, 1990).

Wong-Baker FACES pain rating scale (WB-FACES)

The Wong-Baker FACES Pain Rating Scale (WB-FACES) was developed by Wong and Baker in 1981 and revised in 1983. The scale is used to diagnose pain in children aged 3–18 years. It consists of six facial expressions, each one representing an increasing degree of pain scored on a scale 0 to 5 from left to right (0 = very happy/no pain, 5 = the worst pain imaginable). The first face is a happy face representing “no pain” (0), while the last face is a crying face representing “the worst pain imaginable” (5). Higher scores indicate low pain tolerance. Participants are asked to choose the facial expression that best represents

Fig. 2. WB-FACES (Wong & Baker, 1988).

their pain (Fig. 2) (Wong & Baker, 1988). The WB-FACES is a robust measure for the Turkish population (Gerçeker et al., 2020; Sahiner & Bal, 2016; Sahiner, Inal, & Akbay, 2015). The scale was assessed using self-report and reports from the parents and the researcher in this study.

Children's Fear Scale (CFS)

The Children's Fear Scale (CFS) was developed by McMurtry, Noel, Chambers, and McGrath (2011) and adapted to Turkish by Gerçeker, Binay, et al. (2018). It consists of five facial expressions representing a range from neutral (0) to extreme fear (4). Both researchers and family members can use the CFS to measure fear and anxiety in children before and during procedures (Fig. 3) (McMurtry et al., 2011).

Distraction Cards (DC)

The Distraction Cards (DC) (Flippits1, MMJ Labs, Atlanta, Georgia, ABD) contain various hidden pictures and patterns visible only when looked at carefully. During a procedure, the child is expected to focus on the cards and answer the questions asked about what they see in them (Aydin et al., 2016; Inal & Kelleci, 2012a). In this study, DCs with 5 × 8 cm pictures and shapes were used (Fig. 4).

Virtual Reality (VR)

Virtual reality (VR) isolates the user from real life and allows them to visit a three-dimensional world. Virtual reality is a 360-degree audiovisual simulation that surrounds the user and allows them to look around in all directions (Minute et al., 2012). In this study, the VR intervention was performed using a smartphone (Samsung Galaxy Note 5 N920, Android 5.1.1, Lollipop Processor: Quad-core 1.5 GHz Cortex-A53 & Quad-core 2.1 GHz Cortex-A57), VR glasses (7.66 × 5.50 × 4.32 in., weigh 0.414 kg, Cyber, VR BOX 3.0), and a headset (Samsung Galaxy, microphone, Bluetooth, wired). The VR intervention was a 3D Dinosaur animation appropriate for the age group. The VR glasses have a 4–6 in screen compatible with IOS/Android operating systems and smartphones.

Fig. 4. Distraction cards (Flippits1, MMJ Labs, Atlanta, Georgia, ABD).

Buzzy®

In this study, Buzzy® (MMJ Labs, Atlanta, Georgia, USA) was used for local cold application and vibration as a pain relief measure (Fig. 5). Buzzy® applies high-frequency vibration and concentrated cold at the injection site for procedural pain management and distraction before the shot in children and adults. Buzzy® is an 8X5X2.5 cm reusable medical device with a battery for vibration and cold application. It has ice-pack wings to numb the injection site before the shot. The ice pack is stored in the freezer and inserted into the device before the procedure. After the procedure, it is wiped up with 70% alcohol and then put back in the freezer (Baxter et al., 2009).

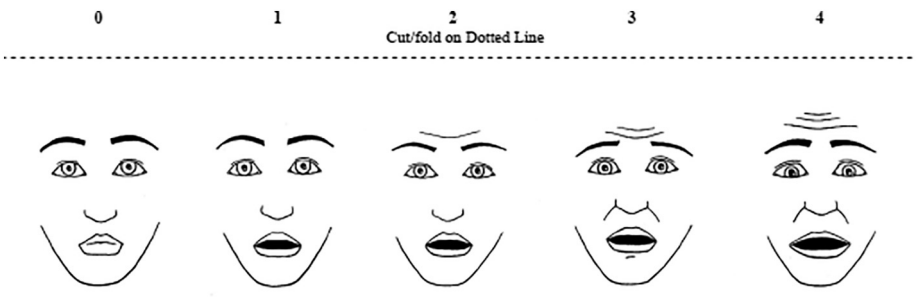

Fig. 3. Children's Fear Scale (McMurtry et al., 2011).

Fig. 5. Buzzy® (MMJ Labs, Atlanta, Georgia, USA).

Cold application and vibration begin before the procedure and continue until the end. Vibration causes numbness, paranesthesia, and anesthesia, and thereby reducing or eliminating pain. Cold application slows or blocks the electrical signals in the peripheral nerves, and hence, reduces pain, and also activates the gate-control mechanism and stimulates the touch receptors, increasing the release of endogenous opioids, and thus, provides pain relief (Dickenson, 1995).

Procedure

The blood collection room, which was decorated with cartoon characters and animated visual elements, consisted of three pediatric venipuncture units, each of which had a nurse. Only one of those units was used in the study. Each participant was admitted to the unit with their parent seated in the chair next to the venipuncture seat. The venipuncture unit had the same environmental conditions (phlebotomy seat, heat, light, noise, etc.).

The researcher used the descriptive characteristics form in face-to-face interviews to collect data on participants and their families. Data collection lasted about five minutes. Participants were randomly assigned to the groups. The researcher informed the participants and their parents about the nonpharmacological methods and the scales (VAS, WB-FACES, and CFS).

Venipuncture was performed by a volunteer nurse with at least five years of experience in pediatric venipuncture in accordance with the procedures of the venipuncture unit. The nurse did not have a conflict of interest. The same pediatrician made the venipuncture decision. No pharmacological painkillers were administered before, during, or after venipuncture. Venipuncture was performed on the first try at the antecubital site using a 21 Gauge × 1.5-in. needle. The procedure adhered to the procedures of the blood collection service.

Immediately after the procedure, participants completed the VAS and WB-FACES (pain levels) and CFS (anxiety levels). Meanwhile, a volunteer parent and the researcher observed the participants' behavior and completed the WB-FACES and CFS. The procedure took about three minutes in all groups.

The control group ($n = 34$): The control group received the routine venipuncture procedure and did not receive any other nonpharmacological intervention.

The distraction card group ($n = 35$): Just before the venipuncture, participants were allowed to check the cards and were asked what they saw in them. The distraction interventions started just before the venipuncture and continued until the end of the procedure. Participants were asked several questions, such as "How many eyes can you find?, How many big red dots in squares do you see?, and How many small black dots are above the diamonds?," to which only those who checked the cards carefully could provide correct answers. The questions were translated into Turkish by an English-speaking expert because participants did not speak English. The DC intervention and venipuncture were terminated at the same time.

The virtual reality group ($n = 37$): The VD participants put on the VR glasses and headsets about two minutes before the venipuncture and watched the 3D Dinosaur Animation movie throughout the procedure. The VR intervention and venipuncture were terminated at the same time.

The Buzzy® group ($n = 36$): Buzzy® was placed on the injection site (antecubital fossa) of the Buzzy® participants, and cold application and vibration were turned on 60 s before the procedure. After the 60 s, the nurse moved Buzzy® about 3 cm above the injection site and applied a tourniquet and performed the procedure. Buzzy® was on throughout the procedure. The Buzzy® intervention and venipuncture were terminated at the same time.

Analysis

Data were analyzed using the Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, USA) for Windows (version 18.0) at a significance level of 0.05. Normality was tested using skewness and kurtosis coefficients. The results indicated that the data were normally distributed. Data were analyzed using percentage distributions, mean, standard deviation, chi-square test, variance analysis, and effect size. For further analysis, group variances were determined using Levene's test. A post hoc Bonferroni test was used in the case of equal variances, while Dunnett's T3 pairwise comparison post hoc test was used to determine significant differences in the case of unequal variances.

Results

The mean age of participants ($n = 142$) was 9.38 ± 1.65 years (min: 7; max: 12 years). The DC, VR, Buzzy®, and control participants had a mean age of 9.20 ± 1.62, 9.48 ± 1.75, 9.44 ± 1.66, and 9.38 ± 1.63, respectively. Half of the controls were aged 7 to 9 years, 52.9% were girls, and 52.9% stated that they were not afraid of getting shots. More than half of DC participants (54.3%) were aged 7 to 9 years, 51.4% were girls, and 54.3% stated that they were afraid of getting shots. More than half of VD participants (54.1%) were aged 10 to 12 years, 54.1% were boys, and 51.4% stated that they were afraid of getting shots. More than half of Buzzy® participants (55.6%) were aged 7 to 9 years, 52.8% were girls, and half of them stated that they were not afraid of getting shots. Participants were compared in terms of mean age, age group, gender, and fear of venipuncture. There was no statistically significant difference between the control, DC, VR, and Buzzy® groups ($p > 0.05$) (Table 1).

The groups were compared for their mean VAS, WB-FACES, and CFS scores (Table 2). Participants (self-report) and their parents and the researcher completed the scales. The Buzzy® group had the lowest mean pain score (VAS = 2.2 ± 2.0; WB-FACES / self-report = 0.9 ± 0.9, parent-report = 0.8 ± 0.9 and researcher report = 0.8 ± 0.9), followed by the VR, DC, and control groups. There was a significant difference in pain scores between the groups ($p < 0.05$). The effect sizes were as follows: $\eta 2$(VAS) = 0.157 (small effect size), $\eta 2$(WB-FACES/self-report) =0.215 (small effect size), $\eta 2$(WB-FACES/parent-report) =0.462 (medium effect size), $\eta 2$(WB-FACES/researcher-report) = 0.516 (medium effect size) (Table 2).

The Buzzy® group had the lowest mean anxiety score (self-report = 0.5 ± 0.6, parent-report = 0.5 ± 0.6 and researcher report = 0.5 ± 0.6), followed by the VR, DC, and control groups. There was a significant difference in anxiety scores between the groups ($p < 0.05$). The effect sizes

Table 1
Comparison of groups according to the children's descriptive characteristics and venipuncture-related characteristics.

Characteristics	Control group (n = 34)		DC group (n = 35)		VR group (n = 37)		Buzzy® group (n = 36)		χ2	p
	n	%	n	%	n	%	n	%		
Age (Mean ± SD)[a]	9.38 ± 1.63		9.20 ± 1.62		9.48 ± 1.75		9.44 ± 1.66		F = 0.203	0.894
Age group										0.842
7–9 years	17	50.0	19	54.3	17	45.9	20	55.6	0.833	
10–12 years	17	50.0	16	45.7	20	54.1	16	44.4		
Gender										0.925
Female	18	52.9	18	51.4	17	45.9	19	52.8	0.472	
Male	16	47.1	17	48.6	20	54.1	17	47.2		
Fear of venipuncture										0.946
Yes	16	47.1	19	54.3	19	51.4	18	50.0	0.374	
No	18	52.9	16	45.7	18	48.6	18	50.0		
Total	**34**	**100.0**	**35**	**100.0**	**37**	**100.0**	**36**	**100.0**		

[a] Mean ± Standard Deviation.

were as follows: η2(CFS/self-report) =0.255 (medium effect size), η2 (CFS/parent-report) =0.400 (medium effect size), η2(CFS/researcher-report) =0.503 (medium effect size) (Table 2).

The groups were compared pairwise for their mean VAS, WB-FACES, and CFS scores (Table 3). According to all raters, there was a statistically significant difference in pain and anxiety scores between all experimental groups and controls ($p < 0.05$). According to the parent and researcher report, there was a significant difference in pain scores between the DC and Buzzy® groups ($p < 0.05$). According to all raters, there was a significant difference in anxiety scores between the DC and Buzzy® groups ($p < 0.05$). There was no significant difference in pain and anxiety scores between the DC and VR groups and between the VR and Buzzy® groups ($p > 0.05$) (Table 3).

Discussion

This study investigated the effect of three nonpharmacological methods (DC, VR, and Buzzy®) on venipuncture pain and anxiety in children 7–12 years of age. This is the first study to examine and compare the performance of DC, VR, and Buzzy® methods on venipuncture pain and anxiety in children. Besides, venipuncture pain and anxiety were assessed by the participants themselves, their parents, and the researcher. The results show that all three methods help reduce venipuncture pain and anxiety in children.

Distraction cards are an effective distraction method used in medical procedures (Canbulat et al., 2015; Inal & Kelleci, 2012a). Our results show that the DC participants had lower pain and anxiety scores than controls. This result supported the first and second hypothesis (The DC group will have less venipuncture pain and anxiety than the control group). Few RCTs investigate the effect of DC on venipuncture pain or anxiety in children of similar age group (Aydin et al., 2016; Aydin & Sahiner, 2017; Canbulat et al., 2014; Inal & Kelleci, 2012a; Inal & Kelleci, 2020; Sahiner & Bal, 2016; Tork, 2017). Those studies have reported that DC helps with IV procedure (venipuncture, phlebotomy) pain and anxiety in children (Canbulat et al., 2014; Inal & Kelleci, 2012a; Inal & Kelleci, 2020; Sahiner & Bal, 2016; Tork, 2017). Another RCT divided children 6–12 years of age ($n = 218$) into four groups (control, Buzzy®, DC and Buzzy® + DC groups) and examined the effect of those distraction methods on venipuncture pain and reported that the DC and Buzzy® + DC groups had lower pain scores than controls (Inal & Kelleci, 2020). Tork (2017) investigated the effect of three distraction methods (Buzzy®, DC, and balloon inflating) on venipuncture pain and anxiety relief in children 7–12 years of age and reported that the DC group had lower pain and anxiety scores than controls. Our results confirm the results of earlier RCTs.

Our results showed that VR is another effective method that helps reduce venipuncture pain and anxiety in children. This result supported the third and fourth hypothesis (The VR group will have less venipuncture pain and anxiety than the control group). Few RCTs investigate the effect of VR on venipuncture/phlebotomy pain and anxiety management in children (Chan et al., 2019; Gerçeker et al., 2020; Gerçeker, Binay, et al., 2018; Mahrer, 2018), and only two of them address the effect of VR on both procedural pain and procedural anxiety (Gerçeker et al., 2020; Mahrer, 2018). Eijlers et al. (2019) conducted a systematic review and meta-analysis of the effect of VR on pain and anxiety in children and suggested that more research is warranted. Gerçeker et al. (2020) focused on the effect of VR on venipuncture pain, fear, and anxiety in children 5–12 years of age ($n = 136$) and concluded that VR is effective in venipuncture pain, fear, and anxiety relief. Mahrer (2018) examined the effect of VR on venipuncture pain, anxiety, and satisfaction in children 10–21 years of age ($n = 143$) and reported that VR helped reduce acute procedural pain and anxiety, confirming the results of two earlier RCTs.

This study also investigated the effect of Buzzy® on venipuncture pain and anxiety relief in children. Buzzy® is an easy-to-use, fast, non-invasive, cost-effective, and reusable method for procedural pain and

Table 2
Comparison of procedural pain and anxiety scores of the study groups.

Scale	Reporter	Control group (n = 34)	DC group (n = 35)	VR group (n = 37)	Buzzy® group (n = 36)	F	p	Effect size (η2)	95% CI
		Mean ± SD[a]	Mean ± SD	Mean ± SD	Mean ± SD				
VAS	Self-report	5.2 ± 2.8	3.4 ± 2.4	2.7 ± 2.8	2.2 ± 2.0	8.537	**<0.001**	0.157	2.93–3.85
WB-FACES	Self-report	2.5 ± 1.7	1.4 ± 1.2	0.9 ± 0.9	0.9 ± 0.9	12.635	**<0.001**	0.215	1.21–1.68
	Parent report	3.3 ± 1.3	1.6 ± 1.3	0.8 ± 0.9	0.8 ± 0.9	39.486	**<0.001**	0.462	1.38–1.89
	Researcher report	3.5 ± 1.1	1.6 ± 1.3	0.8 ± 0.9	0.8 ± 0.9	49.123	**<0.001**	0.516	1.43–1.94
CFS	Self-report	2.0 ± 1.4	1.2 ± 0.9	0.7 ± 0.7	0.5 ± 0.6	15.753	**<0.001**	0.255	0.94–1.32
	Parent report	2.6 ± 1.3	1.3 ± 1.0	0.8 ± 0.8	0.5 ± 0.6	30.625	**<0.001**	0.400	1.08–1.50
	Researcher report	2.8 ± 1.0	1.2 ± 0.9	0.7 ± 0.8	0.5 ± 0.6	46.575	**<0.001**	0.503	1.11–1.53

[a] Mean ± Standard Deviation.

Table 3
Pairwise comparisons of the study groups.

Scale	Reporter	Control-DC	Control-VR	Control-Buzzy®	DC-VR	DC- Buzzy®	VR- Buzzy®
		p	*p*	*p*	*p*	*p*	*p*
VAS	Self-report	**0.029**	**0.001**	**0.000**	1.000	0.373	1.000
WB-FACES	Self-report	**0.025**	**0.000**	**0.000**	0.307	0.274	1.000
	Parent report	**0.000**	**0.000**	**0.000**	0.059	**0.027**	0.999
	Researcher report	**0.000**	**0.000**	**0.000**	0.050	**0.022**	0.999
CFS	Self-report	**0.025**	**0.000**	**0.000**	0.158	**0.021**	0.948
	Parent report	**0.000**	**0.000**	**0.000**	0.157	**0.002**	0.533
	Researcher report	**0.000**	**0.000**	**0.000**	0.152	**0.004**	1.000

These *p*-values are corrected for multiple comparisons as promised in the data analysis.

anxiety management, especially in acute care settings where there is limited time to prepare for injection procedures (Ballard et al., 2019). Our results showed that the Buzzy® group had significantly lower venipuncture pain and anxiety scores than the control group. This result supported the fifth and sixth hypothesis (The Buzzy® group will have less venipuncture pain and anxiety than the control group). Few RCTs investigate the effect of Buzzy® on IV (venipuncture/phlebotomy) pain and anxiety in children of similar age in our study (Bergamo, Scudeller, Pintaldi, & Molin, 2018; Canbulat et al., 2015; Gerçeker, Binay, et al., 2018; Inal & Kelleci, 2012b; Inal & Kelleci, 2020; Moadad et al., 2016; Tork, 2017). Most of those trials focus on the effect of Buzzy® on procedural pain, whereas only a few address the effect of Buzzy® on procedural anxiety (Bergamo et al., 2018; Canbulat et al., 2015; Inal & Kelleci, 2012b; Tork, 2017). Earlier studies have shown that Buzzy® helps with IV (venipuncture, phlebotomy) pain and anxiety in children. Ballard et al. (2019) conducted a systematic review to investigate the effect of Buzzy® on injection pain management and argued that studies in this area offered limited quality evidence, and therefore, more RCTs are warranted to better understand the effect of Buzzy® on procedural pain and anxiety (Ballard et al., 2019).

Bergamo et al. (2018) looked into the effect of nonpharmacological methods (Buzzy®, cartoons, Buzzy® + cartoons) on venipuncture pain management in children 5–12 years of age ($n = 160$). They found that all those nonpharmacological methods were effective in venipuncture pain and anxiety relief in children. Another RCT investigated the effect of three methods (Buzzy®, DC, and balloon inflating) on venipuncture pain and anxiety relief in children 7–12 years of age ($n = 180$) and reported that the Buzzy® group had lower pain and anxiety scores than the control group (Tork, 2017). Canbulat et al. (2015) ($n = 176$) and Inal and Kelleci (2012b) ($n = 120$) found that Buzzy® helped reduce venipuncture pain and anxiety in children. Our results confirm the results of earlier RCTs.

Distraction cards and virtual reality helped reduce venipuncture pain and anxiety in children. According to McCaul and Malott (1984), the brain has a limited capacity to concentrate on external stimuli, and thus, focusing on a distracting task reduces its capacity to pay attention to painful stimuli. They also suggest that distraction triggers an internal pain suppression system and alters nociceptive responses. Buzzy® applies vibration and cold to reduce procedural pain, which can be accounted for by the gate control theory (Melzack & Wall, 1965), which suggests that pain is transmitted from the peripheral nervous system to the central nervous system, where it is modulated by a gate system in the dorsal horn of the spinal cord. The afferent pain-receptive nerves (A-delta fibers carrying acute pain and unmyelinated slower C fibers carrying chronic pain messages) are blocked by fast non-noxious motion nerves (A-beta) (Kakigi & Shibasaki, 1992). Prolonged cold stimulates the C fibers and may block the A-delta pain signals. Cold may also activate supraspinal mechanisms, raising the overall pain threshold (Nahra & Plaghki, 2005). There is a positive correlation between procedural pain and anxiety, and therefore, interventions for reducing procedural pain impact procedural anxiety as well (Twycross, 2009). This can explain why DC, VR, and Buzzy® effectively reduced venipuncture pain and anxiety in children.

All groups were compared pairwise. The results showed that all experimental groups (DC, VR, and Buzzy®) had lower pain and anxiety scores than controls. The comparison of all nonpharmacological methods showed that Buzzy® is better at reducing procedural pain and anxiety than DC, according to the parents' and researcher's report. This result supported the seventh and eighth hypothesis (The DC, VR, and Buzzy® methods will affect venipuncture pain and anxiety in children at varying levels). Buzzy® shows both external thermomechanical stimulation and distraction effects in children (Canbulat et al., 2015; Moadad et al., 2016). Buzzy® is more effective in reducing procedural pain and anxiety than DC, which can be accounted for by the bidirectional nonpharmacological effect of the former. Gerçeker, Ayar, Özdemir, and Bektaş (2018) compared the groups pairwise and found a significant difference in pain scores between the VR and Buzzy® groups and the control groups but found no difference in pain scores between the VR and Buzzy® groups. Inal and Kelleci (2020) found that Buzzy® was more effective than DC. Our results also support these two studies.

The advantages of DC and VR are that they are cost-effective, reusable, and easy to access. However, they have two disadvantages. First, apart from the nurse performing the painful intervention, additional staff should be present to manage DC and VR. Second, hygiene measures to eliminate the risk of infection may be money- and time- consuming (Aydin et al., 2016; Canbulat et al., 2015; Chan et al., 2019; Gerçeker et al., 2020; Inal & Kelleci, 2020; Mahrer, 2018; Tork, 2017).

The strengths of Buzzy® are that it is user-friendly, reusable, fast, and does not require any staff other than the nurse performing the painful intervention. However, it is more costly than the other two methods because its battery and 100-use ice-pack wings should be periodically replaced. Its another weakness is that hygiene measures to eliminate the risk of infection may be money- and time- consuming (Ballard et al., 2019; Bergamo et al., 2018; Tork, 2017). Although Buzzy® is an expensive method, its advantages should not be overlooked. Besides, DC and VR require more staff other than nurses performing the intervention, which is an additional financial burden. Earlier studies have also shown that Buzzy® is better at reducing procedural pain in children than other nonpharmacological methods, which is also confirmed by our results (Bergamo et al., 2018; Gerçeker, Binay, et al., 2018; Inal & Kelleci, 2012b; Inal & Kelleci, 2020; Moadad et al., 2016; Tork, 2017). Therefore, Buzzy® is a promising method for pain reduction. Children's age, developmental stage, interests, and preferences should be taken into account to choose the best nonpharmacological method to reduce procedural pain and anxiety in children (Koller & Goldman, 2012).

Implications for nursing practice

The DC, VR, and Buzzy® methods can be safely used for venipuncture pain and anxiety relief in children. Those methods significantly

reduced our participants' venipuncture pain and anxiety. Buzzy® was more effective than DC. Future studies should investigate the effects of those nonpharmacological methods on different painful procedures in children of different ages and also conduct cost-performance analysis. Evidence-based guidelines and protocols should be developed to use those nonpharmacological methods for procedural pain and anxiety management in clinics.

Limitations

The study has three limitations. First, it was not double-blinded because the researcher herself randomized the participants into the groups. However, pain and anxiety levels were scored by more than one rater to reduce researcher bias. Second, the participants, their parents, and the researcher were not blind to the assessment of pain and anxiety. Third, the sample size was small, and therefore, the results are sample-specific and not generalizable to all venipuncture procedures in children.

Conclusions

The DC, VR, and Buzzy® groups had less procedural pain and anxiety than controls, indicating that they are effective methods that can be used to reduce procedural pain and anxiety. Buzzy® is more effective than DC. The fact that venipuncture pain and anxiety were assessed by three different raters (child, parent, and researcher) makes the evidence more cogent. This is the first randomized control trial to investigate the effect of DC, VR, and Buzzy® on venipuncture pain and anxiety in children. The results indicate that those methods can be safely used for venipuncture pain and anxiety management in children 7–12 years of age. It is now time to explore how to integrate those methods into painful interventions.

Funding

No funding.

Declaration of Competing Interest

The author declares that there is no conflict of interest.

References

Ali, S., McGrath, T., & Drendel, A. L. (2016). An evidence-based approach to minimizing acute procedural pain in the emergency department and beyond. *Pediatric Emergency Care*, *32*(1), 36–42. https://doi.org/10.1097/PEC.0000000000000669.

Aminabadi, N. A., Erfanparast, L., Sohrabi, A., Oskouei, S. G., & Naghili, A. (2012). The impact of virtual reality distraction on pain and anxiety during dental treatment in 4–6 year-old children: a randomized controlled clinical trial. *Journal of Dental Research, Dental Clinics, Dental Prospects*, *6*(4), 117. https://doi.org/10.5681/joddd.2012.025.

Arane, K., Behboudi, A., & Goldman, R. D. (2017). Virtual reality for pain and anxiety management in children. *Canadian Family Physician*, *63*(12), 932–934 https://www.cfp.ca/content/63/12/932.full.

Association of Paediatric Anaesthesia (APA) (2012). Good practice in postoperative and procedural pain management, 2nd edition. *Pediatric Anesthesia*, *22*(1), 1–79. https://doi.org/10.1111/j.1460-9592.2012.03838.x.

Aydin, D., & Sahiner, N. C. (2017). Effects of music therapy and distraction cards on pain relief during phlebotomy in children. *Applied Nursing Research*, *33*, 164–168. https://doi.org/10.1016/j.apnr.2016.11.011.

Aydin, D., Şahiner, N. C., & Ciftci, E. K. (2016). Comparison of the effectiveness of three different methods in decreasing pain during venipuncture in children: Ball squeezing, balloon inflating and distraction cards. *Journal of Clinical Nursing*, *25*(15–16), 2328–2335. https://doi.org/10.1111/jocn.13321.

Babl, F. E., Goldfinch, C., Mandrawa, C., Crellin, D., O'Sullivan, R., & Donath, S. (2009). Does nebulized lidocaine reduce the pain and distress of nasogastric tube insertion in young children? A randomized, double-blind, placebo-controlled trial. *Pediatrics*, *123*(6), 1548–1555. https://doi.org/10.1542/peds.2008-1897.

Ball, J. W., Bindler, R. C., & Cowen, K. J. (2010). *Child health nursing: Partnering with children and families* (2 th ed.). London: Pearson Education (Chapter 2).

Ballard, A., Khadra, C., Adler, S., Doyon-Trottier, E., & Le May, S. (2018). Efficacy of the Buzzy® device for pain management of children during needle-related procedures: A systematic review protocol. *Systematic Reviews*, *7*(1), 78. https://doi.org/10.1186/s13643-018-0738-1.

Ballard, A., Khadra, C., Adler, S., Trottier, E. D., & Le May, S. (2019). Efficacy of the Buzzy device for pain management during needle-related procedures. *The Clinical Journal of Pain*, *35*(6), 532–543. https://doi.org/10.1097/AJP.0000000000000690.

Baxter, A. L., Leong, T., & Mathew, B. (2009). External thermomechanical stimulation versus vapocoolant for adult venipuncture pain: Pilot data on a novel device. *The Clinical Journal of Pain*, *25*(8), 705–710. https://doi.org/10.1097/AJP.0b013e3181af1236.

Bergamo, P., Scudeller, L., Pintaldi, S., & Molin, A. D. (2018). Efficacy of nonpharmacological methods of pain management in children undergoing venipuncture in a pediatric outpatient clinic: A randomized controlled trial of audiovisual distraction and external cold and vibration. *Journal of Pediatric Nursing*, *42*, e66–e72. https://doi.org/10.1016/j.pedn.2018.04.011.

Brennan, F., Carr, D. B., & Cousins, M. (2007). Pain management: A fundamental human right. *Anesthesia & Analgesia*, *105*(1), 205–221. https://doi.org/10.1213/01.ane.0000268145.52345.55.

Canbulat, N., Ayhan, F., & Inal, S. (2015). Effectiveness of external cold and vibration for procedural pain relief during peripheral intravenous cannulation in pediatric patients. *Pain Management Nursing*, *16*(1), 33–39. https://doi.org/10.1016/j.pmn.2014.03.003.

Canbulat, N., Inal, S., & Sönmezer, H. (2014). Efficacy of distraction methods on procedural pain and anxiety by applying distraction cards and kaleidoscope in children. *Asian Nursing Research*, *8*(1), 23–28. https://doi.org/10.1016/j.anr.2013.12.001.

Canbulat Şahiner, N., & Türkmen, A. S. (2019). The effect of distraction cards on reducing pain and anxiety during intramuscular injection in children. *Worldviews on Evidence-Based Nursing*, *16*(3), 230–235. https://doi.org/10.1111/wvn.12359.

Chan, E., Hovenden, M., Ramage, E., Ling, N., Pham, J. H., Rahim, A., ... Jeyachanthiran, K. (2019). Virtual reality for pediatric needle procedural pain: Two randomized clinical trials. *The Journal of Pediatrics*, *209*, 160–167. https://doi.org/10.1016/j.jpeds.2019.02.034.

Czarnecki, M. L., Simon, K., Thompson, J. J., Armus, C. L., Hanson, T. C., Berg, K. A., ... Malin, S. (2011). Barriers to pediatric pain management: A nursing perspective. *Pain Management Nursing*, *12*(3), 154–162. https://doi.org/10.1016/j.pmn.2010.07.001.

Dickenson, A. H. (1995). Spinal cord pharmacology of pain. *British Journal of Anaesthesia*, *75*(2), 193–200. https://doi.org/10.1093/bja/75.2.193.

Dunn, A., Patterson, J., Biega, C. F., Grishchenko, A., Luna, J., Stanek, J. R., & Strouse, R. (2019). A novel clinician-orchestrated virtual reality platform for distraction during pediatric intravenous procedures in children with hemophilia: Randomized controlled trial. *JMIR Serious Games*, *7*(1), Article e10902. https://doi.org/10.2196/10902.

Eijlers, R., Utens, E. M., Staals, L. M., de Nijs, P. F., Berghmans, J. M., Wijnen, R. M., ... Legerstee, J. S. (2019). Meta-analysis: Systematic review and meta-analysis of virtual reality in pediatrics: Effects on pain and anxiety. *Anesthesia and Analgesia*, *129*(5), 1344. https://doi.org/10.1213/ANE.0000000000004165.

ENA Clinical Practice Guideline Committee, & ENA Board of Directors Liaisons, Methodologist, Staff Liaisons, Administrative Staff (2019). Clinical Practice Guideline: Needle-related or minor procedural pain in pediatric patients. *Journal of Emergency Nursing*, *45*(4). https://doi.org/10.1016/j.jen.2019.05.015 437.e1–437.e32.

Farion, K. J., Splinter, K. L., Newhook, K., Gaboury, I., & Splinter, W. M. (2008). The effect of vapocoolant spray on pain due to intravenous cannulation in children: A randomized controlled trial. *CMAJ*, *179*(1), 31–36. https://doi.org/10.1503/cmaj.070874.

Faul, F. (2014). G*power version 3.1.9.2. http://www.gpower.hhu.de/.

Fein, J. A., Zempsky, W. T., Cravero, J. P., & Committee on Pediatric Emergency Medicine (2012). Relief of pain and anxiety in pediatric patients in emergency medical systems. *Pediatrics*, *130*(5), e1391–e1405. https://doi.org/10.1542/peds.2012-2536.

Gerçeker, G.Ö., Ayar, D., Özdemir, E. Z., & Bektaş, M. (2018). Gaining of Children's state anxiety and Children's fear scale to Turkish language. *E- Journal of Dokuz Eylul University Nursing Faculty*, *11*(1), 9–13https://dergipark.org.tr/en/pub/deuhfed/issue/46786/586670.

Gerçeker, G.Ö., Ayar, D., Özdemir, E. Z., & Bektaş, M. (2020). Effects of virtual reality on pain, fear and anxiety during blood draw in children aged 5–12 years old: A randomised controlled study. *Journal of Clinical Nursing*, *29*(7–8), 1151–1161 https://clinicaltrials.gov/ct2/show/NCT04040036.

Gerçeker, G.Ö., Binay, Ş., Bilsin, E., Kahraman, A., & Yılmaz, H. B. (2018). Effects of virtual reality and external cold and vibration on pain in 7-to 12-year-old children during phlebotomy: A randomized controlled trial. *Journal of Perianesthesia Nursing*, *33*(6), 981–989. https://doi.org/10.1016/j.jopan.2017.12.010.

Gold, J. I., & Mahrer, N. E. (2018). Is virtual reality ready for prime time in the medical space? A randomized control trial of pediatric virtual reality for acute procedural pain management. *Journal of Pediatric Psychology*, *43*(3), 266–275. https://doi.org/10.1093/jpepsy/jsx129.

Gupta, A., Scott, K., & Dukewich, M. (2018). Innovative technology using virtual reality in the treatment of pain: Does it reduce pain via distraction, or is there more to it? *Pain Medicine*, *19*(1), 151–159. https://doi.org/10.1093/pm/pnx109.

Hayes, M. H. S., & Patterson, D. G. (1921). Experimental development of the graphic rating method. *Psychological Bulletin*, *18*, 98–99.

Inal, S., & Kelleci, M. (2012a). Distracting children during blood draw: Looking through distraction cards is effective in pain relief of children during blood draw. *International Journal of Nursing Practice*, *18*(2), 210–219. https://doi.org/10.1111/j.1440-172X.2012.02016.x.

Inal, S., & Kelleci, M. (2012b). Relief of pain during blood specimen collection in pediatric patients. *MCN, The American Journal of Maternal/Child Nursing*, *37*(5), 339–345. https://doi.org/10.1097/NMC.0b013e31825a8aa5.

Inal, S., & Kelleci, M. (2020). The effect of external thermomechanical stimulation and distraction on reducing pain experienced by children during blood drawing. *Pediatric Emergency Care*, *36*(2), 66–69. https://doi.org/10.1097/PEC.0000000000001264.

Kakigi, R., & Shibasaki, H. (1992). Mechanisms of pain relief by vibration and movement. *Journal of Neurology, Neurosurgery & Psychiatry*, *55*, 282–286. https://doi.org/10.1136/jnnp.55.4.282.

Koller, D., & Goldman, R. D. (2012). Distraction techniques for children undergoing procedures: A critical review of pediatric research. *Journal of Pediatric Nursing*, *27*(6), 652–681. https://doi.org/10.1016/j.pedn.2011.08.001.

Leahy, S., Kennedy, R. M., Hesselgrave, J., Gurwitch, K., Barkey, M., & Millar, T. F. (2008). On the front lines: Lessons learned in implementing multidisciplinary peripheral venous access pain-management programs in pediatric hospitals. *Pediatrics*, *122*(supplement 3), S161–S170. https://doi.org/10.1542/peds.2008-1055i.

Li, L., Yu, F., Shi, D., Shi, J., Tian, Z., Yang, J., ... Jiang, Q. (2017). Application of virtual reality technology in clinical medicine. *American Journal of Translational Research*, *9*(9), 3867–3880 http://www.ajtr.org/V9_No9.html.

McCaul, K. D., & Malott, J. M. (1984). Distraction and coping with pain. *Psychological Bulleten*, *95*(3), 516–533. https://doi.org/10.1037/0033-2909.95.3.516.

McMurtry, C. M., Noel, M., Chambers, C. T., & McGrath, P. J. (2011). Children's fear during procedural pain: Preliminary investigation of the Children's fear scale. *Health Psychology*, *30*(6), 780. https://doi.org/10.1037/a0024817.

Melzack, R., & Wall, P. D. (1965). Pain mechanisms: A new theory. *Science*, *150*(3699), 971–979. https://doi.org/10.1126/science.150.3699.971.

Minute, M., Badina, L., Cont, G., Montico, M., Ronfani, L., & Barbi, E. (2012). Videogame playing as distraction technique in course of venipuncture. *La Pediatria Medica e Chirurgica*, *34*(2), 77–83. https://doi.org/10.4081/pmc.2012.64.

Moadad, N., Kozman, K., Shahine, R., Ohanian, S., & Badr, L. K. (2016). Distraction using the BUZZY for children during an IV insertion. *Journal of Pediatric Nursing*, *31*(1), 64–72. https://doi.org/10.1016/j.pedn.2015.07.010.

Nahra, H., & Plaghki, L. (2005). Innocuous skin cooling modulates perception and neurophysiological correlates of brief CO_2 laser stimuli in humans. *Europen Journal of Pain*, *9*(5), 521–530. https://doi.org/10.1016/j.ejpain.2004.11.007.

Potts, D. A., Davis, K. F., Elci, O. U., & Fein, J. A. (2019). A vibrating cold device to reduce pain in the pediatric emergency department: A randomized clinical trial. *Pediatric Emergency Care*, *35*(6), 419–425. https://doi.org/10.1097/PEC.0000000000001041.

Pourmand, A., Davis, S., Marchak, A., Whiteside, T., & Sikka, N. (2018). Virtual reality as a clinical tool for pain management. *Current Pain and Headache Reports*, *22*(8), 53. https://doi.org/10.1007/s11916-018-0708-2.

Redfern, R. E., Chen, J. T., & Sibrel, S. (2018). Effects of thermomechanical stimulation during vaccination on anxiety, pain, and satisfaction in pediatric patients: A randomized controlled trial. *Journal of Pediatric Nursing*, *38*, 1–7. https://doi.org/10.1016/j.pedn.2017.09.009.

Sahiner, N. C., & Bal, M. D. (2016). The effects of three different distraction methods on pain and anxiety. *Journal of Child Health Care*, *20*(3), 277–285.

Sahiner, N. C., Inal, S., & Akbay, A. S. (2015). The effect of combined stimulation of external cold and vibration during immunization on pain and anxiety levels in children. *Journal of Perianesthesia Nursing*, *30*(3), 228–235. https://doi.org/10.1016/j.jopan.2014.05.011.

Schreiber, S., Cozzi, G., Rutigliano, R., Assandro, P., Tubaro, M., Cortellazzo Wiel, L., ... Barbi, E. (2016). Analgesia by cooling vibration during venipuncture in children with cognitive impairment. *Acta Paediatrica*, *105*(1), e12–e16. https://doi.org/10.1111/apa.13224.

Schulz, K. F., Altman, D. G., Moher, D., & the CONSORT Group (2010). CONSORT 2010 statement: Updated guidelines for reporting parallel group randomized trials. *British Medical Journal*, *340*, c332. https://doi.org/10.1136/bmj.c332.

Sealed Envelope Ltd (2018). Create a blocked randomisation list. (Online) Available from https://www.sealedenvelope.com/simple-randomiser/v1/lists (Accessed January 20 2018).

Tork, H. M. M. (2017). Comparison of the effectiveness of Buzzy, distracting cards and balloon inflating on mitigating pain and anxiety during venipuncture in a pediatric emergency department. *American Journal of Nursing Science*, *6*(1), 26–32http://www.sciencepublishinggroup.com/j/ajns.

Twycross, A. (2009). Managing pain in children. In S. J. Dowden, & E. Bruce (Eds.), *A clinical guide* (pp. 42–49). New Jersey: Blackwell Publishing Ltd.

Wewers, M. E., & Lowe, N. K. (1990). A critical review of visual analogue scales in the measurement of clinical phenomena. *Research in Nursing & Health*, *13*(4), 227–236. https://doi.org/10.1002/nur.47701304056.

Whelan, H. M., Kunselman, A. R., Thomas, N. J., Moore, J., & Tamburro, R. F. (2014). The impact of a locally applied vibrating device on outpatient venipuncture in children. *Clinical Pediatrics*, *53*(12), 1189–1195. https://doi.org/10.1177/0009922814538494.

Wong, D. L., & Baker, C. M. (1988). Pain in children: Comparison of assessment scales. *Pediatric Nursing*, *14*(1), 9–17http://www.pediatricnursing.net/interestarticles/1401_Wong.pdf.