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Effectiveness of kaleidoscope on pain and behavioural responses among children during intravenous cannulation- An open-label randomised controlled study.

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Original Research

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Abstract

Introduction: Children experience significant pain and distress during paediatric procedures, especially during intravenous (IV) cannulation. Several non-pharmacological interventions are in use for this purpose. Many distraction techniques are suggested. **Objectives:** A randomized controlled trial was conducted among 60 children belonging to the age group of 4-12 years who were undergoing their first IV cannulation after admission to evaluate the effectiveness of a kaleidoscope compared to standard treatment on pain and behavioural responses. **Methods:** Through block randomization, 30 children were allocated to each group. Standard tools were used to assess pain and behavioural responses. **Results:** A total of 102 children were admitted to the paediatric ward during the study period and 42 were excluded due to various reasons. Sixty children underwent randomization into two groups, 30 each in one group. All were analysed for the outcome. The median (IQR) pain score in the experimental group was 0 (0) and in the control group was 8 (4) and the difference was statistically significant. The median (IQR) behavioural response score in the experimental group was 0 (1) and the control group was 5 (3) which also was statistically significant. The control group had an 80% excess risk for moderate to severe pain than the experimental group and there was a relative risk reduction of 75% by kaleidoscope. The calculated number needed to treat (NNT) was 1.25. The control group had a 60% excess risk for moderate to severe behavioural distress and a kaleidoscope could effectively reduce the relative risk by 69%. The NNT was 1.67. **Conclusion:** Kaleidoscope is effective in reducing pain and behavioural response among children during IV cannulation.

Keywords: Behavioural response, Children, IV cannulation, Kaleidoscope, Pain.

Introduction

Pain is a highly individualized and subjective experience which can affect persons of any age. This complex phenomenon involves multiple components that are influenced by innumerable factors. Pain is defined as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage" (Treede, 2018). Considering the importance of pain assessment and measurement in the wellbeing of patients, the American Pain Society labelled it as 'the fifth vital sign' in 1995 (Levy, Sturgess, and Mills, 2018). The goal of the American Pain Society was reported to be encouraging healthcare professionals to monitor patients' pain on a regular basis, record their temperature, pulse, respiration, and blood pressure readings and implement pain management strategies.

Many medical interventions cause pain and anxiety in children, which can adversely affect treatment and recovery (Bekar, Erkul, and Efe, 2022). Several distraction methods have been suggested to relieve procedural pain and anxiety among children. Studies reported that kaleidoscopes can be used as an effective method of relieving pain anxiety among children during painful medical procedures (Bekar et al., 2022; Prajapati, 2018; Semerci and Kostak, 2020). Several

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other cognitive and behavioural (Srouji, Ratnapalan, and Schneeweiss, 2010) methods of distraction (Bukola and Paula, 2017) have been reported, viz., virtual reality (Chan et al., 2019; Dumoulin et al., 2019), audiovisual distraction (Guinot et al., 2021), bubble blowing and cartoon watching (Ugucu et al., 2022), distraction cards (Erdogan and Aytekin Ozdemir, 2021), and several such methods.

The Wong-Baker Faces Pain Rating Scale is one of the most widely used subjective pain scales for children. It is reported that the FLACC (Face, Leg, Activity, Cry, Consolability) scale is a good instrument for measuring pain behaviour by observational method in infants and children (Peng et al., 2023; Shaker and Taha, 2018).

Though there are available evidences, practices, and standard recommendations for paediatric pain management, there is still an inadequacy of paediatric pain management in clinical settings. This study aimed to compare the difference in pain and behavioural responses of children with and without kaleidoscopes during intravenous cannulation.

Materials and Methods

Study design, setting, and duration

This study was an open-label, two-arm, parallel design, randomised controlled trial conducted in a tertiary care hospital in Kerala, India. The study was approved by a competent institutional human ethics committee and registered in the Clinical Trial Registry of India. Enrolment started in February 2022 and was completed in April 2022. Informed assent was obtained from all children above 7 years of age and from the mothers of all children. The Government College of Nursing Alappuzha Institutional Ethics Committee issued approval GCNA/IHEC No.P6/18/2021, dated 29 September 2021. This trial had been registered with the CTRI (Clinical Trial Registry of India) (CTRI Number-CTRI/2022/02/039997 Reregistered on 03 February 2022-Trial Registered Prospectively).

Methods

The study aimed to evaluate the effects of the kaleidoscope (experimental group) on the pain and behavioural responses of children during IV cannulation in comparison to the standard treatment.

Inclusion and Exclusion Criteria of Study Population

The study included children in the age group of 4-12 years admitted to the paediatric medical ward who were conscious and oriented. Children with cannula insertion failure on the first attempt, cognitive and behavioural problems, other sources of pain (reported a pain score >0 on the Wong-Baker Faces Pain Scale at the time of recruitment), and parents who did not give consent for participation were excluded.

A pilot study was conducted among six children (three each in both arms) to assess the feasibility and test the tools. The study was found to be feasible, with appropriate tools and data amenable to analysis. No modifications were made to the original protocol after the pilot study.

Randomization and Blinding

Included children were randomly assigned to one of two groups (Kaleidoscope or standard treatment group). The WINPEPI software was used to generate a Random sequence with a block size of four. The digits assigned for the four blocks of children in the two treatments (A- Kaleidoscope and B- standard treatment) were AABB (1), ABBA (2), ABAB (3), BBAA (4), BAAB (5), BABA (6). For allocation concealment, a serially numbered opaque sealed envelope was used, and the nurse-in-charge of the ward did the random allocation. As the kaleidoscope is a device held in the hands of a child, participant blinding was impossible. As the investigator herself was assessing the outcomes, blinding of the outcome assessment was not possible. Strict adherence to the study protocol was attempted to minimise bias.

Intervention

Children allocated to the experimental group received the kaleidoscope. A kaleidoscope is a tube containing mirrors and pieces of coloured glass or paper whose reflections produce a changing pattern when the tube is rotated. Five minutes before the intravenous cannulation, the child was given a kaleidoscope and asked to look at the coloured pattern through the eyepiece. The child held the kaleidoscope in the other

hand during and after cannulation. It was continued until the procedure was completed. It was used to distract the child's attention from a painful procedure. An individual kaleidoscope was used for each child as an aseptic precaution. During the IV cannulation, the child was kept in the lap of the mother, and the mother was talking and restraining the child during the procedure.

Children allocated to the control group received standard treatment. The mother accompanied the child to the injection room. She kept the child in her lap, talking to the child during the IV cannulation procedure and restraining the child as and when required.

Monitoring trial progress

In this study, the protocol compliance was good, as the outcome assessment was done after one minute and five minutes of the procedure. There were no immediate or delayed adverse events in either group. No participants left the study, and all 60 completed the trial. There was no noncompliance, incomplete evaluation, or protocol violation. Confidentiality of data was assured.

Outcomes

Demographic data were collected using a structured interview schedule. Children's pain and behavioural responses were assessed during the procedure. The Wong-Baker Faces Pain Rating Scale developed by Wong and Baker in 1983 (Figure 1) was used to assess the pain during IV cannulation. It is a subjective scale that is used to assess the severity of pain among children above the age of three years. It is a 6-point rating scale, with 0 representing no pain with a smiling face and 10 for the worst pain with a crying face. Pain scores reported <4 were regarded as mild pain, and scores >4 were regarded as moderate to severe pain. The scale showed good reliability scores (r=0.725, p=0.001) (Balasubramanian, Kamki, and Kalaskar, 2022).

Figure 1: Wong-Baker Faces Pain Rating Scale

To get an objective finding, the behavioural response was assessed using the FLACC scale. Each item was scored on a scale of 0 to 2 resulting in a minimum score of 0 and a maximum score of 10. Scores of 4 or less were regarded as mild discomfort, and scores >4 were regarded as moderate to severe discomfort. The scale was found to be reliable (kappa=0.85, p<0.001) (Nilsson, Finnström, and Kokinsky, 2008).

Sample size

A sample size was calculated for the difference in behavioural response score between the experimental group and the control group after the cannulation. The mean pain score for the experimental group was 2.27 (SD 0.62) and for the control group was 4.47 (SD 0.707) based on a previous study (Rawat, Sharma, and Sharma 2021). The calculated sample size was 30 in one group for power at 80% and precision at 5%. The total sample size calculated was 60. There was only one outcome assessment, and so failure to follow up was not considered. The study sample was recruited using consecutive sampling techniques.

Statistical Analysis

The data was entered in an MS Excel spreadsheet and analysed using SPSS (version 26, SPSS Inc., Chicago, IL). The baseline variables were presented as frequency and percentage for categorical variables and median (IQR) for continuous variables. The pain was categorised as mild, moderate, or severe and behavioural responses were classified as mild, moderate, or severe discomfort and were analysed using the Mann-Whitney U test and relative risks. The number needed to treat (NNT) was also calculated, which is a measure of the impact of the intervention.

Results

A total of 102 children were admitted to the ward and 42 were excluded due to various reasons, as indicated in Figure 2. A total of 60 children underwent randomization into two groups, with 30 in each group. All were analysed for the outcomes. The comparison of baseline characteristics among the groups are represented in the following Table 1. Baseline characteristics were comparable between the two groups.

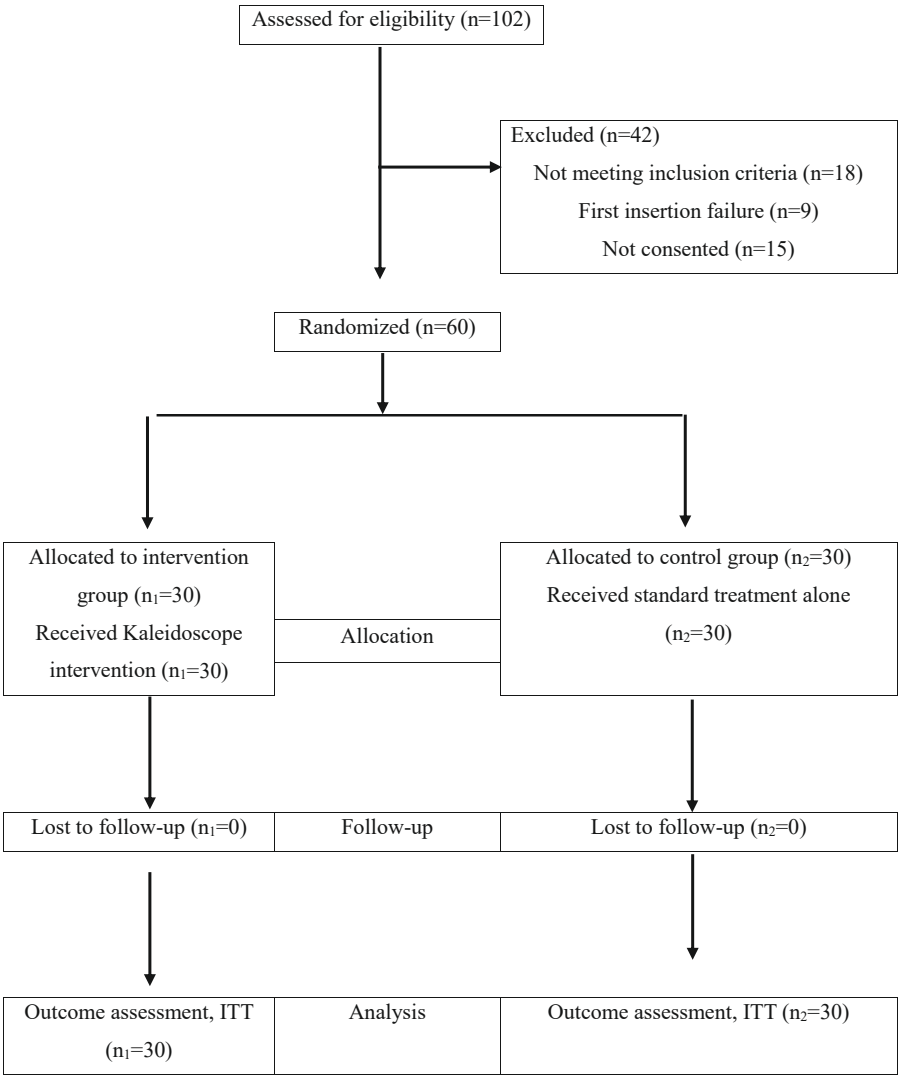

Figure 2: CONSORT Flow Diagram

Table 1

Baseline characteristics of the study participants

Baseline Variables		Experimental (n_1=30)		Control (n_2=30)	
		f	%	f	%
1. Age (years)	4 to 6	23	76.7	18	60
	6 to 8	6	20	7	23.3
	8 to 10	1	3.3	5	16.7
2. Gender	Male	18	60	15	50
	Female	12	40	15	50

Baseline Variables			Experimental (n_1=30)		Control (n_2=30)	
			f	%	f	%
3.	Birth order	First	15	50	22	73.4
		Second	13	43.3	7	23.3
		Third	2	6.7	1	3.3
4.	Number of siblings	None	9	30	7	23.3
		One or more	21	70	23	76.7
5.	Type of family	Nuclear	25	83.3	25	83.3
		Others	5	16.7	5	16.7
6.	Monthly family income (INR)	46,129 to 61,662	11	36.7	6	20
		30,831 to 46,128	15	50	13	43.3
		18,497 to 30,830	4	13.3	11	36.7
7.	Number of previous hospitalizations	Nil	5	16.7	9	30
		1 to 2 times	22	73.3	19	63.3
		3 or more	3	10	2	6.7
8.	Previous experience of IV cannulation	Yes	25	83.3	20	66.7
		No	5	16.7	10	33.3

The effectiveness of the kaleidoscope on pain score and behavioural response are given in the following Table 2. In both cases, the observation in the experimental group showed statistical significance ($p<0.001$).

Table 2

Comparison of pain score and behavioural response score between the experimental and control group

Outcome	Overall score (median, IQR)		Mann-Whitney U test	
	Experimental group (n_1=30)	Control group (n_2=30)	Z value	p value
Pain	0 (0)	8 (4)	6.93***	0.0001
Behavioural response	0 (1)	5 (3)	6.85***	0.0001

*** $p<0.001$

Absolute and relative risks for moderate to severe pain and moderate to severe discomfort for the groups were calculated based on the following Table 3.

Table 3

Comparison of the proportion of pain score and behavioural response score among the experimental and control groups

Pain score	Treatment groups		Behavioural response score	Treatment groups	
	Experimental group (n_1=30)	Control group (n_2=30)		Experimental group (n=30)	Control group (n=30)
Mild pain (≤4)	24 (80%)	0	Mild discomfort (≤4)	22 (73%)	4 (13%)
Moderate to severe pain (>4)	6 (20%)	30 (100%)	Moderate to severe discomfort (>4)	8 (27%)	26 (87%)

The findings indicated that the standard treatment group had an 80% excess risk of having moderate to severe pain during IV cannulation compared to the kaleidoscope group. In terms of relative risk, the kaleidoscope had reduced the risk of moderate to severe pain by 75%. The calculated NNT was 1.25 and it is indicated that the intervention achieved one more success in reducing moderate to severe pain for every patient when 1.25 patients received the intervention compared with standard treatment.

It was also evident that the standard treatment group had a 60% excess risk of having moderate to severe discomfort during IV cannulation compared to the Kaleidoscope group. In terms of relative risk, the kaleidoscope reduced the risk of moderate to severe discomfort by 69%. The calculated NNT was 1.67, indicating that the intervention achieved one more success in reducing moderate to severe discomfort for every patient when 1.67 patients received the intervention compared with standard treatment.

Discussion

This study found that the kaleidoscope is an effective distraction method that produces less pain during IV cannulation. The median pain score was zero for the experimental group and eight (IQR 4) for the control group, and the difference was statistically significant ($p<0.001$). The median behavioural response score was zero (IQR 1) and five (IQR 3) for the experimental and control groups and that difference had statistical significance ($p<0.001$). A study that used squeezing a swishy object during IV cannulation among children aged 3 to 15 years reported a statistically significant difference ($p<0.001$) in median pain of 2 in the experimental group and 6 in the control group (Sirtin Tumakaka, Nurhaeni, and Wanda, 2020). Another study among children aged 4 to 10 years using virtual reality and a kaleidoscope against standard care reported significantly lower pain scores among the two experimental groups ($p=0.000$) (Koç Özkan and Polat, 2020). A study from Odisha, India, that used music and distraction cards as interventions among children aged 6 to 12 years found that the mean pain score was 6.374±2.365 in the control group and 2.571±2.006 in the experimental group and was statistically significant ($p=0.000$) (Debnath, Das, and Sahoo, 2020). A study on procedural pain among children aged 6 to 12 years using art-based intervention reported that the mean pain score among the experimental group was 3.50 and among the control group was 6.53, which was statistically significant (Suleman, Atrushi, and Enskär, 2022). Most of the studies have used the Wong-Baker Faces Pain Rating Scale or FLACC scale (Bagnasco et al., n.d.; Debnath et al., 2020; Guinot et al., 2021; Kunjumon 2018; Rawat et al., 2021; Shaker and Taha 2018).

Strengths and limitations

The major strength of this study was the design, an RCT that used block randomization and allocation concealment. Both objective and patient-reported outcomes were measured. The primary analysis was an intention to treat analysis that provided an unbiased evaluation of the effectiveness of the intervention. Still, there were some limitations. There was only a single setting. Blinding could not be achieved owing to the nature of the intervention.

Implications

This study urges nurses to use non-pharmacological pain relief interventions in paediatric clinical practice, which enhances the quality of nursing care and the satisfaction of the child and parent.

Recommendation for future studies

Further studies should be undertaken with a large sample size and preferably multi-centric with blinding.

Conclusions

Based on the study findings, kaleidoscopes can effectively reduce procedural pain and behavioural response among children. Distraction is an effective nonpharmacological measure to reduce procedural pain and distress among children. Kaleidoscope is an effective and low-cost method that can be used in our setting. Paediatric nurses should take the initiative to implement such methods into their practice so that hospitalisation is a less painful experience for our children. They can influence the policymakers to implement paediatric pain management guidelines.

Additional information

Ethical issues: Assent and consent were obtained from participants in this study. The Government College of Nursing Alappuzha Institutional Ethics Committee issued approval GCNA/IHEC No.P6/18/2021, dated 29 September 2021. This trial had been registered with the CTRI (Clinical Trial Registry of India) (CTRI Number- CTRI/2022/02/039997 Reregistered on 03 February 2022-Trial Registered Prospectively).

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Data sharing policy

Data can be made available on request.

References

Bagnasco, A., E. Pezzi, F. Rosa, L. Fornoni, and L. Sasso. n.d. "Distraction Techniques in Children during Venipuncture: An Italian Experience."

Balasubramanian, Shruti, Henpu Kamki, and Ritesh R. Kalaskar. 2022. "Evaluation of Effectiveness of Graphics Interchange Format and Wong–Baker FACES Pain Rating Scale as Pain Assessment Tool in Children." *The Journal of Contemporary Dental Practice* 23(6):634–38. doi: 10.5005/jp-journals-10024-3365.

Bekar, Pınar, Münevver Erkul, and Emine Efe. 2022. "The Effect of Using a Kaleidoscope during Central Venous Catheter Dressing Changes on Pain and Anxiety in Children with Cancer: A Randomised Controlled Trial." *European Journal of Oncology Nursing: The Official Journal of European Oncology Nursing Society* 57:102114. doi: 10.1016/j.ejon.2022.102114.

Bukola, Ibitoye M., and Dawson Paula. 2017. "The Effectiveness of Distraction as Procedural Pain Management Technique in Pediatric Oncology Patients: A Meta-Analysis and Systematic Review." *Journal of Pain and Symptom Management* 54(4):589-600.e1. doi: 10.1016/j.jpainsymman.2017.07.006.

Chan, Evelyn, Michael Hovenden, Emma Ramage, Norman Ling, Jeanette H. Pham, Ayesha Rahim, Connie Lam, Linly Liu, Samantha Foster, Ryan Sambell, Kasthoori Jeyachanthiran, Catherine Crock, Amanda Stock, Sandy M. Hopper, Simon Cohen, Andrew Davidson, Karin Plummer, Erin Mills, Simon S. Craig, Gary Deng, and Paul Leong. 2019. "Virtual Reality for Pediatric Needle Procedural Pain: Two Randomized Clinical Trials." *The Journal of Pediatrics* 209:160-167.e4. doi: 10.1016/j.jpeds.2019.02.034.

Debnath, Soumika, Niyati Das, and Purnima Sahoo. 2020. "Effectiveness of Distraction Therapy on Pain Relief among Children Undergoing Vein-

Puncture in a Selected Hospital, Bhubaneswar." *Journal of Advanced Research in Medicine (E-ISSN: 2349-7181 & P-ISSN: 2394-7047)* 7(2):15–21.

Dumoulin, Stéphanie, Stéphane Bouchard, Jacqueline Ellis, Kim L. Lavoie, Marie-Pier Vézina, Priscilla Charbonneau, Jessica Tardif, and Alain Hajjar. 2019. "A Randomized Controlled Trial on the Use of Virtual Reality for Needle-Related Procedures in Children and Adolescents in the Emergency Department." *Games for Health Journal* 8(4):285–93. doi: 10.1089/g4h.2018.0111.

Erdogan, Birgül, and Aynur Aytekin Ozdemir. 2021. "The Effect of Three Different Methods on Venipuncture Pain and Anxiety in Children: Distraction Cards, Virtual Reality, and Buzzy® (Randomized Controlled Trial)." *Journal of Pediatric Nursing* 58:e54–62. doi: 10.1016/j.pedn.2021.01.001.

Guinot, F., M. Mercadé, L. Oprysnyk, A. Veloso, and J. R. Boj. 2021. "Comparison of Active versus Passive Audiovisual Distraction Tools on Children's Behavioural, Anxiety and Pain in Paediatric Dentistry: A Randomised Crossover Clinical Trial." *EUROPEAN JOURNAL OF PAEDIATRIC DENTISTRY* 22(3):230–36. doi: 10.23804/ejpd.2021.22.03.10.

Koç Özkan, Tuba, and Filiz Polat. 2020. "The Effect of Virtual Reality and Kaleidoscope on Pain and Anxiety Levels During Venipuncture in Children." *Journal of PeriAnesthesia Nursing* 35(2):206–11. doi: 10.1016/j.jopan.2019.08.010.

Kunjumon, Dipeesh. 2018. "Effect of Kaleidoscope on Pain Perception of Children Aged 4-6 Years During Intravenous Cannulation." *American Journal of Nursing Science* 7(4):137. doi: 10.11648/j.ajns.20180704.14.

Levy, N., J. Sturgess, and P. Mills. 2018. "'Pain as the Fifth Vital Sign' and Dependence on the 'Numerical Pain Scale' Is Being Abandoned in the US: Why?" *British Journal of Anaesthesia* 120(3):435–38. doi: 10.1016/j.bja.2017.11.098.

Nilsson, Stefan, Berit Finnström, and Eva Kokinsky. 2008. "The FLACC Behavioral Scale for Procedural Pain Assessment in Children Aged 5-16 Years." *Paediatric Anaesthesia* 18(8):767–74. doi: 10.1111/j.1460-9592.2008.02655.x.

Peng, Tuochao, Shuangquan Qu, Zhen Du, Zheng Chen, Ting Xiao, and Ru Chen. 2023. "A Systematic Review of the Measurement Properties of Face, Legs, Activity, Cry and Consolability Scale for Pediatric Pain Assessment." *Journal of Pain Research* 16:1185–96. doi: 10.2147/JPR.S397064.

Prajapati, Himali Raj. 2018. "A Study to Assess the Effectiveness of Kaleidoscope in Reducing Physical Stress during Venipuncture Procedure among Hospitalized Pre-School Children at Selected Hospital of Ahmadabad City, Gujarat State." *International Journal of Nursing Education and Research* 6(1):44. doi: 10.5958/2454-2660.2018.00011.X.

Rawat, Varsha, Praveen Kumar Sharma, and Bijayata Sharma. 2021. "A Quasi-Experimental Study to Assess the Effectiveness of Kaleidoscope on the Pain and Behavioural Responses of Children (4-10yrs) during Intravenous Cannulation in Paediatric Unit of Shri Mahant Indresh Hospital, Dehradun."

Semerci, Remziye, and Melahat Akgün Kostak. 2020. "The Efficacy of Distraction Cards and Kaleidoscope for Reducing Pain During Phlebotomy: A Randomized Controlled Trial." *Journal of PeriAnesthesia Nursing* 35(4):397–402. doi: 10.1016/j.jopan.2020.02.003.

Shaker, Norhan Zeki, and Ari Ahmed Taha. 2018. "Effectiveness of Distraction Therapy on Children's Pain Perceptions During Peripheral Venous Cannulation at Pediatric Teaching Hospital in Erbil City." *Erbil Journal of Nursing and Midwifery* 1(2):75–84. doi: 10.15218/ejnm.2018.10.

Sirtin Tumakaka, Grace Yuliona, Nani Nurhaeni, and Dessie Wanda. 2020. "Squeezing a Squishy Object Effectively Controls Pain in Children during Intravenous Catheter Insertion." *Pediatric Reports* 12(Suppl 1):8692. doi: 10.4081/pr.2020.8692.

Srouji, Rasha, Savithiri Ratnapalan, and Suzan Schneeweiss. 2010. "Pain in Children: Assessment and Nonpharmacological Management." *International Journal of Pediatrics* 2010:e474838. doi: 10.1155/2010/474838.

Suleman, Sherzad Khudeida, Akaram Atrushi, and Karin Enskär. 2022. "Effectiveness of Art-Based Distraction on Reducing Pediatric Patients' Pain and Anxiety during Venipuncture: A Randomized

Controlled Trial." *Complementary Therapies in Clinical Practice* 48:101597. doi: 10.1016/j.ctcp.2022.101597.

Treede, Rolf-Detlef. 2018. "The International Association for the Study of Pain Definition of Pain: As Valid in 2018 as in 1979, but in Need of Regularly Updated Footnotes." *Pain Reports* 3(2):e643. doi: 10.1097/PR9.0000000000000643.

Ugucu, Guzide, Derya Akdeniz Uysal, Ozlem Guzel Polat, Zuhal Artuvan, Didem Polat Kulcu, Done Aksu, Melek Gulgun Altintas, Hacer Cetin, and Gulhan Orekici Temel. 2022. "Effects of Cartoon Watching and Bubble-Blowing during Venipuncture on Pain, Fear, and Anxiety in Children Aged 6-8 Years: A Randomized Experimental Study." *Journal of Pediatric Nursing* 65:e107–14. doi: 10.1016/j.pedn.2022.03.016.