

Research Article

The effect of using vibrating tourniquet and distraction cards on pain, fear and anxiety during phlebotomy in children

Çocuklarda kan alma işlemi sırasında titreşimli turnike ve distraksiyon kartları kullanımının ağrı, korku ve anksiyete düzeylerine etkisi

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Abstract

Introduction: Children suffer from pain due to invasive procedures. Unrelieved pain can lead to social and psychological problems. The aim of this study was to evaluate the effectiveness of vibrating tourniquet and distraction cards on children's pain, fear and anxiety levels during phlebotomy.

Methods: This randomized, controlled study was carried out with 120 children included 40 children in vibrating tourniquet group, 40 children in distraction cards group and 40 children in control group in pediatric blood collection unit at a training and research hospital in Ankara. Data were collected with Child and Parent Data Collection Form, Visual Analog Scale, Child Fear Scale and Child Anxiety-State Scale. The primary outcome measure was the Visual Analog Scale for pain. Secondary outcome measure was the Child Fear Scale for fear and Child Anxiety-State Scale for anxiety.

Results: After procedure pain score was significantly lower in the distraction cards group ($p=0.006$), whereas there was no statistically significant difference in pain scores before and during the procedure in all groups. During procedure fear score was significantly lower in the distraction card group ($p=0.042$).

Conclusion: In this study it was concluded that the use of distraction cards was found to be effective in reducing children's pain and anxiety after the phlebotomy, and fear levels during and after the phlebotomy for the children aged between 6 and 10 years.

Keywords: Anxiety, child, fear, nursing, pain management

Öz

Giriş: Çocuklar invaziv işlemler nedeniyle ağrı çekmektedir. Giderilemeyen ağrı, çocukluk çağında sosyal ve psikolojik sorunlara yol açabilir. Bu çalışmanın amacı, flebotomi sırasında titreşimli turnike ve dikkat dağıtıcı kartların çocukların ağrı, korku ve anksiyete düzeyleri üzerindeki etkinliğini değerlendirmektir.

Yöntemler: Bu randomize, kontrollü çalışma Ankara'da bir eğitim ve araştırma hastanesinin pediatrik kan alma ünitesinde titreşimli turnike grubunda 40 çocuk, dikkat dağıtıcı kartlar grubunda 40 çocuk ve kontrol grubunda 40 çocuk olmak üzere toplam 120 çocuk ile gerçekleştirildi. Veriler Çocuk ve Ebeveyn Veri Toplama Formu, Görsel Analog Skala, Çocuk Korku Ölçeği ve Çocuk Anksiyete-Durum Ölçeği ile toplanmıştır. Birincil sonuç ölçütü ağrı için Görsel Analog Skala idi. İkincil sonuç ölçütü korku için Çocuk Korku Ölçeği ve anksiyete için Çocuk Anksiyete-Durum Ölçeği idi.

Bulgular: İşlem sonrası ağrı skoru distraksiyon kart grubunda anlamlı derecede düşüken ($p=0,006$), tüm gruplarda işlem öncesi ve sırasında ağrı skorlarında istatistiksel olarak anlamlı bir fark yoktu. İşlem sırasında korku skoru distraksiyon kart grubunda anlamlı olarak daha düşüktü ($p=0,042$).

Sonuç: Bu çalışmada, dikkat dağıtıcı kartların kullanımının 6-10 yaş arası çocuklarda flebotomi işlemi sonrasında çocukların ağrı ve kaygılarını, flebotomi sırasında ve sonrasında ise korku düzeylerini azaltmada etkili olduğu sonucuna varılmıştır.

Anahtar Kelimeler: Anksiyete, çocuk, korku, hemşirelik, ağrı yönetimi

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Key Points

1. Use of distraction cards is effective in reducing children's pain and anxiety after the phlebotomy.
2. Use of distraction cards is effective in reducing children's fear levels during and after the phlebotomy.
3. The healthcare professionals need be encouraged to use non-pharmacological distraction methods more in painful procedures.

Introduction

Invasive procedures such as vaccination, intravenous cannula insertion, heel prick and phlebotomy cause pain in children [1]. The International Association for the Study of Pain (IASP) defines pain as "an unpleasant sensory and emotional experience radiating or defined in terms of actual or potential tissue damage" [2]. Unrelieved pain can have implications across the lifespan and can be associated with social and psychological problems such as pain, psychological distress, psychological fragility and anxiety in childhood [3]. For these reasons, stress and pain should be managed or relieved in all procedures that may cause pain as recommended by The American Academy of Pediatrics (AAP) [4].

The pain and stress should be minimized in all procedures that may cause pain in children [4]. It is recommended that treatment of pain in children must include both pharmacological and non-pharmacological methods [4]. Non-opioid, opioid analgesics and adjuvants are the most commonly used pharmacological methods in childhood [1]. Non-pharmacological methods in the management of pain in children include all interventions without the use of drugs. Non-pharmacological methods used especially during painful procedures in children are hot/cold applications, distraction, using a pacifier, listening to music and providing parental support for pain management [5-10].

The fact that non-pharmacological methods have no side effects, reducing the consumption of analgesics and that they can be applied easily are the power of these methods [11]. In a systematic review including seven studies by Bukola and Paula [12] (2017), distraction methods were shown to significantly reduce systematic pain. In a meta-analysis study by Gates et al. (2020) in which 106 studies were compiled, it was seen that the use of digital distraction techniques (virtual reality glasses, video games) in painful procedures in children was effective in reducing the pain felt, but it was not superior to non-digital distraction methods [13]. In a study conducted by Gerceker et al. (2018) with 121 children to compare non-pharmacological methods during phlebotomy, it was found that virtual reality glasses and Buzzy device were effective in reducing pain, but they were not superior to each other [14]. In another study conducted by Erdogan and Ozdemir (2021) with 160 children, the Buzzy device was shown to be more effective than distraction cards in reducing procedural pain [15].

In the literature, it is reported that pharmacological and non-pharmacological methods are widely used to relieve pain, fear and anxiety due to invasive intervention. However, while there are studies evaluating the effectiveness of the vibrating tourniquet method to prevent pain, anxiety and fear due to invasive intervention in children, according to our knowledge no studies comparing the effectiveness of vibrating tourniquet and distraction cards have been found [16]. In this study, the effects of non-pharmacological methods which are vibrating tourniquet and distraction cards on pain, fear and anxiety levels were searched during phlebotomy in children aged 6-10 years. It is thought that this study will be useful in providing an evidence based source for the literature on which of the vibrating tourniquet and distraction card method is more effective on the pain, anxiety and fear associated with phlebotomy in children

Methods

This randomized, controlled study was carried out between May 2021 and March 2022 in Pediatric Blood Collection Unit at Gülhane Training and Research Hospital, Ankara, Turkey.

Research population, sample and randomization

In determining the sample size, using G*Power version 3.1.9.7, 0.95 power, α type error rate 0.05 and three groups were calculated. The effect size ($f = 0.38$) was calculated by using the pain scores from a study in which the distraction method was used to manage pain, fear and anxiety in children [17]. As a result, the total number of samples was calculated as 111, with 37 each in the Vibrating Tourniquet Group (Intervention Group 1/IG1), Distraction Cards Group (Intervention Group 2/IG2) and Control Group. However, since this was a follow-up study and considering that there would likely be losses, the number of samples was increased by 10% and determined as 120.

Children who were accepted to participate in the study by themselves and their parents were randomly assigned to three groups as Vibrating Tourniquet Group (Intervention Group 1/IG1), Distraction Cards Group (Intervention Group 2/IG2) and Control Group. Randomization was performed by using a random numbers table in a computer. Children came to the unit for phlebotomy during the study were given row numbers according to the order they came. According to the random numbers table, for example children given the numbers 3, 9, 12, 15 and 26 were assigned to IG1, numbers 6, 10, 13 were assigned to IG2 and numbers 4, 7, 15, 21 were assigned to control group. The sample of the study consist of 120 children, were assigned as 40 children to each group. Since the researcher was involved in the study as explaining the method to the participants, blinding of the participants and researchers could not be done.

Since the researcher was involved in the application the study and the method being applied to the participants was explained to them, blinding of the participants and researchers could not be done. This study was registered at ClinicalTrials.gov, number NCT05758584. The design and writing of the study were carried out in accordance with Consolidated Standards of Reporting Trials (CONSORT).

Inclusion criteria: Inclusion criteria for the study were children who were between the ages of 6-10 who are proper for measures for present study, whose first phlebotomy attempt was successful, did not taken any analgesic in the last 6 hours, did not have a hearing problem, did not have mental disorders, can speak and understand Turkish comfortably and parents and children are willing to participate in the study.

Exclusion criteria: Inability to phlebotomy successfully in the first application and who had a history of oncological disease, epilepsy, migraine or vestibular disorder were not included in the study.

A computer-based number sequence generator was used for randomization (www.random.org). The assignment of the participants to the groups is showed in the CONSORT Flow Diagram (Figure 1). Intervention and control group CONSORT (2017) flow chart of the study on the effect of vibrating tourniquet, and distraction cards on pain, anxiety and fear levels before blood sampling in children aged 6-10 years [18].

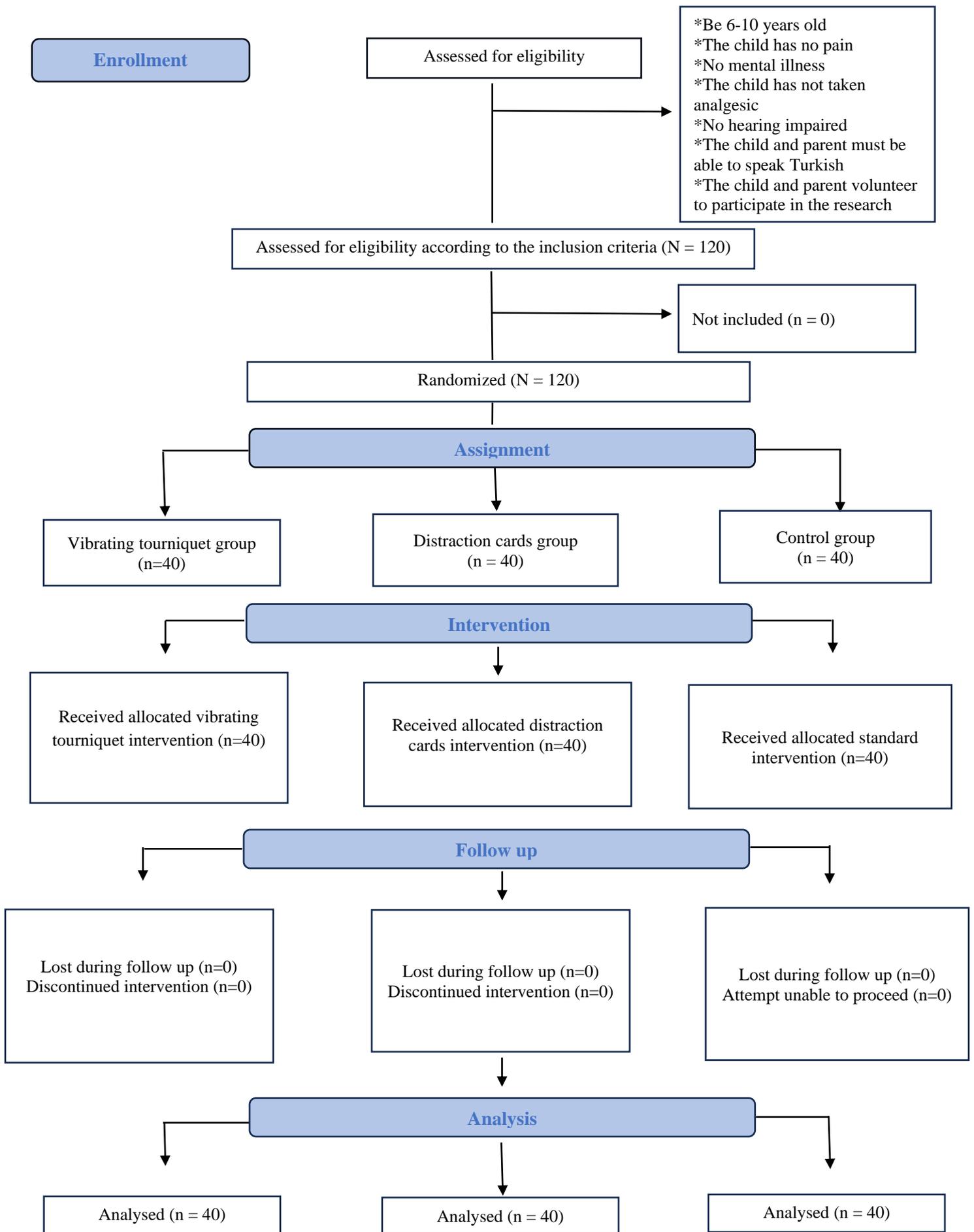


Fig. 1. Flow chart of the study

Instruments

Data were collected with Child and Parent Collection Data Form, Visual Analog Scale, Child Fear Scale and Child Anxiety-State Scale.

Child and Parent Data Collection Form

This form, which was created by the researchers in line with the literature, consists of 23 questions in total, including the previous phlebotomy experiences of child and the socio-demographic characteristics of the child and family [5,15,17,19].

Visual Analog Scale (VAS)

The Visual Analog Scale is a scale used by Hayes and Patterson to evaluate pain in children between aged 3 and 18 years [20]. It is a scale widely used by children, adolescents and adults [21]. There are 6 facial expressions in the scale. The first facial expression, '0', represents the lowest level of pain, and the sixth facial expression, '5', represents the most severe pain level. In the original of the scale, the Cronbach Alpha coefficient was between 0.73 and 0.93.

Child Fear Scale (CFS)

Child Fear Scale is a scale developed by McMurtry et al. to measure the fear levels of children between 5-10 years of age [22]. Turkish validity and reliability study was performed by Gerceker and et al. [17]. The scale has a scoring system between 0-4 point. The first picture (0) indicates the least level of fear, and the fifth picture (4), indicates the most felt level of fear.

Child Anxiety-State Scale (CAS-S)

Child Anxiety-State Scale (CAS-S), was developed by Ersig et al. to measure the anxiety levels of children aged 4-10 years [23]. The Turkish validity and reliability study of the scale was performed by Gerceker et al. [17]. The scale is in the form of a thermometer with horizontal lines. For 10 horizontal lines, the line at the bottom of the thermometer, i.e. '0', represents the lowest anxiety level, and the line at the top of the thermometer, i.e., '10', represents the highest anxiety level.

Data Collection Process

The blood collection unit is located on the first floor of the Gülhane Training and Research Hospital Pediatrics Building. There are four blood collection stretchers and four nurses in the unit. In the blood collection unit, an average of 150-200 pediatric patients are accepted daily and non-pharmacological methods are not used routinely during phlebotomy. Phlebotomy were performed by the same nurse working in the unit. Data were collected by the same researcher (HE) before, during and after the phlebotomy between May 2021 and March 2022.

Vibrating Tourniquet Group (Intervention Group 1/IG1): In the vibrating tourniquet group IG1, the tourniquet was introduced to the children before phlebotomy and the tourniquet was placed before the phlebotomy, allowing the child to recognize the intervention. Vibrating tourniquet adapted by Ozel and Cetin was used for the first time in Ozel's study. Vibrating tourniquet, consist of two parts as tourniquet and vibration providing material [16]. The tourniquet is an elastic band and has a locking mechanism so that it can be adjusted to child's arm. This lock is used to apply pressure to the arm so that the vein can be seen and felt more clearly. The motor that provides vibration was removed from the mobile phone and placed in a case prepared by researcher. This cover is fixed on the tourniquet. The motor placed on the tourniquet works with two 12 volt batteries (supplementary file). VAS, CAS-S, and CFS scores were noted by the researcher (HE) before, during and after the phlebotomy procedure.

Distraction Cards Group (Intervention Group 2/IG2): In the distraction card group, IG2, cards were introduced to children before phlebotomy, and cards were given to the child before phlebotomy, allowing the child to recognize the cards. Distraction cards were prepared by the researcher using 10 images of cartoon characters. Opinions were obtained from two child development specialist working in the clinic for the visual suitability of the distraction cards planned to be used during phlebotomy of the children in Intervention Group 2, and no changes were made to the cards. Distraction cards were visual cards with the size of (Flippits1, MMJ Labs, Atlanta, Georgia, USA) $10 \times 8 \text{ cm}^2$ and put together by drilling with a hole punch from the upper left corners. (Supplementary files). VAS, CAS-S and CFS scores were recorded by the researcher (HE) before, during and after the phlebotomy. During the phlebotomy process, the children were asked several questions about the cartoon characters on the cards such as "Which card did you like more??" "What is the name of this character?," "In which cartoon did you see this character?"

Control Group (CG): No non-pharmacological method was used for the children in the control group. VAS, CAS-S, and CFS scores were recorded by the researcher (HE) before, during and after the phlebotomy.

Outcome

Primary Outcomes

The primary outcome was the change in the level of pain, fear, and anxiety during and after the procedure compared to before the blood draw procedure in the IG1, IG2, and control groups.

Secondary Outcomes

According to the independent variables of the study (socio-demographic characteristics of the child and parent), it was the change in pain and anxiety levels during and after the procedure compared to before the blood draw procedure in the IG1, IG2 and control group.

Ethical approval

The study was approved by the University of Health Sciences Gulhane Scientific Research Ethics Committee Research Ethics Committee (on 08/04/2021 with the number 2021/127). At all stages of the research, the Helsinki Declaration Principles, Research, and Publication Ethics were complied with. Written and verbal consent was obtained from the children and their families, who agreed to participate in the study.

Statistical Analysis

The data were analyzed on the SPSS 21.0 (IBM, Armonk, NY: IBM Corp.) software package. Data were expressed as counts, frequency, mean, standard deviation, medians and quartiles 1–3 (Q1–Q3). The conformity of the data to the normal distribution was evaluated with the Shapiro-Wilk Test. Chi-square test was used in the evaluation of socio-demographic data. The Kruskal Wallis, One Way Anova test was used to evaluate whether there was a difference between the 3 groups that did not comply with the normal distribution, the Dunn test was used to evaluate which group the difference originated from, and the Friedman test was used to determine the difference between the measurements in dependent groups. $p < 0.05$ was considered significant.

Results

A total of 120 children who met the inclusion criteria and agreed to participate in the study were evaluated in this study. There was no statistical difference between the control group and the experimental groups in terms of the age ($p = 0.968$) and gender ($p = 0.521$) variables of the children. There was no statistical difference between the control group and the experimental groups according to the variables of age ($p = 0.587$), educational status ($p = 0.649$) and income status ($p = 0.614$) of the parents (Table 1).

Table 1. The comparison of the descriptive characteristics of the participants (n=120)

	IG1 (n=40)	IG2 (n=40)	CG (n=40)	Test	p
Child characteristic					
Age, year, median (min-max)	8 (6-10)	8.5 (6-10)	9 (6-10)	0.066**	0.968
Gender, n (%)					
Male	19 (47.5)	17 (42.5)	14 (35.0)	1.303*	0.521
Female	21 (52.5)	23 (57.5)	26 (65.0)		
Parental characteristic					
Age, year, mean \pm SD	36.6 \pm 6.7	36.7 \pm 4.8	35.5 \pm 5.6	0.535***	0.587
Educational status, n (%)					
Illiterate	-	-	1 (2.5)	4.204*	0.649
Primary school/secondary school	15 (37.5)	16 (40.0)	13 (32.5)		
High school	9 (22.5)	12 (30.0)	14 (35.0)		
University and above	16 (40.0)	12 (30.0)	12 (30.0)		
Monthly family income, n (%)					
Income less than expenses	7 (17.5)	8 (20.0)	6 (15.0)	2.671*	0.614
Income equals expense	25 (62.5)	24 (60.0)	30 (75.0)		
Income more than expenses	8 (20.0)	8 (20.0)	4 (10.0)		

* χ^2 : Pearson Chi-Square; **Kruskal-Wallis, ***F: One Way Anova, IG1: Vibrating Tourniquet Group, IG2: Distraction Cards Group, CG: Control Group, SD: Standard deviation

Table 2 shows the comparisons of the mean scores of the scales according to the groups. There was a statistically significant difference in the IG1, IG2 and control group in terms of VAS, CFS and CAS-S scores before, during and after the procedure ($p < 0.01$). There was no statistically significant difference among IG1, IG2 and CG in terms of VAS ($p = 0.606$, $p = 0.069$, respectively) and CAS-S scores ($p = 0.581$, $p = 0.061$, respectively) before and during the procedure. There was no statistically significant difference in terms of CFS values before procedure in all three groups ($p = 0.823$).

When the intra-group pairwise comparisons were examined in terms of VAS and CAS-S values after procedure, it was found that there was a statistically significant difference between the distraction cards and the control group ($p = 0.006$, $p = 0.014$, respectively). When the intra-group pairwise comparisons were examined in terms of CFS values before and after procedure, it was found that there was a statistically significant difference between the IG2 and the control group as a result of the further analysis ($p = 0.042$, $p = 0.008$).

Table 2. Comparison of scale scores by groups

Scales	IG1		IG2		CG		Test	p*
	Mean \pm SD	Median (Q1–Q3)	Mean \pm SD	Median (Q1–Q3)	Mean \pm SD	Median (Q1–Q3)		
VAS								
Before	4 \pm 2.7 ^x	4 (2-6)	4.1 \pm 2.2 ^x	4 (2-6)	4.6 \pm 2.8 ^x	4 (2-6)	1.001	0.606
During	2.5 \pm 3 ^y	2 (0-4)	1.9 \pm 1.9 ^y	2 (0-2)	3.4 \pm 2.9 ^y	3 (0-6)	5.358	0.069
After	1.3 \pm 2.4 ^z	0 (0-2) ^{ab}	0.4 \pm 0.9 ^z	0 (0-0) ^b	1.5 \pm 1.9 ^z	0 (0-2) ^a	10.173	0.006
Test	49.750	63.826	52.070					
p**	<0.001	<0.001	<0.001					
CFS								
Before	1.8 \pm 1.1 ^x	2 (1-2)	1.9 \pm 1 ^x	2 (1-3)	2 \pm 1.2 ^x	2 (1-3)	0.390	0.823
During	1 \pm 1.2 ^y	1 (0-1.75) ^{ab}	0.7 \pm 0.7 ^y	1 (0-1) ^b	1.4 \pm 1.3 ^y	1 (0-2.75) ^a	6.329	0.042
After	0.4 \pm 0.9 ^z	0 (0-0) ^{ab}	0.1 \pm 0.2 ^z	0 (0-0) ^b	0.4 \pm 0.7 ^z	0 (0-1) ^a	9.750	0.008
Test	51.116	62.541	50.130					
p**	<0.001	<0.001	<0.001					
CAS-S								
Before	4.15 \pm 2.41 ^x	3.5 (2-6)	4.48 \pm 2.18 ^x	4 (3-6.75)	4.7 \pm 2.8 ^x	4 (2.25-6)	1.085	0.581
During	2.9 \pm 2.4 ^y	2 (1-4)	2.5 \pm 1.5 ^y	2 (1-4)	3.7 \pm 2.4 ^y	3 (2-5.75)	5.595	0.061
After	1.7 \pm 1.7 ^z	1 (1-2) ^{ab}	1.3 \pm 0.7 ^z	1 (1-1) ^b	2 \pm 1.3 ^z	1.5 (1-2.75) ^a	8.588	0.014
Test	58.037	67.781	56.234					
p**	<0.001	<0.001	<0.001					

*Kruskal Wallis, ^{a,b}: There is no difference between groups with the same letter for each measurement. (Dunn Test) **Friedman, ^{x,y}: There is no difference between groups with the same letter for each measurement, VAS: Visual Analog Scale, CFS: Child Fear Scale, CAS-S: Child Anxiety-State Scale, IG1: Vibrating Tourniquet Group, IG2: Distraction Cards Group, CG: Control Group

Discussion

In this randomized controlled study, the effects of the use of vibrating tourniquet and distraction cards, which are non-pharmacological methods of coping with pain, on pain and anxiety levels during phlebotomy were searched. The distraction cards which is the one of the non-pharmacological methods, was found to be more effective in the management of pain, anxiety and fear in children than those in the control group during and after phlebotomy in children aged 6-10 years.

In the present study, the severity of pain was found significantly lower in children who were in distraction cards group after the invasive procedure. Non-pharmacological methods in pediatric patients are easily accessible and they are used according to the age group and cognitive status of each child, and they can be quite effective in relieving or reducing pain [9,24,25]. The studies in the literature investigating the effects of distraction cards and buzzy use on pain show that using both methods together or distraction cards alone are effective in reducing pain [26-30]. In a study conducted by Canbulat et al. (2014) with 188 children to investigate the effects of the use of distraction cards and kaleidoscope during the phlebotomy on the pain and anxiety levels of children, the lowest pain level was obtained in the distraction card group [26]. In a study conducted by Susam et al. (2018) with 72 children and investigating the effects of using Buzzy and distraction cards simultaneously in invasive procedures on children's pain levels, the lowest pain level was found in the combined method [27]. In a study conducted by Garcia Arasil et al. in Spain (2018) with 88 children, it was found that the combined use of distraction cards and Buzzy device or only the use of distraction cards during phlebotomy in the emergency room caused a lower level of pain compared to the control group [28]. These studies show that distraction cards used during invasive procedures in children had a positive effect on pain. In this study also, it is thought that the fact that the children were active and answered the questions asked by the researcher about cartoon characters during the phlebotomy contributed to the children experiencing less pain after the phlebotomy than the children in the vibrating tourniquet group.

The medical procedures are a source of fear in children, especially because of the pain [30]. The use of non-pharmacological methods, especially in procedures that may cause the child to feel fear, such as invasive procedures, facilitates the child's coping with fear, and helps the procedure to end more quickly and less traumatically [30]. The literature shows that the use of non-pharmacological methods reduces fear more in children compared to children in the control group [30,31]. In the present study, the children in the distraction cards group had the lowest fear scores during and after the phlebotomy. This finding shows that the use of non-pharmacological methods in medical procedures helps to reduce children's fear levels.

The hospital is a place that causes children to feel anxiety due to the unknown environment and a lot of uncertainty [1]. Being away from their own safe environment, witnessing other children cry, increased anxiety of parents, fear of not knowing what will happen are situations that increase children's anxiety levels [1,32]. The literature shows that the use of non-pharmacological methods reduces anxiety in children [10,33]. In a study conducted by Sahiner and Turkmen (2019) with 60 children in which it was aimed to investigate the effect of distraction card use on pain and anxiety levels during intramuscular injection, the use of a distraction card was more effective in reducing the level of anxiety compared to the control group [10]. In a study of Erdim with 104 children (2022), the effect of using distraction cards during the skin prick test (allergy test) on pain and anxiety were investigated [33]. It was found that the anxiety levels during and after the procedure were lower in the card-used group than in the control group. Similar to the studies in the literature, after phlebotomy the lowest fear was found in the distraction cards group in the present study. In line with these studies, the healthcare professionals may prefer distraction cards as one of the non-pharmacological methods to reduce the anxiety level of children after and during the invasive procedures.

Limitations

Limitation of this study is blinding could not be performed. The reason is the researcher was involved in the study as explaining the method to the participants.

Conclusion

In our study, the use of distraction cards was found to be effective in reducing the pain, anxiety and fear of children. Although it is difficult to evaluate the concepts of pain, anxiety and fear in clinical practice, it is possible to reduce children's pain and anxiety after the phlebotomy process, and fear levels during and after the phlebotomy process for the children aged between 6 and 10 years by using of distraction cards in line with the philosophy of atraumatic care. It is thought that the preference of distraction cards as an effective method will be a good example in terms of atraumatic care practices, since they are easily accessible, updated and the cartoon characters on the cards can be changed according to age groups. The use of distraction cards, which is one of the techniques for diverting attention in the phlebotomy in children aged 6-10 years, is effective in the management of pain, anxiety and fear in children, and it is important to include them in painful nursing interventions. It is recommended that healthcare professionals need be encouraged to use non-pharmacological distraction methods more in painful procedures. Moreover, there is a need for a nurse-driven protocols for non-pharmacological interventions for pediatric blood collection units in which have not been used non-pharmacological interventions to reduce pain in invasive procedures.

Conflict of interest: None

	Author Contributions	Author Initials
SCD	Study Conception and Design	DS, HE
AD	Acquisition of Data	DS, HE
AID	Analysis and Interpretation of Data	DS, HE, MBC, DY

DM	Drafting of Manuscript	DS, HE, MBC, DY
CR	Critical Revision	DS, HE, MBC, DY

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