Original Article

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The Effects of Virtual Reality and Kaleidoscope on Pain and Fear During Blood Draw in Children: A Randomized Controlled Trial

Çocuklarda Kan Alma Sırasında Sanal Gerçeklik ve Kaleideskopun Ağrı ve Korkuya Etkisi: Randomize Kontrollü Bir Çalışma

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ABSTRACT

Objective: This study was carried out to determine the effect of cartoon watching with virtual reality (VR) glasses and kaleidoscope used during blood draw on the pain and fear of children.

Methods: The universe of this randomized controlled study was composed of 7-12-year-old children who were admitted to blood draw unit of a hospital between January-April 2020. Data of the study were collected by using "Participant Information Form", "Visual Analog Scale", "Wong-Baker FACES Pain Rating Scale" and "The Children's Fear Scale (CFS)."

Results: Mean pain scores of the children in kaleidoscope and VR groups were found to be significantly lower than the ones in the control group in the study ($p<0.05$). Mean fear scores of the children in kaleidoscope and VR groups were significantly lower than the control group based on CFS ($p<0.05$).

Conclusion: It was concluded that kaleidoscope and VR methods were found to be effective in alleviating pain and fear among 7-12-year-old children during blood draw.

Keywords: Acute pain, virtual reality, kaleidoscope, vascular access, child, nursing

ÖZ

Amaç: Bu araştırma çocuklara kan alma işlemi esnasında uygulanan kaleidoskop ve sanal gerçeklik (VR) gözlüğü ile çizgi film izletme yöntemlerinin, çocukların ağrı ve korku durumuna etkisini belirlemek amacıyla yapılmıştır.

Yöntemler: Bu randomize kontrollü çalışmanın evreni bir hastanenin çocuk kan alma birimine Ocak-Nisan 2020 tarihleri arasında başvuran 7-12 yaş arası çocuklar oluşturmuştur. Araştırmanın verileri "Tanıtıcı Bilgi Formu", "Visual Anolog Scale", "Wong-Baker Yüz İfadeleri Derecelendirme Ölçeği" ve "Çocuk Korku Ölçeği (ÇKÖ)" ile toplanmıştır.

Bulgular: Araştırmada kaleidoskop grubu ve VR gözlüğü grubundaki çocukların ağrı puan ortalamaları kontrol grubuna göre anlamlı derecede düşük bulunmuştur ($p<0,05$). Kaleidoskop grubu ve VR gözlüğü grubundaki çocukların ÇKÖ'ye göre puan ortalamaları kontrol grubuna göre anlamlı derecede düşük bulunmuştur ($p<0,05$).

Sonuç: Yedi-on iki yaş arası çocuklara kan alma işlemi sırasında uygulanan kaleidoskop ve VR gözlüğü yöntemlerinin çocukların ağrı ve korku düzeylerini azaltmada etkili olduğu bulunmuştur.

Anahtar Sözcükler: Akut ağrı, sanal gerçeklik, kaleideskop, damar yolu, çocuk, hemşirelik

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Introduction

Children's reactions to the hospital environment and the disease are closely related to the painful medical procedures applied for diagnosis and treatment (1). Children who fear the unknown and perceive that their control is under threat experience the fear that the medical procedures performed on them in the hospital will hurt them and they worry that these procedures will harm them (2). Children are exposed to many medical procedures such as venous blood draw during their lives. Pain, that is experienced during invasive interventions, is generally perceived as a scary experience by the children and shapes future pain responses of the individual (3). It is highly important to make pain experiences less traumatic during childhood. Non-pharmacological methods are among the techniques that can be applied effectively for acute pain as well as chronic pain (4,5). Distraction is an active coping strategy whereby a patient diverts his or her attention from nociceptive stimuli to decrease awareness of the pain. Distraction is often used during medical procedures for managing pain (6). In literature review, many studies have been found to support positive effects of various distraction methods in the alleviation of pain and fear created by invasive procedures (3,7,8). Among these methods, there are watching cartoon, inflating balloon, distracting with non-interventional conversations, using virtual reality (VR) glasses, listening to music, using kaleidoscope and distraction cards (3,8-10). Kaleidoscope is a playing material where colorful patterns are seen inside (11). VR glasses are technological products that are attached to the patient's head to isolate him/her from real life and that enable to watch the prepared images inside larger and clearer in 3-dimensions with its special lenses (4,8). They have a relaxing and pain-relieving effect on the patient due to its distractive ability (11,12). Although it has been supported with the studies in the literature how these methods should be according to cognitive development level, the search for the most suitable ones according to the age groups still continues. In this context, there are a limited number of studies in the literature on reducing the pain and fear of school-age children through distraction techniques. It is known that children in this age group, unlike previous age groups, need detailed information about procedures in addition to family support. In addition, it is important to choose distraction techniques to be used in this age group, which is interested in technological tools and willing to learn. It is important that the methods to be chosen appeal to more than one sense, arouse curiosity and be interesting (2,13). Therefore, this study was carried out to determine the effects of kaleidoscope and cartoon watching using the VR glasses on the pain and fear states of children during blood draw.

Methods

Study Design

This study was planned as a three-group randomized controlled intervention trial.

Setting and Sample

This study was carried out with 7-12-year-old children who were admitted to blood draw unit of a hospital in Turkey between January 21-April 21, 2020. G*Power 3.0.10 program was used to calculate sample size. Power of the study was determined as 0.95 at a confidence interval of 0.95, significance level of 0.05 and an effect size of 0.1 (small effect) by using One-Way ANOVA to compare three groups through G*Power 3.0.10 program. Sample size was calculated as 156 including 52 individuals per each group in the study. However, 2 children were lost in all groups due to the inability to draw blood with one entry and data were completed with a total of 150 children. Groups were generated by using randomization method. Randomization method was determined by using an online program provided that the number of children in study and control groups regardless of the characteristics of the children such as age and sex. The variables of age (7-12 years), gender (girls and boys) were used for block randomization. The blocks were repeated five times in each group, and 50 participants were assigned to each. A 5X2X5 blocked randomization list was developed using an online randomization tool (14). The researcher was not blinded to the group allocation because she performed the randomization herself. Randomization list was prepared by a third individual and given to the researcher only during the implementation.

The inclusion criteria were (1) being between the ages of 7 to 12 years, (2) being literate, and (3) requiring blood tests. The exclusion 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.The study protocol prepared on the basis of the literature (4,6,8) was reviewed and the trial was registered through Clinical Trials.gov (NCT05564260)."

Hypotheses of the Study

H_0: There are no significant differences in the mean pain and fear scores of the children who have used kaleidoscope and watched cartoon using VR glasses.

H_1: Mean pain and fear score of the children who have used kaleidoscope during blood draw is lower than the ones who have not.

H_2: Mean pain and fear score of the children who have used VR glasses during blood draw is lower than the ones who have not.

Data Collection

Participant Information Form: This form included sociodemographic characteristics (age, sex, presence of chronic disease) of the children.

Visual Analog Scale (VAS): VAS developed by Hayes and Patterson (15) is used to measure and monitor pain intensity. VAS, which is used to measure severity of pain consists of a horizontal or vertical ruler at a length of 10 cm or 100 mm which has "no pain" on one side and "the most severe pain possible" on the other side. While there is "no pain" expression on the left side of the ruler, there is "unberable pain" expression on the right side. VAS is described as understandable and easy-to-use for the children over 7 years old (16). Its validity and reliability have been shown in the previous studies (17-19).

Wong-Baker FACES Pain Rating Scale (FACES): The scale is commonly used for children aged 3 to 18 years (20). Besides, the psychometric properties of the Wong-Baker is suitable for evaluating parent proxy (21). It has been translated into many languages including Turkish (22). In this numerical rating scale, scores given by the child range between 0 and 10. Faces show emotions from smiling (0= very happy/no pain) to crying (10= the most painful) (14). In this study, children were assessed by the researcher and nurse in the clinic during post-procedure period. FACES is a commonly used scale to evaluate pain in pediatric group in Turkish population (11,13).

The Children's Fear Scale (CFS): This is a one-item self-report scale which is used to measure pain-associated fear. CFS was developed by McMurtry et al. (23), and adapted to Turkish by Özalp Gerçeker et al. (9). This one-item scale is composed of five neutral faces in terms of sex. There is a face showing no fear on the left and a face showing extreme fear on the right. The response of the evaluator shows the level of fear. It can be used by the parents and researchers before and during the procedure for the children aged 5-10 years old (23,24). Psychometric properties of the scale in Turkish population were carried out by Özalp Gerçeker et al. (24). Fear scale was assessed before and after the blood draw by the child, parent and researcher during the study (24).

Kaleidoscope

Kaleidoscope is an instrument that shows colorful patterns when viewed. When looked inside, patterns that are retrieved by the reflection of light from two mirrors adjacent to each other with an angle of 60 degrees are seen. Created using mirrors and reflected light, these patterns continuously change as glass is turned. These patterns in different shapes draw the attention of the children and provide distraction (11,25).

Virtual Reality Glasses

VR are technological products that provide 360-degree audio visual simulation that surround the user and allow them to look around in all directions (2,5). In this study, the VR intervention was performed using a smartphone (Samsung Note 4), VR glasses BOX 3D/Fuchsia7/20x11x13 in./weigh 550 g) and a headset (Samsung Galaxy, microphone, Bluetooth, wired). While using VR, there is no need for any power or connection unit other than the phone. All children in the study were made to watch the same video (Puss in Boots The Three Musketeers/Looney Tunes Road Runner) recommended by the experts based on children ages. Five children between 7-12 years old were made to watch selected videos before starting the study. There was no negative feedback.

Procedures

Before venous blood draw: The method to be used during blood draw was explained to the child and parent by the researcher; and measurement tools to be scored were introduced during the procedure. The parents were told to be with their children in the room and to observe them during the procedure. CFS scoring was done by the children, one parent and the researcher in all groups before blood draw. Intervention groups were introduced kaleidoscope and VR and they were told how to use them and they would watch these materials during the procedure.

At 2-3 minutes before blood draw: Children in the kaleidoscope group were given kaleidoscope and they were made to watch it during the procedure. VR group was made to choose one of the different videos/cartoons found in the phone for the implementation of VR glasses. The glasses were put on as soon as the child sit on the armchair and he/she was made to watch 3D video during the procedure. The parts of the device which were in contact with children's faces were cleaned before each practice. Control group received routine venous blood draw in the clinic and no other intervention was made.

Following venous blood draw: Children in all groups were made to score VAS and FACES for pain level and CFS for fear level during the procedure. A parent and researcher who stayed besides the children and observed them determined their pain and fear levels and scored FACES for pain and CFS for fear. Venous blood draw was performed by an experienced nurse in all groups (Figure 1).

Ethical Considerations

The study was conducted after formal permissions for the study were obtained from the Directorates of the Ondokuz Mayıs University Hospitals and the Ethic Commission of university hospital (approval number: KAEK 2019/846, date: 12.12.2019).

Before the launch of the research, parents and children were informed about the subject and the objectives of the research and parents' written consent and children's verbal assents were obtained (clinicaltrials: NCT05564260).

Statistical Analysis

Data were analyzed by IBM SPSS V23 (SPSS Inc., Chicago, IL, USA). Normality assumption was tested by Kolmogorov-Smirnov and Shapiro-Wilk tests. Chi-square was used to compare categorical variables between the groups. Mann-Whitney U test was used to compare non-parametric variables in two independent groups. Non-parametric quantitative data in three and more groups were compared by Kruskal-Wallis test. Moreover, Wilcoxon test was used to compare non-parametric variables before and after the procedure within the groups. Dunnett's T3 pairwise comparison post hoc test was used to determine significant differences in the case of unequal variances. Significance level was considered as $p<0.050$.

Results

It was determined that the distribution of sex and age of the children according to the groups was homogenous (Table 1).

Table 2 shows the comparisons of mean pain scores. When VAS values were compared between the groups, it was determined that mean pain scores of kaleidoscope and VR groups were lower than the control group and the difference was found to be statistically significant ($p<0.001$). When FACES pain scores were compared between the groups, mean pain score of the control group was found to be higher than the other groups and the difference was found to be statistically significant ($p<0.001$) (Table 2).

Table 3 shows the comparisons of mean fear scores of the child, parent and researcher. Accordingly, no statistically significant difference was observed between the groups before blood draw according to the child, parent and researcher (p>0.05). It was found that mean fear score was higher in the control group compared to the other two groups following blood draw, and the difference was statistically significant (p<0.05). The statistically significant difference was found between the fear scores before and after the procedure in each group. It was determined that the mean fear score was the lowest in the VR group followed by the kaleidoscope group and the control group, respectively (p<0.001).

Discussion

In this study, the effects of kaleidoscope and VR glasses methods used during blood draw on the pain and anxiety of 7-12-year-old children were investigated and some of the distraction methods found in the literature which were used in various areas such as blood draw and other invasive procedures were discussed.

In the study, it was determined that VR group was more effective than control group in alleviating pain and fear. Similar results have been reported in many studies in the literature. It was also found that interventions such as VR reducing pain during the blood draw was effective in reducing perceived pain in children of various age groups (8,12,26,27). Özalp Gerçeker et al. (13) compared two different VR methods and revealed that both methods were effective in alleviating pain of children during blood draw based on the reports by the child, parent and researcher. In the study by Gold and Mahrer (12) which was carried out with 143 children and adolescents between 10-21 years, it was found that pain scores of the children in the study group using VR glasses were lower than the scores of children in the control group. Also in the study by Piskorz and Czub (28) with pediatric nephrology patients between 7-17 years, VR was found to decrease pain intensity and stress level significantly. Moreover, Dumoulin et al. (6) reported that VR was effective in reducing pain among 8-17-year-old children during blood draw in the emergency service. VR was also reported to be effective in

Table 1. Sex and age characteristics of the children according to the groups

Characteristic		Kaleidoscope group		VR group		Control group		X^2	p
		n (%)		n (%)		n (%)			
Sex	Female	27 (54.0)		25 (50.0)		26 (52.0)		0.160[1]	0.923
	Male	23 (46.0)		25 (50.0)		24 (48.0)			
		$\bar{X}$ ± SD	Min.-max.	$\bar{X}$ ± SD	Min.-max.	$\bar{X}$ ± SD	Min.-max.		
Child's age		9.2±1.6	7-12	8.9±1.4	7-12	9.1±1.4	7-12	0.590[2]	0.745

$\bar{X}$ ± SD: Mean ± standard deviation, min.: Minimum, max.: Maximum, [1]Chi-sqaure test, [2]Kruskal-Wallis test, p<0.05, VR: Virtual reality

Table 2. Comparisons of mean VAS, FACES scores between kaleidoscope, VR and control groups

Characteristic	Kaleidoscope group[a]; mean ± SD (min.-max.)	VR group[b]; mean ± SD (min.-max.)	Control group[c]; mean ± SD (min.-max.)	Test statistic, (p)
VAS	0.8±1.3 (0-7)	1±1.7 (0-8)	3±2.5 (0-9)	KW: 35.750, p<0.001 *a<b, p>0.909 *a<c, p=0.000 *b<c, p=0.000
FACES-child reported	0.6±0.9 (0-4)	0.4±0.7 (0-3)	1.9±1.5 (0-5)	KW: 36.836, p<0.01 *a>b, p>0.691 *a<c, p=0.000 *b<c, p=0.000
FACES-parent reported	0.8±0.9 (0-4)	0.6±0.8 (0-3)	2±1.5 (0-5)	KW: 25.366, p<0.01 *a>b, p>0.793 *a<c, p=0.000 *b<c, p=0.000
FACES-researcher reported	0.8±1 (0-4)	0.5±0.8 (0-4)	1.9±1.6 (0-5)	KW: 26.927, p<0.001 *a>b, p>0.272 *a<c, p=0.000 *b<c, p=0.000

*Post-hoc test=Dunnett T3 p<0.05, VAS: Visual Analog Scale, FACES: Wong-Baker FACES Pain Rating Scale, VR: Virtual reality, KW: Kruskal-Wallis, SD: Standard deviation, min.: Minimum, max.: Maximum

Table 3. Comparisons of mean CFS scores between kaleidoscope, VR and control groups

CFS		Kaleidoscope group[a]; mean ± SD (min.-max.)	VR group[b]; mean ± SD (min.-max.)	Control group[c]; mean ± SD (min.-max.)	Test statistic, (p)
Self reported	Pre	2.0±1.1 (0-4)	2.4±1.1 (0-4)	2.2±1.1 (0-4)	3.564; 0.168
	Post	0.8±0.9 (0-4)	0.3±0.6 (0-3)	1.5±1.3 (0-4)	**23.961; <0.001** *a>b, p>0.016 *a<c, p=0.009 *b<c, p=0.000
	Diff.	1.2±1.3 (-2-4)	2.1±1.1 (0-4)	0.7±0.8 (-1-3)	36.782; <0.001
Parent reported	Pre	2.4±1.3 (0-4)	2.2±1.1 (0-4)	2.4±1.2 (0-4)	0.622; 0.733
	Post	1.0±1.0 (0-4)	0.6±0.7 (0-3)	2.4±1.2 (0-4)	**10.889; 0.004** *a>b, p>0.103 *a<c, p=0.049 *b<c, p=0.000
	Diff.	1.4±1.4 (-2-4)	1.6±1.1 (-1-4)	0.8±0.9 (0-3)	13.391; <0.001
Observer reported	Pre	2.5±1.3 (0-4)	2.3±1.1 (0-4)	2.2±1.1 (0-4)	1.488; 0.475
	Post	0.9±1.1 (0-4)	0.5±0.7 (0-3)	1.4±1.4 (0-4)	**14.850; <0.001** *a>b, p>0.039 *a<c, p=0.122 *b<c, p=0.000
	Diff.	1.5±1.4 (-3-4)	1.8±1.1 (0-4)	0.8±0.8 (0-3)	21.120; <0.001

*Post-hoc test=Dunnett T3 p<0.05, SD: Standard deviation, KW: Kruskal-Wallis, CFS: Children's Fear Scale, VR: Virtual reality, SD: Standard deviation, min.: Minimum, max.: Maximum

alleviating pain, fear and anxiety during some invasive procedures such as vaccination, dental procedures and changing dressing in wound and burn cases (29-31). Our research findings are similar to the results reported in the literature.

In the study, it was determined that distraction by using kaleidoscope during blood draw was effective in alleviating the level of perceived pain. Also in the previous studies, various distraction methods and kaleidoscope were reported to be effective in alleviating pain, anxiety and fear among children during blood draw (6,11,25,32,33). Karakaya and Gozen (25) reported that distraction by using kaleidoscope during blood draw from 7-12-year-old children was effective in alleviating their perceived pain. Kunjumon and Upendrababu (32) also showed that kaleidoscope was effective in managing pain during intravenous cannulation among 4-6-year-old children. Canbulat et al. (11) found that distraction cards and kaleidoscope were effective in alleviating perceived pain compared to control group among 7-11-year-old children. Moreover, the study by Prajapati (33) showed that kaleidoscope was more effective in alleviating pain during blood draw compared to the control group. In their study, Tüfekçi Güdücü et al. (34) determined that kaleidoscope method was effective in reducing pain during blood draw among school age children. Also, Bulut et al. (35) investigated the effects of music therapy, hand massage and kaleidoscope use following circumcision on nausea, vomiting, fear and stress in their study; and reported that mean postoperative pain scores in kaleidoscope and music group were lower than the control group and fear and anxiety scores were lowest in the kaleidoscope group. In addition, Koç Özkan and Polat (36) reported that kaleidoscope and VR use during blood draw had positive effects on pain and anxiety compared to control group among 4-10 year old children.

Our results showed that VR was an effective method that helped reduce venipuncture fear in children. In the study by Koç Özkan and Polat (36), it was found that VR was more effective on the pain and anxiety compared to kaleidoscope according to the child, parent and researcher. In a randomized clinical trial by Walther-Larsen et al. (37), the effect of VR pain reduction during venipuncture was investigated in children aged 7 to 16 years, and it was found not effective on pain. A systematic review and meta-analysis of the effect of VR on pain and anxiety in children conducted and suggested that more research was warranted (38). In addition, most VR manufacturers do not recommend the use of VR in children younger than the age of 6 years due to their neurodevelopmental characteristics (39). Therefore, it can be concluded that VR is more effective in children aged 7 years and older.

Study Limitations

There were some limitations in this research. First of all, the study was carried out at a single hospital and on 7-12-year-old children, which made the generalization of the study results limited. Secondly, before conducting the study, children in the VR group were informed by the researcher about the purpose of the study. This explanation might have relieved children's fear about the procedure, so they might have experienced less pain. Third, the sample size was small, and therefore, the results were sample-specific and not generalizable to all venipuncture procedures in children.

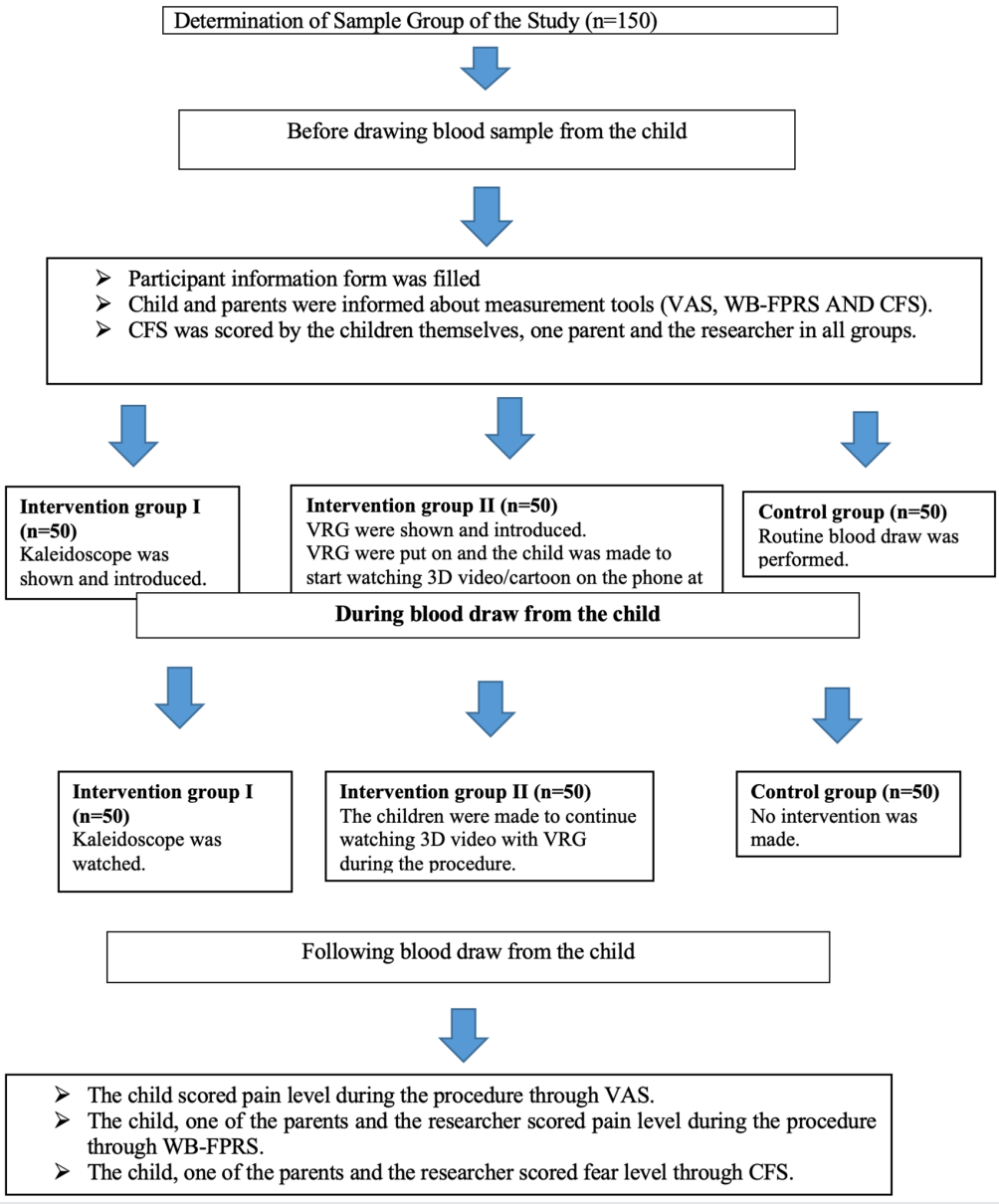

Figure 1. Flowchart based on the CONSORT diagram

VAS: Visual Analog Scale, WB-FPRS: Wong Baker-FACES Pain Rating Scale, CFS: Children's Fear Scale, VRG: Virtual reality glasses

Conclusion

In the study, kaleidoscope and VR groups were found to be effective in alleviating pain and fear levels compared to the control group according to the child, parent and researcher. Moreover, VR was observed to be more effective in reducing fear levels compared to the kaleidoscope group. Although VR was an effective tool, it would be more efficient to use it together with another non-pharmacological or/and pharmacological method so that the method could give more favorable results. Many relevant studies in the literature have reported similar outcomes; and it can be stated that kaleidoscope and VR can be safely used as a distraction method for alleviating pain and fear in children during invasive procedures.

The results of the present study might contribute to the use of evidence-based and non-pharmacological pain management methods for pediatric nurses. Based on the results, it is recommended to inform nurses and other healthcare professionals working in the pediatric units about the use of VR and kaleidoscope, to make the use of them more common during invasive procedures and to conduct evidence-based studies. Randomized controlled trials are required to increase the level of evidence of VR and kaleidoscope method. Further research should be conducted in different age groups, and VR and kaleidoscop effect should be compared with other distraction methods.

Ethics

Ethics Committee Approval: The study was conducted after formal permissions for the study were obtained from the Directorates of the On Dokuz Mayıs University Hospitals and the Ethic Commission of university hospital (approval number: KAEK 2019/846, date: 12.12.2019).

Informed Consent: Before the launch of the research, parents and children were informed about the subject and the objectives of the research and parents' written consent and children's verbal assents were obtained.

Peer-review: Externally and internally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: N.T., Concept: E.T.B., Design: E.T.B., Data Collection or Processing: N.T., E.T.B., Analysis or Interpretation: N.T., E.T.B., Literature Search: N.T., E.T.B., Writing: N.T., E.T.B.

Conflict of Interest: No conflict of interest was declared by the authors.

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