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Efficacy of Cartoon Viewing Devices During Phlebotomy in Children: A Randomized Controlled Trial

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A B S T R A C T

Purpose: The purpose of this study was to examine the efficacy of different cartoon viewing devices during phlebotomy in children.

Design: This study was a prospective, randomized controlled trial.

Methods: The study included inpatients from the Biochemical Laboratory of a private university hospital in Turkey and was conducted between September 2017 and April 2018. A computer-based random number generator was used to randomly assign the patients into three groups (virtual reality [VR], tablet, and control) with 40 children each. Data were collected using the Wong-Baker FACES Pain Rating Scale and the Children's Fear Scale. Pain and anxiety scores were reported by children, parents, and observers in tablet and control groups. In the VR group, pain and anxiety were determined only by children's reports.

Findings: According to the children reports, the VR group reported significantly less pain and anxiety than those in the tablet and control groups (P < .05).

Conclusions: The cartoon distraction performed using a VR device reduced the perception of pain and anxiety during phlebotomy in school-age children.

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Pediatric patients frequently give blood samples for the determination of infections, illnesses, or conditions, the causes of which are undetermined.^{1,2} To obtain a blood sample, the needle needs to pass through the dermis, epidermis, and the walls of veins.³ With the mechanical trauma created in passing these tissues, damage is inflicted to the tissue, and free nerve endings in these tissues get stimulated. During entrance into the tissue, a short, localized, and sharp primary pain is experienced.⁴ The pain related to phlebotomy also affects children psychologically and leads to negative responses (sweating, contraction, fear, tremor, and shaking, etc).^{5,6} These negative reactions are defined as anxiety that can disrupt communication between nurses and children and cause distress to parents. In addition, this anxiety is an obstacle for other invasive procedures.^{2,5,6} For the management of procedural pain and anxiety, nurses should apply pharmacologic and nonpharmacologic methods.⁷ The International Guidelines in Pediatric Anesthesia (ie, good practice in postoperative and procedural pain management)

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recommend the use of pharmacologic and nonpharmacologic strategies for acute procedural pain management in children.⁸

Many studies have investigated the effects of pharmacologic and nonpharmacologic methods for managing pain during phlebotomy in children of different age groups. Rather than pharmacologic methods, nurses have researched nonpharmacologic interventions to eliminate procedural pain and anxiety. These nonpharmacologic methods include using local cold interventions (vapocoolants, buzzy, etc)^{1,9,10} and distraction techniques. It is known that methods of distraction, which is a cognitive-behavioral tool, are effective in reducing pain and anxiety levels in needle-related procedures (phlebotomy, peripheral intravenous [IV] catheter replacement, and intramuscular injection) in children between the ages of 6 and 12.¹¹ These distraction methods include listening to music,^{12,13} playing video games,¹⁴ squeezing a soft ball,¹⁵ balloon-inflation-and-cough trick,^{12,14-17} animal-assisted interventions,¹⁸ breathing exercises,¹⁹ a kaleidoscope,^{1,20,21} distraction cards/flippits,^{12,15,22} and watching cartoon films.²³ All these studies demonstrated that distraction techniques were effective in reducing pain and anxiety levels in children.

Although the literature discusses some of the harms of technology on the social development of children, technological devices attract the attention of individuals of all ages. Audiovisual

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distraction (video cameras, slide-tape presentations, films, television programs, computers, tablets, etc) was demonstrated to be effective in reducing self-reported pain, improving patient cooperation, and increasing success rate in needle-related procedures and was as successful as routine psychological intervention.²³ Miguez-Navarro and Guerrero-Marquez²⁴ determined that video distraction (using a portable digital video disc) was effective in reducing the pain intensity and anxiety scores of children in emergency units. Researchers have suggested that virtual reality (VR) technology can be used to reduce acute procedural pain in school-age children.²⁵⁻²⁹

VR also has an advantage over distraction techniques such as cartoon viewing or traditional audiovisual distraction devices. Body-tracking head-mounted displays and other sensory input devices create a more immersive three-dimensional and interactive setting for the user. The head-mounted display reduces the user's visibility of other people and creates distractions around the medical examination room or intervention room.²⁵⁻²⁹ Studies suggest that VR box devices are effective for decreasing pain and anxiety in children during invasive procedures (port catheter access, IV catheter replacement, and venipuncture).^{25,26,29} Although there have been only a few studies on the efficacy of both devices, no study has been published that compares the efficacy of cartoon viewing devices in children.

Purpose

The purpose of this study was to examine the efficacy of different cartoon viewing devices during phlebotomy in children.

There were two research hypotheses:

H1—Watching cartoon films in a VR box as a distractor would be effective on the pain intensity scores of children during venipuncture.

H2—Watching cartoon films in a VR box as a distractor would be effective on the anxiety scores of children during venipuncture.

Methods

Research Design

A prospective randomized controlled trial design was used to determine the effects of two cartoon watching devices (VR box or tablet) on the pain intensity and anxiety levels of children during phlebotomy. The study complied with the guidelines of Consolidated Standards of Reporting Trials (CONSORT) checklist.

Setting and Sample

This study included inpatients from the Biochemical Laboratory of a private university hospital in Turkey and was conducted between September 2017 and April 2018. The children were required to meet the following inclusion criteria: (1) being in the range of 7 to 12 years, (2) having a blood sample test ordered by the pediatric physician, (3) not having any acute pain or anxiety at the time of the procedure, (4) not having any audiovisual, cognitive sensitivity, or severe physical disability, and (5) having the ability to verbally communicate. The exclusion criteria were as follows: incision or scar tissue in the forearm area, congenital, genetic, developmental, or neurologic disease, feeding or hydration problems, problems with skin integrity, or involuntary movement of arm at the phlebotomy site.

Power analysis was performed based on previous research with a large cohort to estimate the sample size.^{23,25,26,29,30} Assuming a power of 80% and an α risk of 0.05, a sample size of 120 was

appropriate. Pediatric patients (N = 120) were then assessed according to the inclusion criteria and invited to participate depending on their eligibility. A computer-based random number generator was used to assign the patients into groups. To conceal the random assignment of pediatric patients, a data collection form with a random number was kept in a sealed envelope, which was opened by another research nurse only at the time of phlebotomy. According to the randomization result, the research nurse responsible for phlebotomy explained the study to the children and their parents before phlebotomy. Overall, the study sample comprised 120 pediatric patients: 40 in the VR box group, 40 in the tablet group, and 40 in the control group. The flow diagram created by the researchers was based on CONSORT (Figure 1). The study was registered in clinical trials with the registration number of NCT03645213.

Measurements and Instruments

Demographic information (age, gender, reason of visit, previous phlebotomy experience, and educational level of parents) was obtained from all children. Three registered nurses were responsible for the procedure and data collection process. One of them, who had 6 years of experience in pediatric nursing, took all blood samples and applied the cartoon viewing devices. Another nurse, who had 2 years of experience in clinical nursing, collected demographic information and asked the pain intensity and anxiety levels of children and their parents immediately after phlebotomy. The third nurse had 11 years of experience in clinical nursing and only observed pain and anxiety scores in children during phlebotomy.

Wong-Baker FACES Pain Rating Scale

The intensity of pain resulting from phlebotomy was selfreported by each child, as well as through parent and observer reports using the Wong-Baker FACES Pain Rating Scale (WB-FBRS). This scale includes six faces, which are assigned the values of 0, 2, 4, 6, 8, and 10. These numbers refer to no hurts, hurts a little bit, hurts a little more, hurts even more, and hurts the worst, respectively. This instrument is valid between the ages of 3 to 18. Turkish language validity and psychometric properties were tested.³¹ This scale was only used for the children's, parent's, and observer's reports in the tablet and control groups because the face responses of the children in the VR box group could not be observed as it is a head-mounted display. In addition, this scale was used for the selfreport of each child in the VR group.

Children's Fear Scale

The Children's Fear Scale (CFS) was used to evaluate the level of anxiety of the children and as reported by the parents and observer reports. CFS is a 0 to 4 scale showing five cartoon faces. These numbers refer to not scared at all, a little bit scared, a bit more scared, and right up to the most scared possible, respectively. This instrument is valid between the ages of 5 to 15. Turkish language validity and psychometric properties were tested.³² This scale was only used to evaluate the parents' anxiety levels and the observer reports in the tablet and control groups as the face responses of the children could not observed in the VR box group.

Equipment and/or Tools

A cartoon chosen by the children was used as the distractor. In addition, a registered nurse who took all the blood samples checked the film for appropriateness for the children's ages. For the VR group, VR box (Samsung Gear VR box/SM-R323N, Samsung Electronics, Seoul, South Korea), a head-mounted display with

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C O N S O R

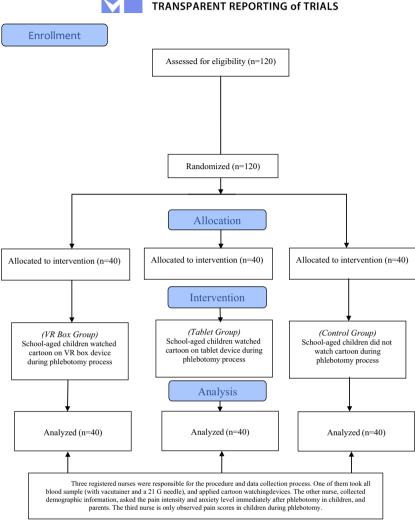


Figure 1. Allocation of subjects according to the Consolidated Standards of Reporting Trials (CONSORT) 2010 flow diagram. This figure is available in color online at www.jopan.org. VR, virtual reality.

stereo earphones, transmitted the cartoon image onto the screen in front of the child's eyes. In the tablet group, the children watched the cartoons on a 7.0-inch tablet computer (Vestel V Tab 7025, Vestel Electronics, Manisa, Turkey). The tablet was placed on a stand. The stand was set in accordance with children's visual range.

Ethical Considerations

Approval for this randomized controlled trial was received from the Hospital's Ethics Committee and institution (number 10840098-604.01.01-E.40485). Before the study, children and parents were informed of the purpose of the research and were assured of their right to refuse to participate in the study or withdraw their consent at any stage.

Procedure

After the assignment, children and their parents were admitted to the phlebotomy unit for the procedure. First, the parents in all groups filled out the demographic information forms. Children sat on the blood-sampling chair and were then asked which cartoon they wanted to watch, and the registered nurse set it up after checking its appropriateness. All parents stayed with their children during the procedure. The cartoons started playing a minute before phlebotomy and lasted about 4 minutes.

Venipuncture was performed between 08:00–12:00 hours and 13:00–16:00 hours with a vacutainer and a 21-gauge needle. No topical anesthetic was used as it is not the standard practice of the unit. Venipuncture was successfully administered at the first attempt in all children. After the procedure, the children's pain levels were assessed by self-report and parent's and the observer's report.

Evaluation of Data

All statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS, Inc, Chicago, IL), version 21.0, for Windows. Baseline demographic information among the groups and all nonparametric data were analyzed using the χ^2 test. Outcomes data such as the intensity of pain and anxiety levels in

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Table 1

Distribution of Characteristics of Children (N = 120)

Characteristics	VR Box Group	Tablet Group	Control Group	Total Groups	χ ² ; <i>P</i>	
	n (%)	n (%)	n (%)			
Child's age						
Mean \pm SD	9.3 ± 1.8	9 ± 1.7	9 ± 1.7	9.1 ± 1.7	1.920; .38	
Child's gender						
Female	20 (50)	18 (45)	16 (40)	54	0.801; .67	
Male	20 (50)	22 (55)	24 (60)	66		
Reason of the visit						
Checked	16 (40)	15 (37.5)	14 (35)	45	5.952; .051	
Sickness	12 (30)	18 (45)	9 (22.5)	39		
Operation	12 (30)	7 (17.5)	17 (42.5)	37		
Previous venipuncture expe	erience					
Yes	27 (67.5)	22 (45)	22 (45)	71	1.710; .425	
No	13 (32.5)	18 (55)	18 (55)	49		
Educational status of paren	t					
Primary school	16 (40)	5 (12.5)	14 (35)	35	1.463; .481	
High school	9 (22.5)	22 (55)	16 (40)	47		
Higher education	15 (37.5)	13 (32.5)	10 (25)	38		

VR, virtual reality.

children were compared using Kruskal-Wallis analysis of variance for three groups (children's, parent's, and observer's scores), and *t* test was used for pairwise groups (parent's and observer's scores). Relations between mean scores were determined by Pearson correlation. Statistical significance was set at P < .05, and Bonferroni test was performed as a post hoc analysis.

Findings

The final cohort included 120 patients (54 females and 66 males), with 40 enrolled in the VR box group, 40 in the tablet group, and 40 in the control group. The mean age was 9.1 ± 1.7 years. Of the sample, 37.5% visited the physician for checking their developmental status, 59.1% had phlebotomy experience, and 39.1% of the parents were high school graduates. There was no statistically significant difference among the groups regarding the demographic variables (Table 1).

Research Hypothesis 1: Pain Intensity Scores

According to children reports, WB-FBRS scores were significantly higher in the control (4.95 ± 3.65) and the tablet (4.55 ± 3.44) groups than in the VR box (1.3 ± 2.15) group during phlebotomy (P < .001) (Table 2). Post hoc pairwise comparisons with the Bonferroni correction showed significant differences in the pain intensity scores in the VR box group (P < .001). There were no significant differences between the tablet and control groups in terms of WB-FBRS scores according to parents and observer reports (P > .05) (Table 2). In addition, there was a positive correlation between the pain levels reported by the children, parents, and observer in the tablet and control groups (P < .001) (Table 3). Thus, research hypothesis 1 was confirmed.

Table 2

Comparison of Pain Intensity Scores (N = 120)

Pain Intensity Scores (WB-FBRS)	VR Box Group ($n = 40$)	Tablet Group $(n = 40)$ Control Group $(n = 40)$		<i>F</i> [*] or <i>t</i> , <i>P</i>
	Mean ± SD	Mean ± SD	Mean ± SD	
Children-reported	1.3 ± 2.15	4.55 ± 3.44	4.95 ± 3.65	27.857, <.001
Parent-reported	ND	3.5 ± 2.70	4.65 ± 3.46	1.65, .102
Observer-reported	ND	3.45 ± 2.71	4.85 ± 3.41	2.02, .052

WB-FBRS, Wong-Baker FACES Pain Rating Scale; ND, no data. * Kruskal-Wallis analysis of variance.

Research Hypothesis 2: Anxiety Level Scores

According to children's reports, CFS scores were significantly higher in the control (2.52 ± 1.33) and tablet (2.27 ± 1.56) groups than in the VR box (0.65 ± 0.92) group during phlebotomy (P < .001) (Table 4). Post hoc pairwise comparisons with the Bonferroni correction showed significant differences in the anxiety level scores of the VR box group (P < .001). In addition, there was a positive correlation between the anxiety levels reported by the children, parents, and observer in tablet and control groups (P < .001) (Table 3). Thus, research hypothesis 2 was confirmed.

Discussion

This study was conducted to compare and determine the effects of VR box device and tablet technologies and routine management on pain and anxiety levels during phlebotomy in school-age children. As hypothesized with a VR box device, the pain and anxiety experienced by school-age children during phlebotomy was significantly less compared with using a tablet and to using no device. This study provided additional evidence showing the VR box device to be more effective than other distraction methods (tablet) in needle procedures for children. This is the first study to examine the effectiveness of different devices in phlebotomy in school-age children.

Nonpharmacologic interventions are defined in the literature as distracting, providing relaxation by reducing muscle tension and helping ease pain and anxiety levels.⁴ As reviewed in the introduction section, numerous studies demonstrated that distraction methods were effective in reducing pain and anxiety during needle-related procedures in children. In addition, researchers determined that audiovisual distraction methods were effective on pain and anxiety management in children.^{23,24} Furthermore, in the

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Table 3
The Correlation of Pain and Anxiety Scores Between Children, Parents, and Observer

Groups	Pain Intensity Scores (WB-FBRS)		Anxiety Level Scores	(CFS)		
	Children/Parents	Children/Observer	Parents/Observer	Children/Parents	Children/Observer	Parents/Observer
Tablet group $(n = 40)$ Control group $(n = 40)$	r = 0.749, P < .001 r = 0.900, P < .001	r = 0.759, P < .001 r = 0.904, P < .001	r = 0.937, P < .001 r = 0.965, P < .001	r = 0.898, P < .001 r = 0.885, P < .001	r = 0.844, P < .001 r = 0.843, P < .001	r = 0.930, P < .001 r = 0.959, P < .001

WB-FBRS, Wong-Baker FACES Pain Rating Scale; CFS, Children's Fear Scale.

technology market. VR box devices are marketed such that putting this device over your eyes will leave you blind to the current world, but will expand your senses with experiences within (https://www. cramer.com/story/the-difference-between-ar-and-vr/).³³ Although the nurses communicate with and define the intervention to children, pediatric patients mostly fear this invasive procedure. By its definition, the VR glass completely closes the user's field of vision to the outside world, so the children cannot see the entrance of the needle, and this may have played a role in reducing the perception of pain and anxiety. In this study, the pain intensity and anxiety levels of the children in the VR box group were lower than the other groups. Similar to our study results, the literature showed that VR technology was effective on acute procedural pain (dressing changes, acute medical interventions, port access procedure, etc).^{25,30,34} Another study carried out on school-age children during phlebotomy found that the VR distraction method had similar scores to the external cold-vibration method (buzzy) in terms of pain intensity.³⁵ Similarly, researchers determined that the VR box was effective on pain and anxiety among pediatric patients undergoing venipuncture.^{31,36} In addition, the scores reported by the children, parents, and observer were at similar levels. This finding was similar to previous research results.^{1,15}

Limitations

There were some limitations of our study. First, the data for the pain intensity and anxiety levels were self-reports by the children, parents, and observer. Second, the sample consisted only of schoolage children. Third, the effectiveness of these devices on physiological parameters (heart rate, respiratory, and blood pressure, etc) and hormonal response (eg, endorphin secretion) were not evaluated.

Conclusion

Our study adds to the evidence the benefits of nonpharmacologic intervention in reducing pain and anxiety in schoolage children. The VR-based cartoon distraction method reduced the pain intensity and anxiety levels of school-age children during phlebotomy. Thus, it can be suggested that this distraction technique (especially VR based) should be routinely applied in schoolage children during needle-related procedures. Further studies

Table 4		
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Comparison of Anxiety	Level Scores ($N = 120$)
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Anxiety Level Scores (CFS)	VR Box Group $(n = 40)$	Tablet Group $(n = 40)$	Control Group $(n = 40)$	<i>F</i> [*] or <i>t</i> , <i>P</i>
	Mean \pm SD	$\text{Mean} \pm \text{SD}$	Mean \pm SD	
Children- reported	0.65 ± 0.92	2.27 ± 1.56	2.52 ± 1.33	27.857, <.001
Parent-reported	ND	1.97 ± 1.51	2.50 ± 1.33	-1.702, .093
Observer- reported	ND	2.07 ± 1.50	2.47 ± 1.35	-1.308, .195

CFS, Children's Fear Scale; VR, virtual reality. * Kruskal-Wallis analysis of variance. are needed to assess the effects of VR box distraction on pain and anxiety levels and physiological and hormonal responses in acute procedural pain in different age groups. Also, for perianesthesia care, the study could be replicated in children requiring insertion of IV catheters.

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