

# The effect of virtual reality glasses against the fear of circumcision: A randomized controlled trial

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## Ethics Committee Approval

In order to conduct the research study, ethics committee permission was obtained from "Karaman University, Faculty of Health Sciences, Ethics Committee of non-Pharmaceuticals and non-Medical Device Researches" (dated 16/06/2017 and numbered 2017/975), and institutional permission was obtained from the "Ministry of Health Karaman Public Hospitals Institution General Secretariat of the Public Hospitals Association of Karaman Province" (dated 13/07/2017, and numbered 50658796-774.99-E.3674). Additionally, written consents were obtained from all of the participant patients and their parents concerning their volition to participate in the study.

All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

## Conflict of Interest

No conflict of interest was declared by the authors.

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## Abstract

**Background/Aim:** Circumcision is an invasive operation that male children undergo in our country and some others. During this process, the child can experience fear, anxiety, and pain simultaneously. As a randomized controlled VR study, this research was conducted to determine the effect of virtual reality (VR) glasses on reducing fear/anxiety and pain during circumcision in children.

**Methods:** The study was conducted on 125 children (6-11 years old). The same healthcare team performed the circumcision of the children in both groups. The children were randomly split into VR and control groups. The children in the VR group, just before the circumcision, watched their preferred cartoon film via VR glasses. No additional procedure was applied to the children in the control group except for ordinary procedures in the hospital. The fear and pain status measured by Wong-Baker Faces Pain Rating Scale and Children Fair Scale of all the children were evaluated before and after the operation by the child, parents, and the observer. Descriptive statistics, chi-square, and t-tests analyzed the data.

**Results:** There was no significant difference between the groups regarding demographic characteristics such as age, BMI, previous hospitalization, and anesthetic drug used before the procedure of the children included in the study. Preoperative (VR = 1.03 (0.18), control = 1.05 (0.22)) and pre-procedural (VR = 2.61 (1.02), control = 2.33 (1.22)) fear levels were also similar ( $P > 0.05$ ). After the procedure, it was determined that the mean duration of the procedure (365.36 (64.73) sec), crying time (21.31 (41.74) sec), and fear scores (0.36 (0.68)) of the children in the VR group were lower ( $P < 0.001$ ). However, pain mean scores were similar ( $P > 0.05$ ).

**Conclusion:** It is thought that watching a cartoon with VR glasses during the circumcision operation may be effective in reducing the child's fear level, crying, and operation time.

**Keywords:** Circumcision, Child, Fear, Pain, Virtual reality glasses

## Introduction

Circumcision is defined as the process of surgical removal of the foreskin, which covers the glans penis by cutting it in a certain way and length [1-5]. There are different applications concerning who makes the operation and where it is made. However, since this procedure is a surgical intervention, the most appropriate method is to conduct it under hospital conditions, even in surgery rooms [6-8].

Circumcision can be conducted at any age. However, since the child is exploring his sexual identity between 3-6 years, the children at these ages can experience a higher level of fear, worrying about losing their sexual organs. This situation, called castration anxiety, can cause psychological problems in the children [4, 9] and recovery from such problems can be difficult [2, 4, 10]. Therefore, it is reported that the most appropriate circumcision age is either before three years old or after six years old [2].

Just after the moment that the boy is informed about his circumcision, he starts to fear. As he doesn't know what to do, he can demonstrate various reactions such as a sense of shame due to revealing his external genital organ, the anxiety of pain, sleeplessness, uneasiness, resistance to those around him, and attacking. In addition, if the child witnesses a previous circumcision operation, it can influence the fear. In the studies conducted on adults, when the adults were asked what they felt about their circumcision operations, they generally stated a feeling of fear and anxiety [11, 12]. Therefore, it is important to use an effective fear-reducing method in fearful and anxious interventions in children [13, 14].

There are numerous approaches involving pharmacological and non-pharmacological methods for reducing the fear and anxiety that emerge during the children's medical operations. One of the most frequently applied non-pharmacological methods to eliminate fear and anxiety during medical operations is distraction. The distraction method is an attempt to focus the attention of the patient on another stimulus in order to decrease the pain; it is based on the hypothesis that the capacity of the mind is limited in focusing the attention on the stimulus [14]. During these processes, it is known that some methods are used, such as blowing up a balloon, distraction cards, listening to music, and kaleidoscope in order to distract the children [15-22]. In parallel with the recent technological developments, the use of virtual reality (VR) glasses was started in order for distraction in the health field. VR is a new technological development that children accept as a distraction and attraction way. This method is an intermediary in the individual-computer interaction, which helps the individual become an active participant in the virtual world through a combination of visual, auditory, and tactual stimuli [23]. Hoffman et al. [24] reported that VR is a "uniquely attractive setting" that successfully pulls away the children from most of their mental focuses and painful processes.

In the literature, it is emphasized that using VR glasses is an effective method in reducing the preoperative anxiety, decreasing the pain in the surgical operations with local anesthesia, medical dressing for burns in children, lumbar puncture in children with cancer, and during phlebotomy in the

children [10, 13, 25-27]. However, in the institution where the research was conducted, there was no method to reduce the fear and the anxiety during circumcision operations, which is one of the most effective causes of fear/anxiety and pain in children. Therefore, by applying a method that has not been used during circumcision operations in children, this research study aims at revealing an effective, simple, economical, and practical method and shortening the operation time, which reduces the fear/anxiety and the pain. If positive results are obtained from this research study, and if it is proved to be an effective and reliable method in reducing the fear/anxiety and the pain, a contribution will be made to using a cheap and effective non-pharmacological method. Moreover, it is aimed at ensuring the children are able to simply tolerate procedures that create fear/anxiety and making contributions at national and international levels to a nursing care approach, which will minimize the fear/anxiety and pain for children in obligatory cases such as going to a hospital and being treated.

## Materials and methods

### Research type

This study was conducted as a Randomized Controlled Experimental Research design with a Pre-Test-Post-Test Control Group in order to determine the effect of virtual reality glasses applied during the procedure to reduce fear/anxiety and pain in children who will be circumcised between 6-11 years old.

### Participants

The population comprised 6-11-year-old children who applied for circumcision at the Pediatric Surgery Unit of Karaman Public Hospital between January and August 2018. The sample size was calculated via the G\*Power program, considering the known scores (4.53+3.23), with 95% strength, a 0.05 significance level, and 10% variation. Therefore, the sample size was determined as 116, but considering the risk of case loss, 64 children in VR and 61 children as control groups were grouped.

### Inclusion criteria for the research;

- The child should be between 6-11 years old (Min: 68 months),
- The same surgeon should conduct the circumcision operation,
- The child should have been given the standard information before the operation,
- The surgery equipment used in operation should be the same,
- The child should have the perception level to evaluate his fear/anxiety scale,
- The child should not have a physical or mental illness,
- The child should be able to communicate,
- The child should not have any hearing, speaking, or sight problems,
- The child should not have a chronic illness,
- The child should not be using a continuous medicine,
- The child should not have consumed analgesics in the last six hours,
- The child should not have a health problem that triggers pain,
- The child and his parents should accept participating in the research.

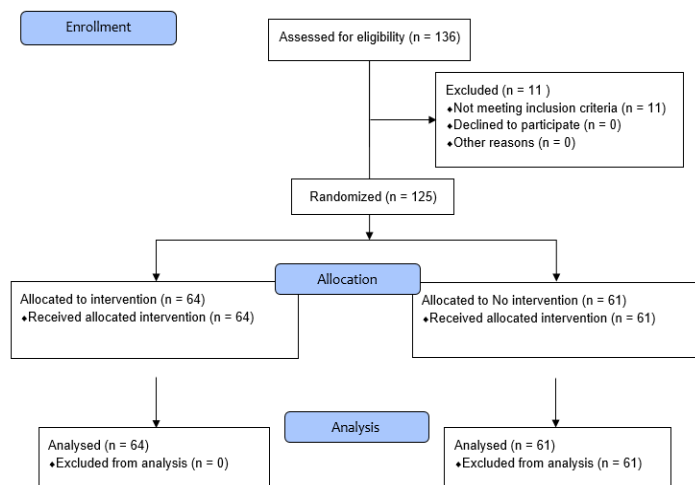
### The refusal criteria

- The child has a cardiac pacemaker,
- There is a defect in continuity of the skin or a skin rash on the area of operation,
- The health condition of the child is unstable,
- The child has a deficiency in development,
- The child has consumed an analgesic in the last six hours,
- The child or the parent does not accept to participate in the study.

## Randomization

The children were classified as VR and control group with a simple random sampling method only after taking the children's consent and written consent of the parents after giving necessary information. Children were included in the VR and control groups using the urn randomization method [28]. Two different balls, including white for the control group and red for the VR group, were placed in a black bag by the researcher. Without any knowledge of the groups, a nurse who worked there asked him to select a ball from the black bag with his eyes closed. Children were assigned to the control or experiment group according to the color of the selected ball. Thus, the children were randomly distributed into two groups (Figure 1).

Figure 1: The flow diagram of the study



## Data Collection Tools

### Interview and Observation Form

This form was created based on the literature by the researchers[29-30]. The question form was sent for the examination of three experts, and it was put into the final form according to the necessary corrections. The interview and observation form is a 21-question form whose 14 questions are open-ended. The researchers collected the data from the child and parents via interviews and observation. The application time of the form is approximately 5 minutes.

### Children's Fear Scale (CFS)

The scale was first introduced in 2003. This scale was developed to assess the child's fear/anxiety level. There are five different facial expressions on the scale, with no fear/anxiety on the one end and intense fear/anxiety on the other. These facial expressions were evaluated between 0 and 4. "0" stands for no fear/anxiety, and "4" stands for extreme fear/anxiety [31, 32].

### Wong-Baker Faces Pain Rating Scale

The scale, which Wong and Baker developed, is suitable for the use of 3-18-year-old children. For example, the smiling face expression 0 stands for 'no pain,' while the crying face expression 10 stands for 'extreme pain' [33].

### Virtual Reality (VR) Glasses

VR glasses are a method in which the patient was made to watch footage taken from a phone by approximating the lenses within a headset, used in order to isolate the patient from real life. The patients in the VR group and their parents were informed about the glasses before the operation. The VR glasses (3D VR Box 2) were placed on the eyes of the child before the circumcision operation, and he was made to watch the footage

during the operation. In addition, the child was made to watch the cartoon film that he preferred through the VR headset, which was considered to attract the children. Thanks to the placement of a VR headset, the children focused on a cartoon film that they liked, and thus, they were prevented from hearing all the sounds and realizing the actions during the operation.

### Timekeeper

It was used to record the duration of the crying of the child.

### Data collection

The data was collected with the face-to-face interview method via the Interview and Observation Form, which was created based on the experts' opinions and in line with the literature. While assessing the children's pain and fear/anxiety levels, it was requested to evaluate the child, the parent, and two nurses to make the evaluation more objective.

The research was conducted according to the following steps: Before the data collection phase, oral and written consent were received from the parents of the children, who were selected based on the sample selection criteria. The equipment was prepared beforehand (Interview and Observation Form, VR Glasses, Timekeeper). Individual characteristics were recorded in the interview and observation form based on the interviews with the children and family members. All of the children to be circumcised were locally anesthetized before the operation, and each child waited for 10 minutes for the anesthetic substance to take effect. Then, the child and his parents were admitted to the circumcision surgery room. The child was asked to lie down on the operation table. In order to determine the preoperative fear/anxiety levels of the children both in the VR and the control groups, the Children's Fear Scale (CFS) was applied. The fear levels of the children were determined via CFS and observations of the child, parents, and two nurses. One of the parents admitted to the operation room was asked to hold the hands of the child on the head side, while the other parent was asked to hold the legs to fasten up the child; subsequently, the circumcision operation was conducted. After these procedures, the children in the control group were circumcised under normal conditions. During the routine circumcision operation, no procedures were applied to the child. As per the VR group, they were allowed to watch a cartoon film up to their choices. The children in the VR group began to watch their cartoon films via VR glasses as soon as they lay down on the table, just one minute before the operation. Thus, the child was prevented from observing the operative process around him, and he focused on the cartoon film. As soon as the children began crying, the timekeeper started and recorded the crying duration. After the circumcision operation, the fear and pain levels of the children in both groups were observed and recorded.

### Statistical analysis

Statistical analyses of the study were made in SPSS 21.0 package program. Numbers, percentages, and mean values (standard deviation) were used from descriptive analyses. In the analysis of differences between groups, t-test, paired t-test, chi-square, Mann Whitney U, and Kruskal Wallis tests were used in independent groups. The significance level was accepted as  $P < 0.05$ .

**Ethical considerations**

In order to conduct the research study, ethics committee permission was obtained from "Karaman University, Faculty of Health Sciences, Ethics Committee of non-Pharmaceuticals and non-Medical Device Researches" (dated 16/06/2017 and numbered 2017/975), and institutional permission was obtained from the "Ministry of Health Karaman Public Hospitals Institution General Secretariat of the Public Hospitals Association of Karaman Province" (dated 13/07/2017, and numbered 50658796-774.99-E.3674). Additionally, written consent was obtained from all participant patients and their parents concerning their volition to participate in the study.

**Results**

In total, 125 children participated in the study. The distribution of the demographical features and pre-operative-pre-circumcision fear levels of the children were similar in the groups (Table 1).

There was statistically no significant difference between the groups concerning the previous hospital experiences of the children and the anesthesia used during the operation (Table 2).

Table 1: Distribution of children by demographic characteristics (n = 125)

	VR group (n = 64) Mean (SD)	Control group (n = 61) Mean (SD)	t	P-value
Child's age (year)	7.03 (1.41)	7.08 (1.43)	0.199	0.842
BMI	18.76 (1.99)	18.32 (1.85)	-1.236	0.219
The preoperative child's fear levels	1.03 (0.18)	1.05 (0.22)	0.508	0.614
The pre-circumcision child's fear levels				
According to the child	2.61 (1.02)	2.33 (1.22)	-1.03	0.163
According to the parent	3.34 (0.72)	3.30 (0.86)	-0.343	-0.732
According to the first observer	3.47 (0.59)	3.34 (0.77)	-1.016	0.312
According to the second observer	3.45 (0.73)	3.41 (0.78)	-0.319	0.750

Table 2: Distribution according to children's hospital experience and analgesic agent applied in circumcision (n = 125)

	VR group (n = 64)		Control group (n = 61)		$\chi^2$	P-value
	n	%	n	%		
Have you been hospitalized before?						
Yes	7	10.9	9	14.8	0.408	0.523
No	57	89.1	52	85.2		
Name and dose of analgesic applied in the circumcision						
Marcaine* 3 cc, Citanest ** 3 cc	29	45.3	27	44.3	0.018	0.991
Marcaine 3 cc, Citanest 4 cc	27	42.2	26	42.6		
Marcaine 4 cc, Citanest 4 cc	8	12.5	8	13.1		

\* Marcaine: The active ingredient is bupivacaine hydrochloride. \*\* Citanest: The active ingredient is Prilocaine hydrochloride.

The mean duration of the procedure for the children in the VR group was 365.36 (64.73) seconds, while it was 538.66 (179.79) seconds in the control group. Process-induced crying time was measured as 21.31 (41.74) seconds in the VR group and 322.21 (188.86) seconds in the control group. When the duration of the procedure and the duration of crying during the procedure were evaluated, it was determined that both periods were shorter in children in the VR group. In this case, it has been observed that VR glasses shorten the processing time as well as the crying times of children. Children's post-procedural fear was evaluated by three people: the child, the parent, and the observer. According to all three evaluations, the fear score averages of the children in the VR group were significantly lower (by child VR = 0.36 (0.68), Control = 3.51 (0.67); by parents VR = 0.39 (0.70), Control = 3.48 (0.72); by observer VR = 0.38 (0.70), Control = 3.54 (0.79)) ( $P < 0.001$ ). On the other hand, no significant difference was found between the groups in terms of pain score averages ( $P > 0.05$ ) (Table 3).

Table 3: Distribution according to groups in terms of the duration of circumcision operation and crying of the child (n = 125)

	VR group (n = 64) Mean (SD)	Control group (n = 61) Mean (SD)	t	P-value
Duration of application (sec) (Min-Max)	365.36 (64.73) (254-522)	538.66 (179.79) (280-1200)	7.236	<0.001
Child's crying time (sec) (Min-Max)	21.31 (41.74) (0-190)	322.21 (188.86) (20-860)	12.434	<0.001
Child's fear after circumcision (according to the child)	0.36 (0.68)	3.51 (0.67)	26.085	<0.001
Child's fear after circumcision (according to the parent)	0.39 (0.70)	3.48 (0.72)	24.195	<0.001
Child's fear after circumcision (according to the observer)	0.38 (0.70)	3.54 (0.79)	23.770	<0.001
Pain levels after circumcision (according to the child)	0.28 (1.00)	0.56 (2.04)	0.969	0.334
Pain levels after circumcision (according to the parent)	0.22 (0.72)	0.46 (1.80)	0.986	0.326
Pain levels after circumcision (according to the observer)	0.28 (0.93)	0.46 (1.73)	0.720	0.473

**Discussion**

This study examined the effect of the distraction method utilizing VR glasses on the pain, fear, and anxiety that are possible to observe in the children during the circumcision operation. No statistically significant difference was determined between the VR and control groups concerning the pre-circumcision fear levels of children evaluated by the child, the parents, and the observer. This situation is an expectable result for determining the effectiveness of the VR glasses. Based on the information provided by parents and observers, we found that children in the VR group had lower anxiety depending on the postoperative situation. Although there is no similar study in the literature concerning the circumcision operation, similar results were observed in studies conducted on other invasive interventions. For example, in a randomized controlled study about the effects of VR glasses on the fear/anxiety levels during phlebotomy of 10-21-year-old children, Gold and Mahrer [34] reported that the use of VR glasses highly reduced acute interventional pain and anxiety and that both the patients and the caregivers were highly satisfied. Similar results have also been reported [26, 35].

The study also determined that the use of distraction via VR glasses reduces the duration of the operation and the crying of the child. This finding is supportive of the positive effects of the VR glasses during the circumcision operation. There are similar results in the literature. For example, Hua et al. [10] reported that the dressing change duration of the group with VR distraction was shorter than the group with standard distraction methods (such as books, toys, and television).

According to the child, parents, and the observer, no significant difference was found between the groups in terms of pain levels after circumcision. However, studies with different results were encountered in the literature. Those studies were conducted on healthy children and children being treated in other clinics such as oncology and burn units. For example, in a randomized controlled study conducted by Gerçeker et al. [36] about the effectiveness of VR glasses and external cold and vibration in reducing the pain during phlebotomy on 121 children of 7-12 age, it was determined that there was statistically no significant difference between the groups that were applied VR and external cold and vibration concerning the pain scores, however, compared to the control group, the pain scores of both groups were determined as lower. There are similar studies in the literature [27, 37-45]. The results obtained from the pain literature

and those obtained from our study differ due to the use of analgesics in this study.

### Limitations

The study was limited to the 6-11 age groups only. It is recommended to evaluate the effectiveness of VR glasses for earlier circumcisions.

### Conclusions

It can be stated that using distraction through VR cartoon films highly reduces the fear emerging in children during circumcision. Furthermore, it significantly decreases the duration of the operation, thus, rendering this operation no more a traumatic event for the child. It was also determined that this method did not influence the pain felt during this operation. The children display more comfortable behaviors after the operation can be attributed to the fact that circumcision is a fear-focused process rather than a pain. Accordingly, the VR method is a non-initiative, non-traumatic, and non-pharmacological, effective method that reduces the fear and decreases the duration of the process. Therefore, it is suggested that the VR method is used during the circumcision process, particularly for children between 6-11 years old.

### Clinical Implications

In circumcision, a method should be used to reduce and prevent anxiety, fear, and pain in the child. For example, having children watch cartoon movies during the circumcision operations is highly effective in reducing the fear, shortening the duration of the crying children, and conducting the procedure faster. Therefore, during circumcision, distraction through VR glasses can be applied to children between 6-11 years old. During interventional procedures in children, VR glasses are an easy-to-use, economical, safe, and practical method that will reduce or prevent fear/anxiety and pain and reduce application time.

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