

The effect of immersive virtual reality and music on anxiety, fear, and pain during circumcision surgery in children: a randomized controlled study

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ABSTRACT

Aims: Circumcision is a surgical procedure that causes pain, anxiety, and fear in children. This study aimed to examine the effectiveness of immersive virtual reality (IVR) and music on anxiety, fear, and pain levels of children during circumcision surgery.

Methods: This randomized controlled trial included boys aged 6-8 years who were circumcised at a university hospital between September 2022 and July 2023. Using stratified block randomization, the sample group's children were split into three groups: music (n=24), IVR (n=24), and control group (n=24). The Wong-Baker Faces Pain Rating Scale, the Children's Anxiety Meter Scale, the Children's Fear Scale, and a Participant Information Form were used to gather the data. Descriptive statistics, t tests, analysis of variance and Duncan and Bonferroni adjustments were used to examine the data.

Results: Children in the IVR and music groups experienced much less worry and dread during and after circumcision than those in the control group. The mean pain scores of the experimental groups during and after circumcision were significantly lower than those of the control group. Fear, anxiety, and pain levels were significantly different in the IVR group compared to the other groups (p<0.05).

Conclusion: Children's anxiety, fear, and pain levels were successfully decreased by the use of IVR and music interventions during the circumcision operation. Health professionals, nurses, can use effective nonpharmacological strategies, such as music and IVR, to manage fear, anxiety and pain associated with surgical procedures in children.

Keywords: Child, virtual reality, pain management, music, surgery

INTRODUCTION

Circumcision, one of the oldest and most common surgeries for children, is performed for medical, religious, and cultural reasons. Despite being seen as a straightforward medical surgery, children must be emotionally and cognitively ready for the circumcision process.^{1,2}

Circumcision is painful for children even under general and local anesthesia.^{3,4} Due to the risks of general anesthesia, the American Academy of Pediatrics recommends local anesthesia for newborns, infants, and compliant children.⁵ Local anesthesia avoids complications like respiratory depression and urinary retention, which is why children over six are often circumcised under local anesthesia. During the procedure, children are aware and feel pain.^{4,6} Circumcision is better tolerated when performed by experienced practitioners under sterile conditions with appropriate pain management.⁵

During the preoperative phase, children feel scared and anxious. Because they are not informed about the circumcision procedure, receive anesthesia, and cannot express their pain. ^{6,7} Previous studies have reported that children experience fear, anxiety, and pain during and after circumcision. ^{4,8} This has negative effects on the child, such as prolonged postoperative recovery time, decreased compliance with treatment and hospitalization, and posttraumatic stress. ^{7,8}

Nonpharmacologic interventions have become more significant in lowering children's anxiety and fear of surgery. In addition to many nonpharmacological methods, such as therapeutic play, puppet shows, video games, cartoons, and music, patient education and operating room visits are also used to reduce preoperative anxiety. Distraction is a nursing intervention that increases pain tolerance in children by distracting them from painful stimuli. 12,13

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Immersive virtual reality (IVR) has become a popular distraction method in recent years. It involves the user actively engaging in a virtual environment through a headmounted screen ¹⁴ and can be used anytime in clinical settings. Evidence supports IVR's effectiveness in reducing anxiety, stress, and pain in children patients receiving needle procedures, burn care, or cancer treatment.^{14,15} Studies have shown that preoperative use of virtual reality (VR) positively impacts anxiety and postoperative pain.^{6,7,16,17}

Musical interventions help children cope with pain and stress. Studies in the literature reveal that musical interventions during surgical procedures positively affect children's levels of pain, fear, and anxiety.¹⁸⁻²⁰

Even though the consequences of distraction techniques or VR on fear and pain before circumcision have been examined in the literature, studies on their use during circumcision surgeries are limited. There is a need to investigate the benefits of innovative distraction techniques such as IVR and music that actively engage the child, which may help the child cope more effectively with the pain and anxiety associated with the circumcision procedure, as these techniques can significantly impact the circumcision experience and recovery process.

This study's objective was to evaluate how music and an IVR intervention affected the children's pain, anxiety, and terror during circumcision surgery. Within the scope of this main objective, the hypotheses of the study were as follows:

- H1: IVR and music interventions have a significant effect on lowering the anxiety levels of children undergoing the circumcision procedure.
- H2: IVR and music interventions have a significant effect on lowering the fear levels of children undergoing the circumcision procedure.
- H3: IVR and music interventions have a major impact on decreasing pain in children undergoing circumcision surgery.

METHODS

Ethical Considerations

The study received ethical approval from the Afyonkarahisar Health Sciences University Non-interventional Clinical Researches Ethics Committee (Date: 05.08.2022, Decision No: 2022/9), and the implementation permission was obtained from the university research hospital. Verbal and written consent was obtained from participating children and their families. This study was retrospectively registered at ClinicalTrials.gov. All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki.

Study Design and Setting

This randomized controlled study was conducted in the pediatric surgery clinic of a university research hospital in western Turkey between September 2022 and July 2023. The study was divided into three groups: the music (n=24), the IVR (n=24), and the control (n=24).

While the control group received only routine clinical care, the music group listened to music of their own choosing, and the IVR group played an interactive video game.

Sample Size

The study's sample size was calculated using the G-power 3.1.9.2 tool. A power of 0.80 required a minimum of 21 participants in each group, an effect size of 0.80, and a significance threshold of α =0.05. Consequently, a total of 72 children-24 in each group-were included in the study, taking into account the possibility that some children might be excluded.

Randomization

An independent researcher used Random Sequence Generator (www.randomizer.org), a computer software, to divide the children into groups. Each volunteer participant who met the criteria was given a number between 1 and 72. This list was only given to the coresearcher during the application. Using stratified block randomization (by age), the children in the sample group were split into three groups: the IVR, the music, and the control group. There were 24 children in each group. The control and experimental groups were created to be homogeneous in terms of age and hospitalization history (p>0.05). Interventions were initiated after local anesthesia. The treatment of the children did not occur during the data collection phase of the study. The study's CONSORT flow diagram is displayed in the Figure.

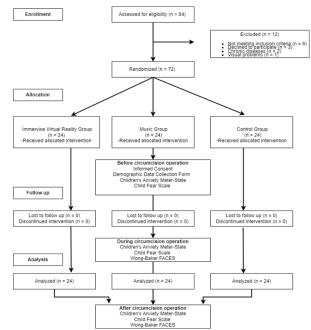


Figure. CONSORT diagram

Participants

A history of circumcision in a pediatric surgery clinic, consent to participate in the study, age between 6 and 8 years, no history of surgical intervention, no persistent discomfort, and no mental health issues were the requirements for inclusion. The following were the exclusion criteria: using any kind of pain medication 24 hours prior to the procedure,

having communication issues, or having any of the following contraindications to the procedure: hypopadias, epispadias, bleeding disorders, or anatomical diseases.

Data Collection Tools

Participant Information Form: The questionnaire asked about the children's and their families' sociodemographic details, such as age, prior hospitalization, education, decision to have circumcised, etc.

Children's Anxiety Meter Scale: Children's anxiety levels during invasive procedures are measured using this scale in healthcare settings. The scale yields scores ranging from 0 to $10^{.21}$ An increase in the score indicates that children's concerns and anxiety increase. The Turkish validity of the scale was established in children aged between 4 and 10 years. This study's Cronbach's alpha was 0.80.

Children's Fear Scale: This single-item self-report scale is used to measure pain-related fear in children. Five genderneutral facial expressions make up the scale, which ranges from neutral on the far left to highly afraid on the far right. The range of points awarded for facial expressions is 0-4. The scale can be used by parents and observers before, during, and after medical procedures for children aged 5-10 years.²³ The Turkish validity of the scale was established.

Wong-Baker Faces Pain Rating Scale: This scale assesses pain in children aged 3 to 18. It was developed by Wong and Baker. The numerical rating scale has scores ranging from 0 to 10. A range of faces is displayed on the scale, from a crying face (10=great pain) to a smiling face (0=very happy/no pain).²⁴

Research Instruments

Virtual reality glasses: In this investigation, the white "Meta Oculus Quest 2" virtual reality headset was utilized. Two Oculus touch controllers and a head-mounted display (HMD) are included with the Oculus Quest 2.The VR HMD is an independent device with built-in tracking and headphones.²⁵

Music headphones: In this study, we used wireless music headphones with Bluetooth and stereo high-resolution sound quality. It is compatible with Android devices such as iPads and can cancel noise. It is a music headphone that complies with the World Health Organization's 75 dB sound level recommendation for children.²⁶

Preintervention Phase

Pilot study: Nine children with the identical sample group characteristics participated in a pilot trial before the intervention. These children didn't have any bad to say about the IVR programs. The study sample did not include children from the pilot study group.

Intervention protocols: On the morning of the surgery, the children were admitted to the clinic early in the morning and prepared according to standard protocol. One of the researchers briefed the children and their families about the study when they arrived at the clinic right after being admitted to the hospital, and both verbal and written consent were acquired. The CAM-S, the CFS, and an introductory information form were then used to gather the data. Children

meeting the inclusion criteria were randomly allocated to groups.

The researcher who would carry out the intervention told the children in the experimental groups after they had been brought to the operation room waiting area. The IVR group was informed about the use of VR glasses, and the music group was informed about the use of headphones. The children in the music group chose the music they wanted to listen to. Additionally, the children were told that if they had a headache, earache, eye pain, or motion sickness, the intervention would end. During the circumcision, children in the IVR group chose the VR game they wanted. For the control group, standard protocols were used.

Intervention phase: In this study, IVR was applied to one group and music intervention was applied to the other group to distract the child during the circumcision procedure. In addition to having a PhD in pediatric nursing, one of the researchers was a trained music therapy practitioner with expertise in virtual reality. This researcher conducted the interventions. In the operating room, the researcher adhered to the rules governing medical and surgical operations. The children in the IVR group were given the remote controls and VR glasses by the researcher shortly before the intervention. Music headphones were worn by the children in the group.

Circumcision surgical procedure: All circumcisions were conducted in the same operating room by the same pediatric surgeon and support team. Local anesthesia was applied to all children using the same technique. All children (in the experimental and control groups) were given bupivacaine HCl (Marcaine 0.5%; AstraZeneca, İstanbul, Turkiye) and lidocaine HCl+epinephrine (Jetokain; Adeka, İstanbul, Turkiye) local anesthesia with the penile block technique. The block was performed using markers. Interventions were initiated 20 minutes after local anesthesia. All children underwent circumcision using the thermocautery-assisted guillotine technique. ²⁷

The IVR group received both standard medical treatment and virtual reality gaming during the circumcision procedure. Children in the IVR group, who lay on the operating table during circumcision, played the interactive game of their choice for ten minutes.

Two Oculus Quest gallery games were made available to children. These activities have been employed in numerous studies in the literature and have been described as engaging, thrilling, and soothing for children.^{7,22} Before each use, the Oculus Quest was put on a disposable silicone cushion. Before using the gadget, the patients put on a face mask and disposable headgear (personal protection equipment) to reduce direct contact. Before every intervention, the portions of the gadget that came into contact with the faces of the youngsters were cleansed.

The band listened to music at 60 dB through the same headphones and iPads. Children listened to the music they wanted with headphones for ten minutes. In previous studies, music was shown to be preferred by children. Disposable ear pads were preferred, and the headphones were disinfected each time.

No intervention such as IVR or music was applied to the children in the control group during the circumcision process. Routine care was given.

An independent external observer applied the CAM-S, CFS, and WBS to the children in the experimental and control groups at the 12th minute of the circumcision procedure. The surgery was completed by the surgeon in approximately 15 minutes.

Postintervention phase: Two hours after circumcision, CAM-S, CFS, and WBS were applied again to all children in the experimental and control groups. No analgesic was given to the children between the times of scale application. The children in the control group were allowed to experience IVR and music by the researcher in the room in the clinic after the experiment, considering ethical concerns and to avoid affecting the research data.

Statistical Analysis

The IBM SPSS Statistics 23.0 package program was used for the data analysis. Descriptive statistics (frequency, percentage distribution, mean, etc.) were used for the analysis of sociodemographic data. Analysis of variance was used to compare the pain, anxiety, and fear levels of the children according to group. In addition, the differences between the procedure durations for each group were determined by repeated measures ANOVA and paired sample t tests. A post hoc evaluation was performed with Duncan and Bonferroni correction. Statistical analyses were accepted at a confidence interval of 95% and a significance level of p<0.05.

RESULTS

Characteristics of Children and Parents

The sociodemographic details of the children and their families are displayed in **Table 1**. When the participants were analyzed according to age, the mean age of the children was 7.17 ± 0.91 years in the control group, 6.92 ± 0.88 years in the IVR group, and 7.17 ± 0.76 years in the music group. A total of 70.8% of the children in the control group, 45.8% of the children in the IVR group, and 66.7% of the children in the music group made the decision for circumcision together with their parents. A total of 98.8% of the parents were middle school graduates. To prevent bias in the study findings, it was ensured that there was no statistically significant difference between the groups

in terms of children's age (p=0.508), parental education level (p=0.560), or decision for circumcision (p=0.171).

Table 1. Demographic characteristics of the children and parents								
	IVR group	Music group	Control group					
Variables	1	Statistic test						
Age	6.92±0.88	7.17±0.76	7.17±0.91	F=0.683; p=0.508				
Parents								
Mother	13 (54.2)	21 (87.5)	16 (66.7)	X ² =6.415;				
Father	11 (45.8)	3 (12.5)	8 (33.3)	p=0.040*				
Parent education								
Primary	5 (20.8)	5 (20.8)	7 (29.2)					
Secondary	8 (33.3)	9 (37.5)	5 (20.8)	X ² =4.878;				
High school	4 (16.7)	7 (29.2)	8 (33.3)	p=0.560				
≥University	7 (29.2)	3 (12.5)	4 (16.7)					
Circumcision decision								
Child	7 (29.2)	2 (8.3)	5 (20.8)	F=6409; p=0.171				
Family	6 (25.0)	6 (25.0)	2 (8.3)					
Together	11 (45.8)	16 (66.7)	17 (70.8)	1				
*p<0.05, IVR: Immersive virtual reality, SD: Standard deviaiton								

Anxiety Levels

Table 2 shows the test results regarding the comparison of the anxiety levels of circumcised children according to the group and procedure duration. According to the children's evaluations, there was no significant difference between the groups before the procedure (p>0.05). There were significant differences between the anxiety scores measured by both the children and the observer during and after the procedure (p<0.05). According to the mean scores, the anxiety level decreased significantly in both the IVR and music groups compared to the control group. However, although there was no statistically significant difference between the IVR group and the music group after the procedure, there was a greater decrease in the IVR group. Significant differences were detected between the procedure durations in each group (p<0.05). According to the evaluations of the children and the observer, the anxiety level was high in the IVR and music groups before the procedure, and there was a significant

			Table 2. Comparison of anxiety scores according to group and procedure duration								
		Pre-procedure	During procedure	Post-procedure							
Evaluation	Groups	M±SD	M±SD	M±SD	p						
	IVR	3.33±0.48 ^A	2.91 ± 1.50^{bB}	0.37 ± 0.71^{bC}	<0.001						
Child namented	Music	2.83±1.80 ^A	2.62 ± 1.88^{bB}	0.76 ± 1.16^{bC}							
Child reported	Control	3.20±2.02 ^B	4.79±2.12 ^{aA}	3.62 ± 1.88^{aB}							
	p	0.529	< 0.001	< 0.001							
	IVR	3.62±0.71 ^{aA}	3.00±1.53 ^{bB}	0.37±0.71 ^{bC}	<0.001						
01	Music	3.20 ± 1.74^{bA}	2.79 ± 1.97^{bB}	0.62 ± 1.13^{bC}							
Observer reported	Control	3.30±2.02 ^{bB}	4.79±2.12 ^{aA}	3.52 ± 1.88^{aB}							
	p	< 0.001	< 0.001	< 0.001							

gradual decrease during and after the procedure. In the control group, a significant increase was observed during the procedure.

Fear Levels

The test results regarding the comparison of the fear levels of the children participating in the study according to the groups and procedure durations are given in Table 3. According to the evaluations made by the children and the observer, there was no significant difference between the groups before the procedure (p>0.05). In the children's and observers' evaluations, the fear levels during and after the procedure differed significantly between the groups (p<0.05). Both the IVR and music groups had lower scores than did the control group. In both evaluations, the fear levels significantly decreased during and after the procedure compared to before the procedure.

Pain Levels

Table 4 presents the results regarding the comparison of children's and observers' evaluations of pain according to group and procedure duration. According to both the children and observer evaluations, the pain level was much lower in the IVR and music groups than in the control group. However, while there was no significant difference between the IVR and music groups after the procedure (p>0.05), the IVR group had significantly lower pain levels than did the music group during the procedure.

Table 4. Comparison of pain scores according to group and procedure During procedure Post-procedure **Evaluation** Groups M±SD M±SD p 0.41±0.82b 0.714 **IVR** 0.33±0.76 2.33±2.18b 0.66±1.12b Music Child reported Control 3.91 ± 1.50^a 2.75 ± 1.42^a < 0.001 p < 0.001 < 0.001 IVR 0.16 ± 0.56^{b} 0.426 0.33±0.769 Music 2.50±2.58b 0.41 ± 1.01^{b} Observer reported Control 3.91±1.50a 2.75±1.42a < 0.001 < 0.001 < 0.001 differences between groups for each procedure duration. IVR: Immersive ard deviation

DISCUSSION

This randomized controlled trial examined the effects of IVR and music on fear, anxiety, and pain during circumcision. Pain and anxiety levels were lower in the IVR and music groups than in the control group, with the IVR group showing the lowest pain scores.

IVR uniquely integrates multiple sensory experiences, creating an interactive virtual environment.²⁹ In this study, IVR significantly reduced children's anxiety and fear during circumcision. Consistent with previous research, IVR effectively served as a distraction to lower anxiety. Meta-analyses confirm VR's effectiveness in reducing anxiety and pain during surgery.^{30,31} One study found VR animation reduced anxiety at all circumcision stages (p<0.001), while another reported increased anxiety at the start.¹¹ Biophilic VR was also shown to reduce intraoperative pain and anxiety in circumcised children.⁶

Based on the WBS findings in this study, it was determined that both IVR and music successfully reduced the level of intraoperative pain. There was a significant difference in anxiety and pain levels between the groups of circumcised children. This difference originated from the IVR group. There are very few studies in the literature evaluating VR therapies in circumcised children. In these studies, usually, the effect of classical VR on anxiety and pain before circumcision has been evaluated. In a study, it was determined that VR intervention reduced preoperative anxiety in circumcised children.7 In another study, it was found that watching cartoons with VR glasses during circumcision reduced children's fear level.³² In another study, it was reported that VR distraction through a guided imagery mechanism reduced children's anxiety levels during circumcision.³³ These studies were designed to be nonblinded, and bias could not be excluded. IVR is a combination of visual, auditory, and kinesthetic sensory methods. Therefore, IVR outperforms classical A/V distraction methods. 32,33 Our results align with those reported in the literature

Music provides relaxation and calmness to individuals. Studies in the literature have shown that listening to music before a surgical procedure positively affects the physiological parameters and psychological health of individuals. ^{19,20} In this study, listening to music during circumcision

Table 3. Comparison of fear scores according to group and procedure duration								
		Pre-procedure	During procedure	Post-procedure				
Evaluation	Groups	M±SD	M±SD	M±SD	p			
Child reported	IVR	1.91±1.97 ^A	$0.41\pm0.65^{\mathrm{bB}}$	$0.12\pm0.00^{\mathrm{bB}}$	<0.001			
	Music	1.50±1.14 ^A	1.12±1.15 ^{bA}	0.25 ± 0.60^{bB}				
	Control	1.50±0.78 ^B	2.66 ± 0.63^{aA}	1.83±0.86 ^{aB}				
	p	0.240	< 0.001	<0.001				
Observer reported	IVR	1.95±0.95 ^A	$0.41\pm0.65^{\mathrm{bB}}$	$0.12\pm0.00^{\mathrm{bB}}$	<0.001			
	Music	1.75±0.89 ^A	1.29±1.26 ^{bA}	$0.25\pm0.60^{\mathrm{bB}}$				
	Control	1.50±0.78 ^A	2.66±0.63 ^{aB}	1.83±0.86 ^A				
	p	0.203	< 0.001	< 0.001				
abThere were significant differences between groups for each procedure duration; ABThere were significant differences between groups for each procedure duration. IVR: Immersive virtual reality, SD Standard deviation								

significantly reduced children's anxiety, fear, and pain levels. Although some studies have shown that the pain and anxiety responses of pediatric children exposed to different surgical interventions decrease after listening to music, 34,35 very few studies have evaluated the effect of music on pain and anxiety in circumcised children. One study reported that music reduced children's pain and anxiety levels after circumcision.¹⁸ In another study, it was reported that intraoperative music intervention in children undergoing circumcision or inguinal hernia repair reduced the incidence of postoperative maladaptive behavior in children.³⁶ However, unlike our study findings, intraoperative music application did not affect postoperative pain or patient comfort. There is a need for further studies to determine the usefulness of music in reducing anxiety and pain in children during the intraoperative period.

In this study, intraoperative and postoperative pain scores were lower in the IVR and music groups than in the control group. Literature has shown that patient immersion in interactive IVRs can divert attention away from painful stimuli and reduce pain perception. The study results are consistent with studies that have shown that IVR reduces pain symptoms.

Limitations

This study provides strong evidence of causal relationships thanks to its randomized controlled trial design. Blinding of the statistician during data analysis increased the reliability of the data. However, blinding was not implemented during the data collection phase. Data collection by an independent observer may increase the risk of observer bias in the measurements. Additionally, the study was conducted in a single center; this may limit the generalizability of the findings to different institutions and populations. Many factors, including personality traits, developmental levels, and family attitudes, influence children's perception of pain. These factors may also be a limitation of the study.

CONCLUSION

The results revealed that IVR and music were effective in reducing anxiety, fear, and pain during the intraoperative period in children. IVR can be safely used to reduce surgical procedure-related pain and anxiety in children. In future studies, it may be recommended that combinations of IVR and music be applied in larger samples. Pediatric surgeons, nurses can use IVR and music as nonpharmacological methods to increase children's comfort during surgical procedures such as circumcision.

ETHICAL DECLARATIONS

Ethics Committee Approval

The study was carried out with the permission of the Afyonkarahisar Health Sciences University Non-interventional Clinical Researches Ethics Committee (Date: 05.08.2022, Decision No: 2022/9).

Informed Consent

All patients signed and free and informed consent form.

Referee Evaluation Process

Externally peer-reviewed.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Financial Disclosure

The authors declared that this study has received no financial support.

Author Contributions

All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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