

The Effects of Game Intervention on Postoperative Anxiety and Pain Levels in Children: A Randomized Controlled Study

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ABSTRACT

Aim: Surgery is a stressful and painful experience for children and it is important to control postoperative anxiety and pain. The aim of this study is to evaluate the effects of game intervention on postoperative anxiety and pain levels in children.

Materials and Methods: A randomized controlled trial design was employed in the current study. Seventeen children in the intervention group started to play a game at their bedside with their parents at 15 minutes after their arrival at the service from the recovery room (preintervention period); while the twenty children in the control group only obtained the routing service protocol without any game intervention. The effectiveness of the game intervention was assessed at 60 minutes after arrival at the service from the recovery room (post-intervention period) using the facial affective scale for anxiety and the visual analog scale for pain. The analgesic needs of children after the surgery were recorded

Results: In both groups, the pre-intervention anxiety and pain were significantly decreased in the post-intervention period (p<0.05). The reduction of anxiety in the control group was significantly higher than the intervention group (p=0.006) and there was no significant difference between the post-intervention pain levels of the groups. The rate of analgesic need in the control group was significantly higher than the rate in the intervention group (p=0.048).

Conclusion: The results indicate that children who took part in the game intervention with their parents did not have lower levels of anxiety or pain than children in the control group; however, the intervention was effective in decreasing both anxiety and pain levels after surgery. Based on the decreased rates of analgesic needs, it is recommended that nurses encourage parents to play with their children after surgery.

Keywords: Anxiety, children, game intervention, pain, postoperative period

Introduction

Day surgery is being increasingly used for pediatric patients around the world (1,2), and there is a significant rate of use in Turkey, ranging from 21.1% to 67.1% (3,4). Surgery is a stressful and painful experience, and day surgeries are

associated with inadequately managed postoperative pain (5,6). Many study results have indicated that more than 30% of children experience moderate to severe pain after day surgery (7,8), and this can lead to negative psychological outcomes such as anxiety (9). According to a systematic review, a positive relationship exists between postoperative

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anxiety and pain among children who have undergone surgery (10). Hence, to reduce and alleviate pain, it is important and necessary to control postoperative anxiety.

According to the postoperative pain management panel, analgesics in combination with non-pharmacological interventions are recommended to manage postoperative pain in children (11). Given that playing a game takes an important place in the lives of children, games can also be important for helping children cope with anxiety and painful procedures (12,13). In a study conducted by Vagnoli et al. (14), relaxation through guided imagery was found to reduce postoperative pain among children aged 6-12 years. Based on the results of a qualitative exploratory study that examined children's surgical pain experiences, non-pharmacological pain management interventions (such as distraction, playing games on tablets or phones, and watching films) were reported as useful and helpful in dealing with children's pain (8). According to a randomized controlled study by He et al. (15), an hour-long play intervention was found to be effective in reducing postoperative pain in children who had undergone elective inpatient surgery. Similarly, children took part in a playful intervention involving toys and video games in the study by Kumar et al. (16), where play was found to be effective in reducing postoperative anxiety and pain levels in children who had undergone heart surgery.

Among the available postoperative pain management interventions, play is not always applied with a high priority due to time restrictions and the lack of people who are available to work with pediatric patients (12,13). It has been reported in the literature that nurses frequently insufficiently use non-pharmacological pain management methods for postoperative pain management in children (17). Along with the nurses, the children's parents have also been reported to have limited involvement in play interventions (18). As children mostly need the presence and acceptance of their parents when playing games (19), parents joining in the play is a vital part when using non-pharmacological postoperative pain management strategies such as playing games with school-aged children (5). In the literature, it is recommended that parents be actively involved in play interventions in order to increase the positive effects on perioperative anxiety and the relative effects on postoperative pain (18). In order to cope better with postoperative pain, there is a need to develop a collaborative non-pharmacological intervention between the child and their parents. Unfortunately, several previous studies have focused on the impact of preoperative therapeutic play activities on children's perioperative anxiety and postoperative pain levels, but the effects of game interaction between children and parents on postoperative anxiety and pain levels remain unknown. Therefore, this study aimed to evaluate the effects of game intervention on postoperative anxiety and pain levels in children. Eventually, the results of the game interventions between children and their parents might shed light on areas for further research in the field of pediatric surgery.

Study Questions

In this study, two questions were addressed:

Q1: Is playing a game effective in decreasing children's postoperative anxiety levels?

Q2: Is playing a game effective in decreasing children's postoperative pain levels?

Materials and Methods

Study Design and Sample

This study was designed as a randomized controlled trial consisting of 37 children (intervention group n=17; control group n=20) and conducted at the pediatric surgery service of a university hospital in the eastern region of Turkey between January 7^{th} and May 4^{th} , 2018.

The sample size was calculated using power analysis. In a study carried out by William Li et al. (20), where the visual analog scale (VAS) group score standard deviations were 1.18 and 1.24, with the optimal effect size of 0.03 and 95% power, the sample number was calculated to be 16 children in each group. In the present study, the sample size was 40, with a total of 20 children in each group, allowing for an estimated attrition rate of 25%. Randomization was performed using Random Allocation Software (Version 1.0.0) for parallel group randomized studies, and the children followed through with the allowed order. To eliminate any contamination between the groups, the two groups were allocated to different rooms after the randomization.

In this study, the age range was selected dependent on the children's developmental age and because school-aged children are able to cooperate in game interventions and have cognitive ability (21), children for both groups were included if they were between 7 and 12 years old. The other inclusion criteria were; having undergone minor elective day surgery (e.g., circumcision, hernia, cyst resection), being able to converse, a willingness to play the game, having no previous surgical experience, being able to be mobile in the bed, and having a parent who was willing to play the game during the postoperative period.

Outcome Measurements

Data were collected using a data collection form, the facial affective scale (FAS), and the VAS.

The data collection form was prepared by researchers to collect demographic data from the children, and it contained three questions, which were the age, gender, and analgesic needs of the child, including the analgesic's name and time given, to record the child's analgesic needs after surgery.

The FAS was used to evaluate the children's postoperative anxiety in this study. It was previously validated by Quiles et al. (22), and had been used to evaluate anxiety levels in children aged 7-12 years after surgical procedures previously (23). The findings of previous studies indicated that FAS scores were significantly correlated with the scores for anxiety, with concurrent validity (24,25). This self-reported scale has five graded faces where 0 means "I have no anxiety"; 1 means "I have a little anxiety"; 2 means "I have some anxiety"; 3 means "I have high levels of anxiety." In this study, the children were asked to select one of these faces that best described their current level of anxiety.

The VAS was used to evaluate the children's postoperative pain in this study. It is a widely used pain assessment scale, and in many studies, it has been reported to be a valid scale for measuring postoperative pain levels in children over 6 years old, who know how to rate the numbers (8,20,26-28). It is a scale numbered from 1 to 10 and placed horizontally on the paper, with descriptive words between the 0 point and the 10 point. Here, 0 means "I have no pain," and 10 means "I have the worst pain I've ever had." In this study, children were asked to select the number that best described their current level of pain.

Study Procedure and Data Collection

In this study, 37 children who met the study's inclusion criteria were enrolled.

Before the Procedure

At this stage, the staff registered nurse researcher (Ö.G.) and the registered nurse researcher (S.A.) were informed by the principal researcher (S.Ü.) about the study procedure and the usage of the FAS and VAS scales. On the morning of the day surgery, the children and their parents were admitted to the service room and visited by Ö.G. and S.A., who introduced themselves and helped the children and their parents prepare for the surgery. After the children were gowned, they were told by Ö.G. about the purpose of the study and about the scales, and if they were willing to

participate in the study, written permission was obtained from the parents; with verbal permission being obtained from the children by S.A. The possibility of withdrawing from the study was explained whenever the children and the parents wanted. In the intervention group, the children and their parents were informed about the strategy game intervention by Ö.G. that they would play after they arrived at the service area. Findings from the researchers' previous study showed that playing this game was effective at decreasing children's and parents' preoperative anxiety levels (29). Also, after consulting with the pediatric surgeon of the department, this strategy game was selected as the game intervention in this study. This game is suitable for children over 3 years of age and can be played in pairs (30). The game and rules were presented by Ö.G. to the children and their parents on an over-bed table at the child's bedside. According to the rules; the child must first build an 18-layer tower using 54 wooden blocks, then remove one block from any layer of the tower with one hand and place it on the top layer. Then, a parent would do the same for their turn, and the game would continue until the tower falls. The player whose turn it is when the tower falls is the loser, but if they wanted, the game would be restarted, and game duration would not be limited. The children and their parents were allowed to play for one hour before the children were transferred to the operating room. This stage took nearly 15 minutes.

As a routine procedure after the surgery, children were kept in the recovery room for approximately 1 hour before being transferred to the service area until they were awake, able to communicate, and their vital signs were stable.

During the Procedure

In this stage, the children and their parents were visited by Ö.G. and S.A. after arrival in the service area. The children in both groups received routine service postoperative protocol, including vital signs monitoring, awakeness, pain assessment, and analgesic administration (paracetamol 15 mg/kg PRN as needed). After completing these checks, which took approximately 15 minutes, if all the checks were normal, S.A. collected data from the willing participants and asked children to select a face on the FAS that best described their current level of anxiety. Then, she asked them to select a number on the VAS that best described their current level of pain. According to the random assignment by Ö.G., the children in the intervention group were asked if they were ready for the game intervention so that they received both the routine service postoperative protocol and the game intervention with their parents.

After the Procedure

Children in both groups were asked 60 minutes after arrival to the service area from the recovery room to rate their anxiety levels on the FAS and their pain levels on the VAS. Figure 1 shows the CONSORT flow diagram of this study.

Ethical Considerations

Before the study was conducted, ethical permission was obtained from the Ethics Committee of the Trakya University Faculty of Medicine (protocol number: 2017/344), and official permission was obtained from the directorate of the university hospital (number: 54542207-600). Children and their parents were also informed about this study, after which verbal consent was obtained from the children and written informed consent was obtained from the parents. They were also told that it was possible to withdraw from the study if they wanted at any time.

Statistical Analysis

All data were analyzed using the Statistical Package for the Social Sciences version 22.0 statistics software package (IBM, Armonk, NY, USA). The gender of the children is presented as percentages, and the ages of the children are presented both as medians with minimum-maximum (minmax) values and as means with standard deviations (SD).

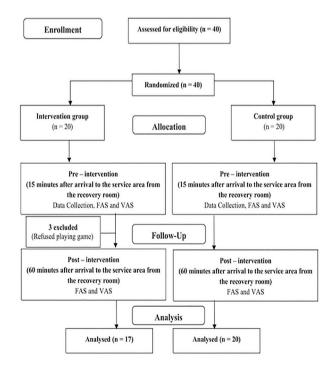


Figure 1. The CONSORT flow diagram of this study FAS: Facial affective scale, VAS: Visual analog scale

Anxiety and pain level scores are also presented as both medians with min-max and means with SD. The data were not normally distributed, and non-parametric tests were performed. To analyze whether the characteristics of the children were comparable in the two groups, Fisher's exact test and the Mann-Whitney U test were used. To compare the pre- and post-intervention anxiety and pain levels of the children within each group, the Wilcoxon test was used, and to compare the children's anxiety and pain levels between groups, the Mann-Whitney U test was used. To compare the analgesic needs of children after surgery between groups, Fisher's exact test was used; p<0.05 was considered as significant.

Results

After the group allocation and the pre-intervention evaluation (at 15 minutes after arrival at the service from the recovery room), three children were excluded from the study as they became bored with the game and refused to play the game after building the tower. In total, data were analyzed for 37 children (intervention group=17; control group=20).

The mean age of all the children was 8.54±1.77 years, 86.5% of them were male and 21.6% of them needed analgesic after the surgery. There were no significant gender or age differences between the groups (p=0.348, p=0.104, respectively). Up to the end of the post-intervention period (at 60 minutes after arrival at the service from the recovery room), 35% of the children in the control group needed to use an analgesic, and this rate was found to be statistically significantly higher than the rate for the intervention group (5.9%; p=0.048) (Table I).

In the intervention group, the median pre-intervention anxiety level of the children was 2 (min-max 1-4) and significantly decreased to 1 (min-max 0-2) in the post-intervention period (z=-3,169; p=0.002). The median pre-intervention pain level of the children was 3 (min-max 0-9) and significantly decreased to 2 (min-max 0-5) in the post-intervention period (z=-2,896; p=0.004) (Table II).

In the control group, the median pre-intervention anxiety level of the children was 2 (min-max 0-4), and it significantly decreased to 0 (min-max 0-2) in the post-intervention period (z=-3,097; p=0.002). The median pre-intervention pain level of the children was 4 (min-max 0-9) and significantly decreased to 1 (min-max 0-5) in the post-intervention period (z=-3,843; p=0.000) (Table II).

In the post-intervention period, the median anxiety level of the children was 0 (min-max 0-2) in the control

group and 1 (min-max 0-2) in the intervention group. The difference between groups was found to be statistically significant (z=-2,947; p=0.006). The median pain level of the children was 1 (min-max 0-5) in the control group and 2 (min-max 0-5) in the intervention group. There was no statistically significant difference between groups (z=-1,567; p=0.133) (Table II).

For the post hoc power analysis, the G Power Program (G Power 3.1 9.2, Kiel, Germany) was used. With the sample size of 37 and the alpha level p<0.05, the statistical power was calculated as 0.93 for anxiety with the effect size of 1.08 (Cohen's $d \ge 0.5$), and as 0.42 for pain with the effect size of 0.50 (Cohen's $d \ge 0.5$).

Discussion

Play is reported to be an important resource for helping children overcome stressful and painful procedures such as hospitalization, burn dressing change, venipuncture, and of course surgery, in addition to others (31,32), but little is known about the effects of play intervention on anxiety and pain relief during the postoperative period. This study primarily focused on the effects of the game intervention on children's postoperative anxiety levels and results showed that the children in both groups experienced significantly decreased levels of anxiety. However, the anxiety reduction was significantly improved in the control group and this difference may be explained by the winning feeling when

Characteristics	Control (n=20)		Intervention (n=17)		Total (n=37)		Charles and the con-	
	n	%	n	%	n	%	Statistical test	
Gender of child								
Male	16	80	16	94.1	32	86.5	p=0.348*	
Female	4	20	1	5.9	5	13.5		
Analgesic need								
Yes	7	35	1	5.9	8	21.6	p=0.048*	
No	13	65	16	94.1	29	78.4		
	Median (min-max) Mean ± SD		Median (min-max) Mean ± SD		Median (min-max) Mean ± SD			
Age of child	8.00 (7-12)		7.00 (7-11)		8 (7-12)		z=-1.713	
	9.00±1.94		8.00±1.41		8.54±1.77		p=0.104**	

Variables		Control (n=20)		Intervention (n=17)	Test		
		Median (min-max)	Mean ± SD	Median (min-max)	Mean ± SD	Z** p-value	
Anxiety							
Pre-intervention		2 (0-4)	1.70±1.34	2 (1-4)	2.17±0.88	-0.979	0.357
Post-intervention		0 (0-2)	0.50±0.60	1 (0-2)	1.17±0.63	-2.947	0.006
Test	Z* p		-3,097 0.002		-3,169 0.002		
Pain	'			-	-	-	'
Pre-intervention		4 (0-9)	4.65±2.36	3 (0-9)	3.70±1.99	-1.242	0.232
Post-intervention		1 (0-5)	1.30±1.52	2 (0-5)	2.05±1.47	-1.567	0.133
Test	Z*		-3,843 0.000		-2,896 0.004		

playing a strategy game. As reported in a previous study, children might expect to win the game so that the game play can positively affect their anxiety levels (33). In the literature, many studies have supported the beneficial effects of playing a game for decreasing anxiety in child patients during hospitalization and painful interventions (34-36). In a randomized controlled study by Al-Yateem et al. (37), the efficacy of play interventions (including coloring activities, pictures, and storytelling) for reducing anxiety among children undergoing day surgery were compared with a pharmacological premedication technique, and the results showed that play interventions were very effective at reducing anxiety as an alternative to pharmacological premedication. Moreover, involving parents in game interventions with their children is reported to have positive effects on reducing the anxiety of both the child and their parents during hospitalization and surgical periods (29,34,38). In a prospective and randomized controlled trial conducted by Fincher et al. (34) in North America, parental presence through play was maintained in a preoperative preparation program with children aged between 3 and 12 years. Although there was no significant difference between groups, this intervention was effective in decreasing the children's and parents' anxiety postoperatively. According to these results, playing a game with parents is beneficial for children in reducing their postoperative anxiety.

As reported previously, anxiety is related with pain and decreasing the anxiety levels of children is important for the reduction of pain levels (10,34). This study was secondly focused on the effects of game intervention on children's postoperative pain levels and results showed that it was not effective in decreasing their pain levels significantly. On the other hand, children in both groups experienced significantly decreased levels of pain at 60 minutes after arrival at the service area from the recovery room. A randomized clinical trial from Spain, Ullán et al. (39) examined the effects of a program that included stuffed toys on the postoperative pain of children between 1 and 7 years of age. Children in the experimental group were allowed to play with their parents postoperatively, and their pain scores were significantly lower than those children who had only received the standard protocol and did not play with any toys. Although the children's ages were between 1 and 7, the results support the effect of playing with toys alongside parents in decreasing postoperative pain. Yayan et al. (40) determined the effects of therapeutic play by including distracting games (such as computer games, puzzles, toy cars, baby dolls) on reducing acute postoperative pain among children 6 to 12 years old. These activities were applied during the postoperative period, and were effective in relieving children's postoperative pain. In the present study, although no statistically significant difference was found between the groups' post-intervention pain levels, the analgesic needs of those children in the control group was meaningfully higher than in the intervention group. This finding suggests that the game intervention had a positive effect on the pain levels of children after surgery. In a randomized trial from Singapore, He et al. (15) examined the effect of therapeutic play intervention on the postoperative pain levels of children who had undergone elective surgery. Children who received therapeutic play intervention for one hour before surgery had 1.5 points lower pain severity scores (2.11 vs. 3.60) than those children in the control group who did not receive play intervention. Consequently, using non-pharmacological pain management methods such as playing games with children preoperatively or postoperatively is helpful in decreasing pain levels after surgery, so it is recommended to encourage parents to play game interventions with their children.

Study Limitations

There were some limitations with the present study. Firstly, blinding the patients and the researchers was not possible because of the nature of the game intervention, and the lack of blinding may have caused some thought bias. Secondly, all of the children's participating parents were their mothers, which may be considered a parental limitation.

Conclusion

The results of this study indicate that children who take part in game intervention with their parents do not have lower levels of anxiety or pain than those children in the control group; however, it was effective in decreasing both anxiety and pain levels after surgery. Children in the game intervention group needed significantly less analgesic than those children in the control group. It is suggested that game intervention be employed with children and their parents as an effective intervention strategy for reducing postoperative anxiety and pain. Based on the decreased rates of analgesic needs, it is also recommended that nurses encourage parents to play with their children after surgery. It supports a basis for a low-cost and easy game intervention that can be used as a non-pharmacologic pain management method to reduce both anxiety and pain levels in children between 7 and 12 years of age who undergo minor elective day surgery. Although one child in the present study's intervention group needed analgesics, the study results are meaningful and promote the effects of non-pharmacological methods of reducing pain after surgery. Parental involvement in postoperative childcare is also a meaningful aspect of this study for promoting holistic care, so it is recommended that nurses encourage parents to play games with their children after surgery. For future studies, it would be beneficial to generalize the effects of this game intervention on other age groups of children and examine its effects on other major surgical procedures.

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Ethics

Ethics Committee Approval: Ethical permission was obtained from the Ethics Committee of the Trakya University Faculty of Medicine (protocol number: 2017/344), and official permission was obtained from the directorate of the university hospital (number: 54542207-600).

Informed Consent: Verbal consent was obtained from the children and written informed consent was obtained from the parents.

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Authorship Contributions

Concept: S.Ü., Ö.G., S.A., Design: S.Ü., Ö.G., S.A., Data Collection or Processing: S.Ü., Ö.G., S.A., Analysis or Interpretation: S.Ü., Ö.G., S.A., Literature Search: S.Ü., Ö.G., S.A., Writing: S.Ü., Ö.G., S.A.

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