The effectiveness of the robotic game kit on anxiety among hospitalized preschool children: A non-randomized controlled trial

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ABSTRACT
Background & Aim: Hospitalization is a challenging experience all children go through in their lives, leading to their utmost anxiety. In this sense, interactive games and activities can help ease this psychological burden. Therefore, we endeavored to determine the effectiveness of a robotic game kit (RGK) on the anxiety of hospitalized preschoolers.

Methods & Materials: This non-randomized controlled clinical trial was conducted in a pediatric hospital, Iran, between March and July 2019. 59 participants were assigned to intervention (n=30) or control (n=29) groups through available sampling. Inclusion criteria were Iranian native children aged 3-7 years with communication ability. The RGK was applied in eight sessions at least seven consecutive days of hospitalization. The collected data by using the demographic information form and the preschool anxiety scale (PAS) were analyzed in descriptive, chi-square, t-test, the one-way ANCOVA (analysis of covariance), and multivariate analysis of covariance (MANCOVA).

Results: Two groups were homogenous in terms of demographic variables (p>0.05). There was no statically significant difference between the mean score of PAS before the intervention in 46.33±15.81 and control groups 37.24±19.65 (p=0.055). However, the mean score of PAS in the intervention group was significantly lower than the control group (P=0.030). Also, using the RGK was effective in two subscales related to separation anxiety and physical injury fears (P=0.034).

Conclusion: The modern RGKs could have a significant place in pediatric health care in hospitals. It is thus an undeniable fact that high-quality, comprehensive care can be boosted through RGK based interventions for children encountering stressful situations.

Introduction
Hospitalization would unquestionably make everyone feel uncomfortable, especially children (1) who are habitually afraid of doctors, nurses, and other health care workers in white lab coats. Thus, fear, anxiety, and despair are among common feelings generally demonstrated by patients' parents and children themselves (2).

Over the past decade, anxiety as one of the psychiatric disorders has also been at the forefront of other illnesses, according to the World Health Organization (WHO) (3). In this respect, one in six American children aged two to eight years has experienced a mental, behavioral, and developmental disorder, wherein 7.1% of them (approximately 4.4 million) have been related to anxiety (4). Moreover, compared with the figures and statistics in Iran in 2018, almost 15.2% of 499 children between six and eighteen years had undergone generalized anxiety as a stressful behavioral response (5).

Accordingly, Gomes et al. in 2016 developed the concept of hospitalization-related anxiety as a multidimensional phenomenon, defined by stimulated biological and psychological characteristics in a stressful and threatening hospital environment, where the children face family deprivation, have no social interactions, and recreational activities, have to communicate with strangers and even put up with aggressive and invasive procedures (6).
Hospitalized children might show their anxiety through regressive behaviors, aggression, lack of cooperation, withdrawal, as well as difficulty recovering from some procedures (7). In this regard, higher levels of anxiety recognized as stressful experiences for hospitalized children can be harmful to their physiological and psychological health status. Furthermore, excessive anxiety can even impede their efficacy in coping with medical treatments and increase their uncooperative behavior and negative emotions towards health care professionals (8).

In this line, many techniques have been proposed to treat mental disorders caused by diseases to reduce the effects of fear and anxiety in hospitalized children, whereby nurses and health care workers can apply them to help this age group adjust to the sources of anxiety. Nowadays, non-pharmacological methods are also being utilized to relieve stress and anxiety in children (9). Florence Nightingale, the founder of modern nursing, emphasized the essential nature of games and related activities to create and maintain therapeutic environments for hospitalized children (8). Regardless of their particular orientation, almost all scholars share a common belief, i.e., the use of toys or play environments is an inevitable feature of diagnosing and treating children that can be taken into account as specific therapeutic regimens to understand the stressful environments and to enjoy adaptation capacity (10). To be more precise, the main impacts of training with robotic game kits (RGKs), particularly the construction ones, on minimizing the levels of anxiety are associated with several factors such as a greater willingness to communicate, a higher motivation, more positive attitudes, and enhanced social skills (11, 12).

Some studies have further found that the same token, such as the LEGO therapy, using self-made RGKs, which help improve children’s intelligence and creativity, has been successful in mitigating anxiety in hospitalized preschoolers (13), lowering stress in parent-child interactions, resolving some behavioral problems (14), and enriching current pediatric treatments (15).

Therefore, it can be concluded that early evaluation and timely diagnosis of anxiety in hospitalized children have received much attention, and the next step should be to design psychotherapy protocols (16). Given the importance of the issue and lack of appropriate RGK interventions to moderate anxiety in hospitalized children as soon as possible, it seems necessary to provide a pleasant robotic-innovative-creative play environment for children along with routine child care services. Therefore, the main purpose of this study was to reflect on the effectiveness of an RGK in managing anxiety in Iranian hospitalized children.

**Methods**

**Study design**

This is a randomized clinical trial study with the control group. It was conducted in the pediatric units of Motahari Educational-Medical Center (affiliated to Urmia University of Medical Sciences) in Iran between March and July 2019.

**Sample size**

Based on the previous study (17), by considering α=0.05 and power of 0.80%, the sample size was calculated to be 25 participants by using G*Power 3.1.2. However, participants were recruited due to a 20% attrition rate (30 participants for each group).

**Statistical population and sampling**

The research population contained all children admitted to two pediatric wards in the hospital. Inclusion criteria for the present study were included Iranian children aged between 3 and 7, the ability to speak Persian, and require to stay in the hospital for at least seven consecutive days with their mothers. In addition, we excluded children who have identified cognitive, learning, neuromotor difficulties, and limb abnormality. Furthermore, different RGKs are currently being taught as creative self-made toys in
some corporate institutions and schools for children aged 3 to 15 years based on various programs (15). For the first time, and RGK was thus used in the hospital environment for children who had no previous experience of teaching robotics. Besides, mothers were over 18 years of age with consent to participate in research, able to read and write, and must be to live in Urmia city.

The research units were selected based on availability according to the study's inclusion criteria and were then assigned to the two groups. Two general pediatric wards of Shahid Motahari educational-medical center affiliated with the Urmia University of Medical Sciences were assigned as the workplace for the intervention group and the control group to prevent contamination. The main researcher registered hospitalized children and assigned them into intervention and control groups. In addition, blinding was not performed in this study.

**Data collection**

The data were collected using the patient’s demographic profile and the Preschool Anxiety Scale (PAS). The demographic information form contained the parameters of gender, age, parents' job, and ages, and educational status, number of total days hospitalized, previous hospital admission, number of hospital admissions, family history of the underlying disease, diagnosis, and the number of children in the family. The PAS is a 28-item parent-report scale that consists of five subscales of anxiety matching the DSM-IV classifications: generalized anxiety (five items), social phobia (five items), obsessive-compulsive (five items), physical injury fears (seven items), and separation anxiety disorder (five items). The items in the questionnaire were scored based on a five-point Likert scale (never true=1, always true=5). The overall anxiety score is the sum of the scores a person scores on these six subscales. Higher total anxiety scores (range: 0–112) indicate severe problems (18). Ghanbari et al. showed that all subscales of PAS displayed moderate to high internal consistency (0.64 to 0.76) and had good reliability. Validity evaluation yielded positive results, in addition to face validity confirming by specialists, criterion-referenced validity was supported by moderate to high (0.41 to 0.67) correlations with the anxiety subscale of Conner’s scale, and high correlation in test-retest (0.73 to 0.82) demonstrated good reliability of this scale (19).

After obtaining informed consent from the children's parents and assigning the groups, the necessary explanations about the study's objectives, stages, and duration were provided to the participants. The confidentiality of the information and the voluntary nature of the participants were observed in the study. Prior to the study, the severity of anxiety was measured and recorded in the two groups during the first 24 hours after admission. The PAS levels were reassessed and documented at the end of the last intervention session.

**Intervention**

Accordingly, the pediatric patients in both groups received standard medical and nursing care, such as vital signs monitoring, pharmacological treatments, and wound and pain management. An RGK was also used for the intervention group, consisting of robotics and non-robotics activities. Although there are now many commercially available RGKs to teach about programming, most of them are pre-built in the sense that children are not involved in any of the construction or design aspects of building a robot (15).

In contrast, this study utilized a warrior RGK, engaging young children in both building and programming without a computer, a tablet, or other forms of screen time. This kit was already developed and designed by the ROBOFA group at the Sharif University of Technology, Tehran, Iran, to learn fundamental engineering and game content for young children between three and seven years of age. The warrior RGK was also chosen for this study because of its large and easy-to-manipulate parts.
open-ended building and programming possibilities, as well as the tangible language of the kit. Furthermore, the core curriculum utilizing the warrior RGK was also aligned with the recommendation by the American Academy of Pediatrics (2004) that young children have a limited amount of screen time per day (20). Besides, the kit contained easy-to-connect robotic materials, including wheels, motors, and light outputs as electronic components and even wooden and plastic blocks as robot decorations.

The intervention protocol and the curricula were also standardized in a meeting held with the presence of the play specialists in the robotics company and the researchers to select the frequency and the duration of the game intervention based on the age and the physical conditions of the children in a safe manner. Next, a panel of psychologists and nursing professors approved the given RGK. The introductory robotics curriculum involved approximately eight hours of work over the course of eight days. Each day lesson was then divided into two parts, namely, 30 minutes to perform an activity with the RGK and the other 30 minutes spent on engineering-related activities. During the non-robotics time, the children could spend a portion of the class participating in a full group activity and then spend the remainder of the time partaking in an activity of their own choice. All through the group-activity time, the children could learn stories (such as one teaching about different parts of the warrior robot) and even listen to picture books being read aloud (aimed to reinforce fundamental engineering concepts like the engineering design process [EDP]). During the robotics time, the children were also given tasks to complete involving their robots. Each child had one robot. Of note, the patients’ mothers, together with the researchers, assisted them. This activity focused on strengthening working memory in young children through trial and error. Besides, it worked on their ability to understand sequences and orders as the early foundational math and literacy components. Furthermore, they arranged various shapes such as cars, houses, airplanes, or other forms using the robotic blocks in session six. See Table 1 for a breakdown of the types of activities completed each day. Although the pediatric patients in the control group were not involved in the intervention, the pediatric patients of both groups received the RGK with their form of leaflets and CDs after the post-test.

**Table 1. A summary of activities in each session**

| Sessions | Robotics activity | Non-robotics activity |
|----------|-------------------|-----------------------|
| First    | ✓ Meet early with the therapists, mothers, and children, and present the project goals. Explore the children’s space and objects, try to communicate with the children to make them accept therapists, observe and identify the children’s interests in a careful manner, and provide basic explanations of the warrior RGK | ✓ Tell a story about inventors and young geniuses (with names and shapes) to motivate and create a competitive spirit in the children  
 ✓ Discuss what is a robot, play games to learn the differences between robots and the warrior robot parts |
| Second   | ✓ create and enhance eye contact in the child through plays and with child support, incentives, and interests  
 ✓ Learn how to make geometric shapes and other objects using some elements (for example: making flower or other shapes with blocks) | ✓ Discuss about what is an engineer and learn about the Engineering Design Process  
 ✓ Complete the building activity with non-robotic materials |
| Third    | ✓ Review parts and the different blocks of warrior robot with free exploration with the robot  
 ✓ create a space with a more active role of mothers, taking turns in social interactions and enduring frustration, | ✓ Read a book about five senses in the direction of the Engineering Design Process  
 ✓ Use intriguing and intuitive examples of familiarization with potential differences and early electronic concepts in a simple manner |
| Forth    | ✓ make Robot control key with wooden blocks  
 ✓ understand the applications of the hand-controlled key with a sense of control over problems and discomfort with the mother's presence as a support person. | ✓ Review what is a sensor and senses  
 ✓ Do similar and different games via telling a story about the importance of control |
Fifth
- Review how you control Robot with the control key
- Teach social responsiveness and responding to the loving behaviors of others with the help of robot games, enhancing the persistence of eye contact and the pursuit of the eye with the challenge of achieving incentives
- Tell a story about how to use a robot in difficult situations in their lives

Sixth
- Create conditions for repeating previous situations by highlighting the more active role of the mother talk about how to attach the gearbox and wheels to the robot body
- Tell a story about a robot that is a car. Thus, in this story, my robot turns on, goes forward, and then stops. Can you make a program that matches this story?

Seventh
- Do Robot Route Testing (the child guides the robot on a specified path), Guided Testing (the child spirals the robot through the obstacles), and Maneuverability Test (the child use the robot to move a small object to the desired location)
- Create in-game situations that enable the mothers, therapists, and children to use first-person pronouns to develop a better understanding of the children to use the warrior robot and to develop emotional perceptions and social responsiveness
- Tell a story about “my robot is going to sleep”
- Give right answers to positive and negative questions raised by the children

Data analysis
Data were analyzed in SPSS software (version 16.0, SPSS Inc., Chicago, IL, USA). The significant level was 0.05. Kolmogorov–Smirnov test was used to assess the normality of variables. According to the results, the assumption of normality was confirmed for all variables. In the present study, descriptive statistics such as means, standard deviation, percentages, and frequencies were used to describe the participants’ characteristics. The Chi-square test and the independent t-test were respectively used to compare the qualitative and quantitative demographic data between two groups. The one-way ANCOVA (analysis of covariance) test was conducted to adjust the pretest means scores of PAS. Moreover, the multivariate analysis of covariance (MANCOVA) test was used to determine the difference between the mean scores of post-test PAS subscales in the intervention and control groups. The level of significance of P<0.05 was also considered for the present study.

Ethical considerations
The Ethics Committee approved this study of Urmia University of Medical Sciences (IR.UMSU.REC.1397.145) and from the Registration Clinical trial Center (IRCT20181022041419N1).

During participant recruitment, the primary researcher conducted informed consent to prevent any possible coercive pressure. In addition, participants were informed about the purpose and benefits of this study. They were also assured that information collected during this study is anonymous and confidential.

Results
Firstly, 66 eligible participants were selected using the convenience sampling method based on inclusion criteria among 235 hospitalized preschool children. In the post-test stage, 30 participants remained in the intervention group (three-person was excluded because he did not complete the sessions), and also 29 participants remained in the control group (four-person was excluded because he did not submit the questionnaire after the intervention) (Figure 1).

Based on our assessment groups, the mean age of the children in the control and intervention groups was 5.53±1.19 and 5.98±0.95, respectively. The majority of our participants in the intervention group, in contrast to the control group, were male (53.33% vs. 26.63%). In addition, the educational status of most fathers and mothers in both groups were elementary levels (above 44% and 51%, respectively).
The demographic characteristics of the participants are summarized in Table 2. There were no statistically significant differences between the groups in terms of some demographic variables (age, gender, the mothers’ and fathers’ jobs, the number of children, the educational status of mothers and fathers) (p> 0.05) (Table 2).

Before ANCOVA, its assumptions, such as homogeneity of regression slope, homogeneity of variances, and normal distribution of data, were evaluated. The assessment of homogeneity of variances using Levene’s test showed that the resulting significance level was higher than 0.05, so the assumption of homogeneity of variances is confirmed (F (1,57)=0.983, p=0.326). Furthermore, the assumption of the normal distribution of data using the Kolmogorov-Simonov test showed that given the significance level higher than 0.05 in this test, there is no significant difference between the distribution of scores and normal distribution. The normal distribution assumption has therefore been met, and it is possible to use analysis of covariance.
Table 2. Demographic characteristics between the experimental and control groups for the children of 3 to 7 years

| Variables                              | Control group (N=29) | Intervention group (N=30) | Statistic test |
|----------------------------------------|----------------------|---------------------------|---------------|
| Fathers age Mean±SD*                   | 37.62±6.21           | 36.96±6.26                | t=-0.402      |
| Mothers age Mean±SD                    | 32.44±5.68           | 32.26±5.98                | t=-0.119      |
| Children age Mean±SD                   | 5.53±1.19            | 5.98±0.95                 | t=1.599       |
| Number of total days hospitalized Mean±SD | 8.82±2.62           | 8.83±2.26                 | t=0.244       |
| Gender of children N (%)               | Male: 11(37.93%)     | Female: 16(53.33%)        | X²=2.450      |
| Mothers' educational status N (%)      | Elementary education: 15(51.72) | 18(60)                   | X²=3.167      |
| Fathers' educational status N (%)      | Elementary education: 13(44.83) | 14(46.67)                | X²=3.713      |
| Mothers' job N (%)                    | Housewife: 10(34.50) | 7(23.33)                  | X²=0.894      |
| Fathers' job N (%)                    | Self-employed: 20(69) | 24(80)                    | X²=0.947      |
| Diagnosis N (%)                        | Respiratory problem: 4(13.79)  | 5(16.67)                  | X²=1.622      |
| Number of hospital admissions N (%)    | 1: 18(62.07)         | 17(56.67)                 | X²=0.677      |
| Family history of underlying disease N (%) | Yes: 6(20.67)       | 8(26.67)                  | X²=0.291      |
| Number of children in the family N (%) | First: 10(34.48)     | 13(43.33)                 | X²=1.15       |

* SD: Standard Deviation, N(%): Number(Percentage), t Independent t-test, d Chi-square test

According to Table 3, the mean scores in the intervention and control groups are not significantly different in the pretest, but a significant decrease in PAS is observed in the intervention group in the post-test compared to the control group. ANCOVA has been used to determine the significance of the changes. As a result, it can be claimed that the RGK has effectively and significantly reduced the anxiety scores of hospitalized children. With regard to the pretest scores, the RGK intervention has resulted in a significant difference between the experimental and control groups about anxiety (F=4.969, P=0.030, Eta2=0.181). As Eta2 shows, 34% of the difference between
Experimental and control groups was due to the independent variable with the adequacy of sample size and statistical accuracy (0.621) (Table 3).

The results of the mean PAS subscales in the intervention group had a significant decrease after receiving the RGK (Table 4). The MANCOVA test was used to determine the significance of the changes, and the results can be seen in Table 5. Regarding pretest scores, the RGT intervention has resulted in a significant difference between both groups in terms of the separation (F=4.722, P=0.034, Eta2=0.176) and Physical injury fears (F=4.711, P=0.034, Eta2 =0.177) dimension of PAS. As Eta2 shows, 17% of the difference between intervention and control groups in the post-test was caused by the independent variable (Table 5).

**Table 3.** Mean and standard deviation of PAS in pretest and post-test and results of ANCOVA test of the experimental and control groups in the post-test stage

| Group          | Stage | Mean±SD     | F   | P-value | Eta2 | Observed power |
|----------------|-------|-------------|-----|---------|------|----------------|
| Intervention   | pretest | 46.33±15.81 |     |         |      |                |
|                | post-test | 27.76±21.82 | 4.969 | 0.030   | 0.181 | 0.621          |
| Control        | pretest | 37.24±19.66 |     |         |      |                |
|                | post-test | 39.89±23.97 |     |         |      |                |

**Table 4.** The mean and standard deviation of five subscales of PAS in both groups in pretest and post-test

| PAS subscales       | Pretest | Posttest |
|---------------------|---------|----------|
|                     | Control group | Intervention group | Control group | Intervention group |
|                     | Mean±SD | Mean±SD  | Mean±SD | Mean±SD |
| Generalized anxiety | 6.55±4.10 | 8.90±3.39 | 6.07±4.71 | 4.87±4.21 |
| Social phobia       | 5.86±4.48 | 8.27±4.31 | 7.52±5.45 | 5.03±4.82 |
| Obsession–incontinence | 6.48±4.57 | 8.03±3.91 | 7.21±4.78 | 5.20±4.89 |
| Physical injury fears | 10.38±6.57 | 12.53±7.16 | 11.21±6.87 | 7.53±6.10 |
| Separation anxiety  | 7.96±4.52 | 8.60±5.01 | 7.89±4.82 | 5.13±4.95 |

**Table 5.** MANCOVA results in post-test scores for all subscales of PAS in both groups

| Different Source | Type III Sum of Squares | df | Mean Square | F   | P-value | Eta² |
|------------------|-------------------------|----|-------------|-----|---------|------|
| Generalized anxiety | 21.315 | 1 | 21.315 | 1.070 | 0.305 | 0.018 |
| Social phobia | 90.978 | 1 | 90.978 | 3.443 | 0.069 | 0.057 |
| Obsession - incontinence | 59.391 | 1 | 59.391 | 2.542 | 0.116 | 0.043 |
| Physical injury fears | 198.995 | 1 | 198.995 | 4.722 | 0.034 | 0.177 |
| Separation anxiety | 112.589 | 1 | 112.589 | 4.711 | 0.034 | 0.176 |

**Discussion**

The study findings of this indicated that using the RGK diminished anxiety in hospitalized preschoolers. Likewise, it could significantly decrease the mean score of the PAS in the experimental group compared with that in the control one.

In a review of the related literature, no studies were found on the effects of RGKs on the levels of anxiety, to the best of authors’ knowledge, but educational methods similar to the LEGO as self-made robotic toys have been thus far explored on anxiety in preschoolers (21, 22).

Nurses need to create a stable and equal environment along with the pediatric patients' parents to facilitate high-quality care and treatment in the pediatric units (23). Given the individual and socioeconomic costs of anxiety disorders, their treatment at an early age can also play a crucial role in

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reducing costs and enhancing public health. Thus, non-pharmacological interventions that can treat anxiety symptoms in children under seven years require much more attention via non-medicinal interventions (24). Furthermore, since children do not have enough cognitive development necessary for cognitive behavioral therapy, parents must provide behavioral skills to shape their behavior (25). To sum up, Robotic tools accordingly seem to be attractive in this respect since they can provide a new environment to address the emotional needs of hospitalized children and improve patient care experiences (26).

Based on the present study's findings, the given intervention had the highest efficacy in reducing anxiety among children aged three to seven years. In line with these results, social robots' emotional and behavioral deviation strategies had also been able to mitigate children's fear and anxiety during vaccinations and increase the levels of happiness in all situations (27). Consistent with the findings of previous studies (28), e.g., Burns-Nader et al., it is very important to mention that playing with medical devices would cause fear and distress in hospitalized children more than watching videos of other children playing medical games (29).

With reference to the analyses of sub-scales, the fear of physical trauma and the levels of separation anxiety were relegated in the intervention group compared with the control one. Other evidence also showed that group play therapy (30) and parent training programs, as interactive, could decrease all of the PAS sub-scales (17). Furthermore, Munalim and Rismawat (2020) in Indonesia had further demonstrated that playing with LEGO as self-made robotic toys could lower the PAS levels in hospitalized preschool children (3-6 years) (21). LEGO games could additionally enhance children's social skills in children with autism and help reduce their social anxiety (22). Accordingly, group-based games and socially-oriented games can make individuals perceive themselves in interaction with others in society.

To wrap up, it was significantly demonstrated that children could get together in the play environments, helping them relieve unhealthy thoughts and attitudes about themselves and their surroundings, build effective personal relationships, enhance group and social interactions, and develop interpersonal experiences (31, 32). According to the results of the present study, it is indispensable to clarify that negative emotions such as fear, stress, and anxiety, including social anxiety, are reduced (33). Although much research has been thus far related to the effects of play therapy environment on mitigating children's anxiety, the present study made use of a new technique recruiting robotics games.

**Limitations**

There were some limitations to this study. Although it was the first attempt to investigate preschoolers in a small region in Iran, much care is needed in interpreting and applying the findings to other groups of children in other countries. It is initially suggested to conduct a large-scale replication study with a larger sample size of different age groups to generalize the study results better. With regard to the children's length of stay, eight days are secondly recommended for the interventions. However, some children received the interventions in the hospital playroom for seven days because of early discharge.

Finally, given the importance of games to children's psychological health, hospital authorities are suggested reorganizing more creative and up-to-date resources and establishing more space and facilities for children to create a comfortable play environment as they are hospitalized. Most importantly, it is vital to employ the Hospital Play Specialists (HPS) to integrate games and related activities into routine care for hospitalized children.

**Conclusion**

The results highlight the importance of combining hospital play to provide
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comprehensive and quality care to reduce the stress of hospitalized children. It promotes knowledge and understanding among health care professionals and parents that play is vital to children's lives and should be played even if they are sick. Therefore, this non-pharmacological behavioral, educational intervention helped to reduce preoperative anxiety in preschool children.

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Conflict of interest

The authors have made substantial contributions to the conception or design of the research and declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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