STUDY PROTOCOL

Study title:

The effect of immersive virtual reality education before pediatric radiography on anxiety and distress of patients: A randomized controlled trial

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I. Summary

Pediatric patients often encounter anxiety and distress in hospital settings and the virtual reality (VR) that provides a vivid, immersive and realistic experience has been introduced as a method of pediatric patient education. This prospective, randomized, and clinical trial is designed to evaluate whether the VR education of the pediatric patients before the chest radiography could reduce anxiety and distress in children and could improve the radiographic process.

One hundred children scheduled for chest radiography will be randomly divided into either the control (n = 50) or VR group (n = 50). Children in the control group enter the radiography room with usual simple instruction for chest radiography, whereas those in the VR group receive a 3-min VR experiencing regarding the process of chest radiography. Anxiety and distress of pediatric patient will be evaluated with behavioral observation using the amended version of Observational Scale of Behavioral Distress (OSBD) scale for radiology procedures. Need of parental presence, parental satisfaction score, procedure time, number of re-take, and process difficulty score will be also recorded.

II. Purpose

To evaluate the effect of VR education of chest radiography on anxiety of pediatric patients and on the efficiency of radiologic procedure.

Hypothesis #1: VR education about radiologic process before the radiography may reduce anxiety and distress in pediatric patients.

Hypothesis #2-a: VR education may reduce need of parental presence to properly perform chest radiography.

Hypothesis #2-b: VR education may reduce procedure time

Hypothesis #2-c: VR education may reduce the difficulty of taking adequate X-ray.

Hypothesis #2-d: VR education may reduce the incidence of re-take

Hypothesis #2-e: VR education may increase parental satisfaction score.

III. Background

Pediatric patients often experience fear and anxiety in unfamiliar hospital setting and procedures. In radiology settings, unfamiliar radiology room and large radiology machines make pediatric patients feel anxiety and distress. Distress of pediatric patients in radiology setting may lead to stress behaviors such as crying, moving and flailing, which result in delay or cancellation of the process of radiology. The stressful nature of radiology procedures for pediatric patients also may result in long-term effects such as post-traumatic stress syndrome or avoidance of healthcare.

Several methods including sedation and distraction have been tried to reduce pediatric patient stress level in pediatric radiology department. Sedation of pediatric patient increased the process time and needed recovery time after procedure. Moreover, sedation administration increased the risk of cardiovascular and respiratory complication such as desaturation. Positive environment distractions such as physical environment distractions including artworks and gardens were provided in pediatric radiology settings and these interventions reduced stress and improved outcome in pediatric patient with radiology examinations.

Recently, virtual reality (VR) systems have been introduced in patient education to reduce anxiety and to improve outcome with the advance of technology. Previous investigations with VR experience or gamification about preoperative process demonstrated significant reduction of preoperative anxiety in pediatric patients. The VR with 360° video can deliver information via a consistent, vivid, and immersive experience to

pediatric patients without physical and financial limitations. High immersion and vividity are the main characteristics provided by VR technology, which can be utilized for the education of pediatric patient.

IV. Inclusion Criteria, Exclusion Criteria

Inclusion:

ASA I or II, aged 4–8 years, undergoing with chest radiography

Exclusion:

History of prematurity or congenital disease

Hearing impairment

Cognitive deficits or cognitive and intellectual developmental disabilities

History of epilepsy or seizure taking psychoactive medications

History of epilepsy or seizure

Prior experience of chest radiography for the past 1 year

V. Targeted Number of Subjects and Calculation Basis

Power analysis was performed using G*Power 3.1.2 (Heinrich-Heine University, Düsseldorf, Germany). A previous study reported that the incidence of stress and anxiety during radiographic process was 53% for children based on the amended OSBD. A reduction of 50% of the incidence of stress and anxiety during radiographic process was considered to be clinically significant of the effect of the VR education. A sample size of 50 children per group was calculated with power of 0.8, significance level of 0.05, and 10% dropout rate.

VI. Recruitment of research subjects

Only researchers participating in this research can explain about the study and acquire informed consent from pediatric patients and their caregivers who visited our department of radiology to perform chest X - ray. Written informed consent will be obtained from all parents/guardians of pediatric patients, and children aged 7 years or older sign additional agreements directly after receiving detailed instructions with their parents/guardians. He/she can refuse to participate in the study at any time during the experience of VR

experience education and the radiographing process after obtaining the consent. The researcher will explain using a general term that can be fully understood by the subject who is not a non-medical person and will give enough information about the contents of this research, and the benefits and disadvantages from the research.

VII. Randomization

The children are randomized to the control or VR group using a computer-generated randomization code (Random Allocation Software version 1.0; University of Medical Sciences, Isfahan, Iran), 10 min before the chest radiography. An opaque envelope containing sequential numbers is transferred to another researcher, and the intervention is performed in the separated area 5 min prior to entering the radiography room.

VIII. Intervention

For pediatric patients in the control group, the chest radiography is performed with usual simple instruction for chest radiography. Children in the VR group receive a 3 min VR education about radiologic process with a head- mounted VR display.

IX. Virtual reality experience of the radiography room

The VR experience is provided as a 360° 3-dimensional virtual environment that introduces and explains the process of chest radiography. The 3-min video was produced in collaboration with a VR producing company (JSC GAMES, Seoul, Korea). Chatan and Ace, famous animation characters of an animated film ‘Hello Carbot’ (ChoiRock Contents Factory, Seoul, Korea), explains the process of chest radiography in detail , encouraging the child to cooperate appropriately. Permission to use these animation characters have been obtained (licensing agreement with ChoiRock Contents Factory). In the VR video, pediatric patients experience the process of chest radiography with Chatan and Ace. They are asked to enter into a radiography room and have the opportunity to experience the radiography room. The child can learn how to posture in front of the radiology machine and to take a deep breath and to cooperate appropriately through the VR education. A head-mounted VR display, Oculus Go (Oculus VR, Menlo Park, CA, USA) will be used to play the VR video.

X. Outcome measurement

Children's stress and anxiety during the radiography process is measured with the amended version of Observational Scale of Behavioral Distress (OSBD) scale for X-ray procedures by a blinded single evaluator to exclude any possible interrater bias. Parental presence due to children's anxiety and parents/guardians' satisfaction score about the overall process of chest radiography using a numerical rating scale (11 NRS; 0, very dissatisfied; 10, very satisfied) will be recorded.

Time for radiography procedure (time from the entrance of radiography room to produce the chest radiographic image) and the number of re-take are recorded by the blinded single evaluator. After taking the chest radiography, the radiology technologist will score the level of difficulty of taking the chest radiography of each child using a NRS (11 NRS; 0, very difficult; 10, very easy).

XI. Statistical analysis

SPSS version 21.0 (SPSS Inc., IBM, Chicago, IL, USA) is utilized for all statistical analyses. The test of normal distribution is assessed using Shapiro-Wilk test. Continuous data (age, height, weight, OSBD score, parental satisfaction score, time for radiography procedure, process difficulty score) will be presented as the median (interquartile range [IQR]), and categorical variables (gender, reason for chest radiography, OSBD group, parental presence, number of re-take) be shown as numbers (%). Mann–Whitney U test is used for the analysis of continuous variables, and chi-square test or Fisher's exact test is used for categorical variables. A full analysis set is used for data analysis. All of the reported p-values are two-sided. A p value of less than 0.050 is considered to indicate statistical significance.

XII. The benefits and risks

In this study, it is considered that there is no additional risk or side effect due to the experience of less than 3 minute VR experience training conducted in this study. In case of VR education experience, it is expected that positive effects on patient cooperation, and the stress and anxiety during the procedure.

XIII. Study stop or drop

After the consent form is obtained, if the subject does not cooperate well or refuses to participate in the

experience of VR education, and if the subject and guardian want to stop participating in the study, the study will be stopped and the subject will be dropped out of the study.

XIV. Patients' Consent

- Who will provide consent: Study subjects and caregivers
- To minimize the possibility of forcible or unjustified effects: Avoid unfair deception, unreasonable pressure or intimidation. Obtaining agreement only after confirming that the subject has an adequate understanding of the participation and the opportunity to take full account of the participation in the study.
- Language that can be understood by research subject or parents: Korean language without difficult Chinese characters or English.

XV. Payment for participation

There is no financial benefit for the study subjects involved in clinical trials. However, small toys are provided to the pediatric patients participating in the study as a gift.

References

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Appendix A. Observational Scale of Behavioral Distress / Amended version for distress during radiographic (x-ray) procedures

Behaviour	Definition	Absent=0, Occasionally=1 or 2, Large extent=2 or 4
Crying	Tears in eyes or running down face	0 ☐ 1 ☐ 2 ☐
Cling	Physically holds on to parent or radiographer	0 ☐ 1 ☐ 2 ☐
Fear verbal	Says 'I'm afraid' or 'I'm scared', etc.	0 ☐ 1 ☐ 2 ☐
Pain verbal	Says 'Ow', 'Owch', etc.	0 ☐ 1 ☐ 2 ☐
Scream	No tears, raises voice	0 ☐ 2 ☐ 4 ☐
Carry	Has to be carried into the room or put on table	0 ☐ 1 ☐ 2 ☐
Flail	Random movement of limbs—intention to make aggressive contact	0 ☐ 2 ☐ 4 ☐
Refusal position	Does not follow instructions re. body placement on treatment table/in front of X-ray machine	0 ☐ 1 ☐ 2 ☐
Restrain	Has to be held down owing to lack of cooperation	0 ☐ 2 ☐ 4 ☐
Muscular rigidity	Any of the following: clenched fist, white knuckles, gritted teeth, eyes clenched shut, body stiffness	0 ☐ 2 ☐ 4 ☐
Emotional support	Seeks reassurance either verbally or nonverbally	0 ☐ 1 ☐ 2 ☐
Total score :	**Not distressed** ☐	**Distressed** ☐

Weightings (a value of 2) were added to the behaviours restrain, scream, flail and muscular rigidity.

Distressed, a score of 4 or below

Not distressed, a score of 5 or above

Appendix B. Flow diagram