INPLASY PROTOCOL

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The authors declare no conflict of interest.

The effectiveness of the virtual reality for needle-related procedural pain and anxiety in children and adolescent: A protocol for systematic review

Zhao, H[1]; Lv, X[2]; Ma, Y[3]; Wang, Y[4].

Review question / Objective: **The aim of this review is to determine the effect of using virtual reality on reducing the pain and anxiety felt during a needle-related procedure in children and adolescents.**
Information sources: **The databases we searched included the Cochrane Library, PubMed, Embase, CINAHL, Web of science, MEDLINE and Scopus. Studies from database inception to 2 April 2020 were included and published in English. We adopted combination of heading term and free term as search strategy. For incomplete study, the author will contacted the original data.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 November 2020 and was last updated on 10 November 2020 (registration number INPLASY2020110038).

INTRODUCTION

Review question / Objective: **The aim of this review is to determine the effect of using virtual reality on reducing the pain and anxiety felt during a needle-related procedure in children and adolescents.**

Condition being studied: **While most of medical procedures could provoke the pain and anxiety, needle-related procedures continue to be most frightening portion in the hospital experience for children and adolescents. Needle-related procedures have no specific concept, which include venipuncture, intravenous insertion, blood**

draw, intramuscular injection, vaccinations. Unpleasant early medical experiences can affect patients' perception of healthcare, can increase pain and suffering during subsequent medical visits, and can reduce preventative healthcare, affecting lifelong health.In recent years , researchers have tried use many ways which were playing distraction cards; squeezing soft balls; and watching TV to help solve these problems, but they produced varying results because users are in different environments, have different experiences, and the human resources and time resources of medical teams vary. Virtual reality (VR) is showing its promising as a nonpharmacologic method for pain and anxiety management during these routine operation. VR is easy to install and are not influenced by hospital environment. A large number of studies have found VR has potential to divert patients' attention away from painful stimuli by keeping then active. To our knowledge, there is no systematic review and meta analysis to assess the effectiveness of VR for pain and anxiety management among children and adolescents during needled related procedures.

METHODS

Participant or population: The review included children and adolescents aged 3-18 years who needed to undergo needle-related procedures; who were clearly conscious; who without any visual and auditory impairments; who had no pain before the medical process; who did not use an analgesic or antianxietic drug in the last 6 hours; who did not have previously used Virtual Reality before the study. Patients and their primary caregivers who could agree to participate in this study and sign written consent forms.

Intervention: This review included studies that estimated the efficiency of using virtual reality (VR) for pain and anxiety management among children and adolescents undergoing needle-related procedures. VR was performed in many forms such as watching video and playing VR game.

Comparator: The control intervention includes standard care (no used VR devices) or other intervention like watching TV, using external cold, kaleidoscope, vibration and distraction cards.

Study designs to be included: Quasi-experimental trials and random controlled trials.

Eligibility criteria: The review included RCTs and quasi-experimental trials with virtual reality intervention and published in English.

Information sources: The databases we searched included the Cochrane Library, PubMed, Embase, CINAHL, Web of science, MEDLINE and Scopus. Studies from database inception to 2 April 2020 were included and published in English. We adopted combination of heading term and free term as search strategy. For incomplete study, the author will contacted the original data.

Main outcome(s): The main outcomes-the total score of pain and the total score of anxiety. The measure tools of pain include: Visual Analogue Scale(VAS); Face Pain Scale-Revised(FPS-R); Colored Analogue Scale (CAS); the Wong-Baker Faces Pain Scale(WBFPS); Wong-Baker Faces Pain Rating Scale(WBPRS). The measure tool of anxiety include: Children Fear Scale(CFS); the Children's Anxiety Meter(CAM); Childhood Anxiety Sensitivity Index (CASI).

Quality assessment / Risk of bias analysis: Two independent reviewers (Z.H.X & L.X.R) critically evaluated the quality of eligible studies. For RCTs, the Cochrane Handbook Version 5.1.0 was used, which evaluated the biases of selection, performance, detection, attrition, reporting and so on.For quasi-experimental trials, Joanna Briggs Institute (JBI) was used as the assesses instruments.Any disagreements between the two independent reviewers (Z.H.X & L.X.R) were resolved by discussion or a third reviewer (M.Y).

Strategy of data synthesis: All studies retrieved were sent into EndNoteX9.

Duplicate studies were eliminated. Titles, abstracts and full text of possibly relevant studies were then screened following the inclusion and exclusion criteria of this review. Any disagreements between the two independent reviewers (Z.H.X & L.X.R) were resolved by discussion or a third reviewer (M.Y). Two researchers extracted data and recorded them on a standard data extraction form. The following related information was recorded: authors, age, country of origin, study design, settings, needle procedure, sample size, the number of male. Disagreements concerning the extracted data were discussed among researchers. If insufficient information was available, then the authors were contacted via e-mails.

Subgroup analysis: If the results of study are heterogeneous, we could conduct the subgroup analysis for different reasons. Heterogeneity is manifested the following several aspects, such as gender, age and the pain and anxiety reported by patient self, primary caregivers/parents, nurses and researchers.

Sensibility analysis: The meta was conducted by used Rev.Man5.3. Because the outcomes were continuous data, effect sizes were expressed as standard mean differences (SMD) due to the use of different rating scales. The results were summarised with 95% confidence intervals (CIs). p-value <0.05 was considered statistically significant. Statistical heterogeneity was estimated using the standard chi-square and I-squared tests. Statistical analyses were performed using random ($p \leq 0.10$, $I2 \geq 50\%$) or fixed effects ($p \geq 0.10$, $I2 \leq 50\%$). Besides, we conducted a sensitivity analysis to evaluate the reliability and stability of the meta-analysis outcomes. When meta-analyses cannot be performed, narrative form was used to present the results.

Country(ies) involved: China.

Keywords: anxiety, pain, needle, procedure, virtual reality, effectiveness.

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