

# **Virtual reality for pain and anxiety control during local anesthesia in a pediatric dental teaching clinic: a randomized controlled trial**

## **Background**

Pre-operative anxiety is a condition that impacts both the physiological and psychological well-being of patients (Baytar et al., 2021). It often results in behavioral resistance, making it challenging to provide effective treatment. This condition can lead to adverse outcomes during the current procedure and subsequent appointments (Baytar et al., 2021). Physiological manifestations of anxiety include rapid increase in heart rate and blood pressure, which can interfere with treatment, concerns pediatric patients, and might also lead to a less favorable perception of the dental clinic, potentially discouraging them from seeking future treatments (Baytar et al., 2021).

Furthermore, the effective management of a child's behavior to encourage their cooperation as a dental patient is essential for the treatment's success (Elicherla et al., 2019). Although traditional behavior management methods produce favorable outcomes, there is an ongoing shift in the attitudes of both parents and certain dental professionals regarding these techniques (Aitken et al., 2002). Distraction has been a successful strategy in dentistry for numerous years due to its straightforwardness, safety, and cost-effectiveness. It operates on the premise that pain perception has a significant psychological aspect; if minimal attention is given to a painful stimulus, the perception of pain is reduced. Methods to divert children from discomforting stimuli include the use of television, music, and storytelling. Nevertheless, the effectiveness of watching during dental treatment to alleviate anxiety relies on the child's full engagement (Buldur et al., 2021; Cunningham et al., 2021).

Over the past few years, the public's recognition and utilization of virtual reality (VR) has expanded significantly. VR can be defined as a computer-generated, 3D environment where users engage with virtual objects or characters (Baytar & Bollucuoglu 2021). It offers certain advantages compared to existing non-pharmacological behavior guidance

methods; it is considered a safe approach since patients encounter the virtual depiction of a potential threat in a more gradual and regulated fashion (Buldur et al., 2021).

In a systematic review on the use of VR and dental smartphone apps measuring their effects on anxiety levels (Cunningham et al., 2021), where four randomized controlled trials were examined, one found no statistically significant difference between the outcomes of VR and the use of a tablet, nor between VR and the control group (Al-Halabi et al., 2018), while another reported a significant reduction in anxiety scores associated with VR distraction (Aminabadi et al., 2012).

Despite the numerous benefits that VR offers in dentistry and medicine, there has been a lack of extensive research exploring its effectiveness in mitigating anxiety and pain during dental procedures in children (Buldur et al., 2021). The primary focus of this study is directed towards understanding the impact and potential benefits of utilizing VR technology in the context of dental procedures for children. The researchers aim to investigate how VR affects children's behavior, anxiety levels, and overall experience during dental treatments. By exploring these aspects, the study aims to contribute valuable insights into the effectiveness of VR as a tool for enhancing the dental experience for pediatric patients.

## **Study Aim:**

Primary Objective:

To investigate the effect of virtual reality on dental anxiety in pediatric patients attending for dental treatment under local anesthesia compared with conventional behavior management techniques.

Secondary objectives:

- To assess whether virtual reality affects pain perception in children.
- To assess whether virtual reality affects children's behavior on the dental chair.

## **Study Design**

The study follows a single-blinded randomized clinical trial (RCT) design and will be carried out within the Pediatric Dentistry department. The study will conform to the CONSORT guidelines for proper documentation and will be conducted at Umm Al-Qura University Dental Hospital.

## **Sample**

Participants will be chosen from children who are receiving routine dental care at the Department of Pediatric Dentistry within the Faculty of Dentistry, Umm Al-Qura University. The sample size was determined based on an estimate of the sum of patients included in previously published randomized controlled trials (Alkhotani et al., 2016; Nuna et al., 2019; Shetty et al., 2019). Taking into account potential drop-outs, the sample size needed will be a total of 90.

### **Inclusion criteria:**

1. Children 4-10 years of age.
2. Frankl behavioral score of 2, 3 or 4.
3. Child with ASA I or II
4. Children requiring dental treatment under local anesthesia (LA).
5. Children who have not had LA administered within the past 6 months.
6. Those with written-informed consent received from the parents/guardians.

### **Exclusion criteria:**

- Children with any systemic (particularly those with history of seizures, convulsions, visual problems) or mental health conditions.
- Previous unpleasant experience in medical setting or known dental phobia.
- Children attending the visit suffering from acute dental pain or infection.
- Children or parents who refused participation in the study.

## **Materials and Methods:**

## **Intervention**

VR box: often referred to as a "VR headset" or "virtual reality headset," is a device that allows users to experience virtual reality by wearing it over their eyes. These devices are designed to create immersive, 3D environments or simulations, often in the form of video games. They typically consist of a pair of lenses and a screen, and some are equipped with motion-tracking sensors to allow users to interact with the virtual world. Users can wear these headsets to feel like they are inside a different, computer-generated reality.

All dental treatment will be carried out by four allocated 5<sup>th</sup> year dental students. Participants will be divided into two groups. Group A (Control group) will receive LA with basic behavior guidance techniques and no distraction aids. Group B will receive LA with the use of a 'VR Box' and wireless headphones.

## **Measures taken at different time points:**

During LA administration, validated measures/scales will be taken to assess the child's anxiety, pain and behavior, as follows:

### **Pre-operatively:**

- The initial pulse rate will be documented.
- Child's behavior while on the dental chair will be recorded using a visual analogue scale (VAS) (Kindler et al., 2000)

### **Peri-operatively:**

- As patients sit in the dental chair, a pulse reading will be taken during anesthesia administration.
- Child's behavior while on the dental chair will be recorded using a visual analogue scale (VAS) (Kindler et al., 2000).
- While LA is being administered, a behavioral pain scale will be recorded using The 'Face, Legs, Activity, Cry, Consolability' scale (FLACC) (Malviya et al., 2006).

## **Post-operatively:**

- Immediately after the completion of LA administration, a pulse reading will be taken.
- Child-recorded Wong-Baker FACES pain rating scale (WBPS) (Wong and Baker, 1988).
- Child's behavior while on the dental chair will be recorded using a visual analogue scale (VAS) (Kindler et al., 2000).

## **Validity and Reliability of Data**

Intra- and inter-examiner reliability will be carried out. Calibration of two pediatric consultants will be scored using KAPPA following agreements on the use of the WBPS and FLACC. The VAS scores will be classified and determined following calibration sessions where the score will range from 0-10, with 0 being the most cooperative, and 10 being the least cooperative.

## **Statistical analysis**

Statistical analysis will be conducted using a statistical software package (e.g., SPSS, R, or SAS). Descriptive statistics will be used to summarize participant characteristics, including mean age, gender distribution, and baseline anxiety levels. The primary outcome measure will be the child's anxiety measure. Differences on a nominal scale will be measured using the t-test, whereas those on the ordinal scale (VAS) will be measured using the Mann–Whitney U-test. The two-way ANOVA will be used for analyses of changes between data at baseline, during and after the administration of LA for each group.

## **Ethical approval**

The study will be conducted under ethical approval from the institutional review board (IRB) of Umm Al Qura University and no research activities will be undertaken until IRB approval is obtained. Participation is entirely voluntary and anonymous. Patient

confidentiality will be maintained at all times, and participants will be given special study IDs. Written informed consent will be obtained from the parents/legal guardians wishing for their children to take part in the study. Participants are free to withdraw from the study at any time.

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## Appendix

Figure 1. study flow chart



