

How Can the Sedative and Analgesic Effects of Virtual Reality Technology Be More Precisely Assessed in Pediatric Dental Care? Methodological Insights from an Ongoing Randomized Controlled Trial [Letter]

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Dear editor

Virtual reality (VR) technology is posited to alleviate pediatric dental anxiety and phobia during treatment via distraction mechanisms.¹ In this regard, we commend Cao et al for their ongoing randomized controlled trial (RCT), which aims to generate novel evidence on VR application in pediatric dentistry by evaluating its analgesic and sedative effects in children with acute pulpitis.² Nevertheless, certain methodological aspects of their trial protocol warrant clarification or would benefit from further optimization.

Refining Exclusion Criteria for VR-Induced Motion Sickness Screening and Recent Analgesic Use Definition

Cao et al listed “individuals experiencing motion sickness from VR imagery” as an exclusion criterion.² However, motion sickness generally occurs only upon actual VR exposure.³ For children without prior VR experience, it is not possible to predict VR-induced motion sickness based on inquiry or medical history. Although the authors suggest in the *Safety Assessment* section that children undergo a brief familiarization session with VR equipment (eg, 5–10 minutes) to reduce anxiety or discomfort,² this constitutes adaptive training after enrollment rather than a screening procedure during recruitment. Moreover, this step is recommended rather than mandatory. If motion sickness arises during adaptation, participants may withdraw, leading to missing data. To address this, we propose integrating an independent VR sensitivity screening phase during participant enrollment (eg, a brief VR exposure), coupled with specifying the assessment instruments for motion sickness evaluation (eg, Child Simulator Sickness Questionnaire⁴) and clear exclusion thresholds.

Additionally, the authors excluded “children who have recently taken analgesic medications”² but did not define the time frame for “recently” (eg, 24 hours, one week, or one month). Given the varying half-lives of different analgesics,⁵ uneven distribution of analgesic washout periods between the intervention and control groups could lead to baseline differences in pain, confounding the assessment of VR’s analgesic effects. A clear definition of the time window for “recently”, along with its rationale, would strengthen the protocol.



Clarifying Blinding Implementation Strategies Under Visible VR Intervention Conditions

In the *Abstract*, Cao et al stated that “data collectors will be blinded to the study”.² However, in the *Methods* section, they indicate that the Wong-Baker FACES Pain Rating Scale (WBFPRS) and the Frankl Behavior Rating Scale (FBRS) will be used to assess participants’ pain and compliance, respectively, during the local anesthesia phase (T1) and pulp exposure phase (T2).² At these time points, participants in the intervention group wear VR glasses while controls do not; thus, data collectors can readily infer group allocation by observing the children.

Accordingly, we call for a more detailed description of how blinding of data collectors will be maintained in actual trial settings. If blinding is not feasible, this limitation should be explicitly acknowledged in the *Discussion*, and the potential for observer bias analyzed, as systematic review evidence indicates that lack of blinded outcome assessors in RCTs poses a high risk of observer bias.⁶

Enhancing Anxiety and Immersion Measurement Methods

According to Table 1 of Cao et al’s trial protocol, the Visual Analog Scale for Anxiety (VAS-A) will be used to assess participants’ anxiety, but only at baseline (T0) and immediately after treatment (T3), omitting the two peak anxiety phases: local anesthesia (T1) and pulp exposure (T2).² Notably, the anxiety response at T2 may represent the core target of the VR distraction intervention; omitting these measurements may preclude the RCT from addressing the critical question—whether VR reduces pediatric dental anxiety during local anesthesia and pulp exposure. We therefore encourage the authors to clarify the rationale for omitting VAS-A assessment at T1 and T2. In the absence of sufficient justification, anxiety should be assessed at these time points to provide more clinically relevant evidence.

In addition, Cao et al plan to perform Pearson or Spearman correlation analyses between VR engagement (duration of immersion and reported enjoyment) and primary outcomes (pain/anxiety levels) with intervention group data.² However, specific measurement methods for variables such as immersion duration and enjoyment were not described. Duration of VR glasses use is not equivalent to immersion duration, which reflects the degree of psychological engagement and generally requires eye-tracking technology for assessment.⁷ Specifying the methods for quantifying “duration of immersion” and “reported enjoyment” would enhance methodological transparency.

Finally, physiological parameters such as blood pressure, heart rate, and oxygen saturation will be collected,² but heart rate variability (HRV) does not appear to be considered. HRV reflects autonomic nervous system activity and is associated with affective states; negative affect has been linked to lower values across various HRV measures.⁸ HRV is sensitive to pain and emotional stress, and can serve as an objective supplement to subjective scales in quantifying pain,⁹ fear,¹⁰ and anxiety.¹⁰

Optimizing Control Group Design to Address Non-Specific Psychological Effects

In the trial, the intervention group wears VR glasses while the control group does not,² creating an imbalance in non-specific psychological effects. Specifically, participants in the VR group may experience higher treatment expectations, increased attention, or more positive emotions due to exposure to novel technology; these factors may independently reduce reported pain and anxiety, producing placebo or expectancy effects. Consequently, observed between-group differences may partially reflect non-specific psychological effects rather than the specific analgesic mechanism of VR’s immersive distraction.

To advance this area, future RCTs could consider a more balanced control group, for example, using standard screens to present the same animated video content as the VR group, without the immersive experience. This would provide both groups with audio-visual distraction, differing only in the dimension of immersion, thereby allowing a more unbiased assessment of whether VR’s analgesic and sedative effects in children with acute pulpitis are specific or non-specific.

Specifying Missing Data Handling Methods Under the Intention-to-Treat Framework

Cao et al indicated that statistical analyses will follow the intention-to-treat (ITT) principle, but did not specify how missing data will be addressed.²

We suggest that the authors elaborate on the missing data handling strategy in their protocol. For instance, a missing data pattern analysis could first determine whether data are missing completely at random (MCAR), missing at random (MAR), or missing not at random (MNAR).¹¹ For MCAR or MAR, multiple imputation or mixed-effects models may be applied; for MNAR, a pattern mixture model with sensitivity analysis is recommended. Additionally, dropout or withdrawal reasons should be categorized and reported (eg, VR intolerance, equipment malfunction, voluntary withdrawal by parents/children for other reasons), and their distribution compared between groups. Finally, results from both ITT and per-protocol analyses should be presented; discrepancies between the two should be further addressed in the discussion.

Conclusion

In summary, while Cao et al's trial protocol represents a timely and promising exploration of VR applications in pediatric dentistry, key methodological aspects—including participant screening, assessor blinding, anxiety assessment, control group design, and missing data management—require careful refinement. Subsequent research should build upon such protocols using more rigorous, mechanism-driven designs that combine objective physiological metrics with subjective assessments, thereby offering robust and translatable evidence to inform the integration of VR interventions into comprehensive strategies for managing pediatric anxiety and phobia.

Abbreviations

FBRS, Frankl Behavior Rating Scale; HRV, Heart Rate Variability; ITT, Intention-to-Treat; MAR, Missing at Random; MCAR, Missing Completely at Random; MNAR, Missing Not at Random; RCT, Randomized Controlled Trial; VAS-A, Visual Analog Scale for Anxiety; VR, Virtual Reality; WBFPRS, Wong-Baker FACES Pain Rating Scale.

Data Sharing Statement

Data availability is not applicable as no new data was generated or analyzed in this communication.

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