INPLASY

# The Efficacy of Virtual Reality Distraction in Reducing Pain and Anxiety in Children During Venipuncture: A Meta-Analysis

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## ADMINISTRATIVE INFORMATION

**Support -** Self-raised.

**Review Stage at time of this submission -** The review has not yet started.

**Conflicts of interest -** The authors declare no conflicts of interest. No financial or personal relationships influenced this work. This review was conducted independently without external funding or support from VR-related companies. All decisions regarding study selection, data extraction, and analysis were made objectively based on the protocol.All authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this systematic review and meta-analysis.

**INPLASY registration number:** INPLASY2025120051

**Amendments -** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 December 2025 and was last updated on 26 December 2025.

## INTRODUCTION

**Review question / Objective** Primary Question: Does virtual reality (VR) distraction more effectively reduce children's procedure-related pain and (b) procedure-related anxiety during venipuncture compared to standard care or alternative control interventions?

Secondary Objectives: To explore the influence of moderating factors, including: children's age, VR interactivity level (active vs. passive), VR immersion degree (head-mounted display vs. screen-based), and type of control group.

**Rationale** Venipuncture is one of the most common procedural pain sources in pediatric healthcare, potentially causing significant pain,

anxiety, and subsequent medical fear. Traditional pain management approaches (such as local anesthesia and verbal reassurance) may have limited efficacy. Virtual Reality (VR) distraction, as an emerging non-pharmacological intervention, alleviates the perception of pain stimuli by occupying the patient's attentional resources through immersive experiences. Although several randomized controlled trials have evaluated its effectiveness, results have been inconsistent regarding effect sizes and influencing factors. Therefore, it is necessary to conduct a pre-designed, methodologically rigorous systematic review and meta-analysis to quantitatively synthesize existing evidence, providing high-level evidence to clarify the overall efficacy of VR interventions and identify key factors influencing their effectiveness, thereby guiding clinical practice and future research.

**Condition being studied** Acute procedural pain and anxiety experienced by children and adolescents during venipuncture (blood draw) procedures.

## METHODS

**Search strategy** A comprehensive retrieval strategy encompassing the following key concepts will be developed and tailored for each database:

• Population: ("Child*" OR "Pediatric*" OR "Adolescent" OR "Youth" OR "Teen*" OR "Boy" OR "Girl" OR "Minors")

• Intervention: ("Virtual Reality" OR "VR" OR "Augmented Reality" OR "Mixed Reality" OR "Head-Mounted Display" OR "Immersive")

• Context/Procedure: ("Venipuncture" OR "Phlebotomy" OR "Blood Draw" OR "Blood Sampling" OR "Intravenous Cannulation" OR "Needle*")

• Outcome: ("Pain" OR "Pain Management" OR "Analgesia" OR "Anxiety" OR "Fear" OR "Distress" OR "Stress")

• Study Design: Cochrane highly sensitive retrieval filters will be utilized to restrict to randomized controlled trials.

The search will commence from the inception date of each database, with no language restrictions. Non-English literature will be sought for translation.

**Participant or population** Inclusion criteria include:

(1) Participants: Children aged 3 to 12 years undergoing venipuncture; both genders; no significant cognitive impairments or developmental disorders that would affect their ability to understand the intervention; no history of severe allergic reactions to virtual reality equipment or software.
(2) Interventions: The experimental group received virtual reality distraction during venipuncture, utilizing commercially available VR headsets and age-appropriate VR content designed to engage and distract children.
(3) Comparator: The control group received routine care without any virtual reality distraction during venipuncture, which may include standard verbal reassurance and distraction techniques typically used in clinical settings.
(4) Outcomes: At least one of the following outcomes was reported: self-reported pain levels using a validated pain scale (e.g., Wong-Baker FACES Pain Rating Scale), anxiety levels measured by a validated anxiety scale (e.g., State-Trait Anxiety Inventory for Children), and physiological indicators of pain and anxiety (e.g., heart rate, blood pressure) during and after the procedure.
(5) Study Design: Randomized controlled trials (RCTs) with a minimum follow-up duration of immediate post-procedure assessment; studies must include blinding of outcome assessors to minimize bias.
Routine Care: Standard medical care, which may include topical anesthetic ointment, verbal explanation and reassurance, and no specific distraction measures.

2. Active Non-VR Distraction: Such as playing tablet games, using toys, listening to interactive stories, etc.

3. Passive Non-VR Distraction: Such as watching television, watching movies, listening to music, etc.

4. Other Controls: Such as using only topical anesthesia without other distractions.

**Study designs to be included** Randomized controlled trials (RCTs), including parallel-group RCTs, cluster RCTs, and crossover RCTs (only the first-stage data will be included to avoid carryover effects), will be included. Non-randomized studies, before-and-after studies, case reports, reviews, and protocols will be excluded.

**Eligibility criteria** Study Type: RCT (as described above).

• Population: Children and adolescents (≤18 years) undergoing venipuncture.

• Intervention: VR distraction.

• Control: Any of the aforementioned control interventions.

• Outcomes: At least one quantitative measure of pain or anxiety during or immediately after the procedure must be reported (using a validated scale).

• Publication Status: Published full-text articles and conference abstracts with accessible sufficient data. Articles for which full text or data cannot be obtained will be excluded.

• Language: No language restrictions for initial screening.

**Information sources** Electronic databases: PubMed/MEDLINE, EMBASE, PsycINFO, CINAHL, Web of Science Core Collection, Cochrane Central Register of Controlled Trials (CENTRAL), IEEE Xplore (for technical literature).

• Gray literature and trial registries: ClinicalTrials.gov, WHO International Clinical Trials Registry Platform (ICTRP), ProQuest Dissertations & Theses Global.

• Others: Reference lists of included studies, reference lists of relevant systematic reviews.

**Main outcome(s)** 1.Pain Intensity: Measured during or immediately after the procedure (typically within 5 minutes) using validated self-report scales (such as the Visual Analog Scale VAS, Facial Pain Scale-Revised FPS-R) or observer-report scales (such as the FLACC scale).

2. Anxiety Level: Measured prior to the procedure (anticipatory) or during/after the procedure using validated self-report scales (such as VAS-A, State-Trait Anxiety Inventory for Children STAIC) or observer-report scales.

**Additional outcome(s)** 1. Physiological indicators: Changes in heart rate, heart rate variability, and cortisol levels.

2. Operation-related indicators: Operation success rate (first-attempt success rate), total operation duration, and the degree of cooperation from the child.

3. Satisfaction/Acceptability: Satisfaction ratings of the operation by the child and/or parent.

4. Adverse events: Such as cybersickness, eye discomfort, and intervention interruptions.

**Data management** Use reference management software (such as EndNote, Zotero) to manage retrieval results and de-duplication.
• Extract data using standardized, pre-tested data extraction forms (in Microsoft Excel or similar software). The extracted content includes: research identification information, methodological characteristics, participant characteristics, intervention and control details, outcome data (means, standard deviations, sample sizes), funding sources, author conclusions, etc.

• All steps (literature screening, data extraction, bias risk assessment) are independently completed by two reviewers, with discrepancies resolved through discussion or consultation with a third reviewer.

Search Records: All database search strategies (including filters, date limits) and results (number of records identified) will be saved and archived.
Screening Process: The screening of titles/abstracts and full texts will be managed using specialized software (e.g., Covidence, Rayyan) or a shared spreadsheet. This will log all decisions (include/exclude) and reasons for exclusion at the full-text stage.
Data Extraction: A standardized, piloted electronic form will be used (e.g., in Excel or Google Sheets). It will capture study characteristics, participant details, intervention/comparator specifics, outcomes, results, and funding sources. All extracted data will be linked to the source PDF.
Quality Appraisal: Risk-of-bias assessments will be recorded using the same structured form.
Analysis Files: All statistical analysis scripts (e.g., for RevMan, Stata, R) and output files will be saved.
Storage & Backup: All data files (spreadsheets, analysis scripts, literature PDFs) will be stored on a secure, shared cloud platform (e.g., institutional OneDrive/Google Drive) with regular backups. Access will be limited to the review team.
Workflow & Versioning: A clear, documented workflow will be followed. All key documents (protocol, extraction forms) will be version-controlled. Two reviewers will independently perform screening, extraction, and quality assessment, with conflicts resolved and documented.
This structured approach minimizes errors, facilitates team collaboration, and provides a complete audit trail for the review process.

**Quality assessment / Risk of bias analysis** Use reference management software (such as EndNote, Zotero) to manage retrieval results and de-duplication.

• Extract data using standardized, pre-tested data extraction forms (in Microsoft Excel or similar software). The extracted content includes: research identification information, methodological characteristics, participant characteristics, intervention and control details, outcome data (means, standard deviations, sample sizes), funding sources, author conclusions, etc.

• All steps (literature screening, data extraction, bias risk assessment) are independently completed by two reviewers, with discrepancies resolved through discussion or consultation with a third reviewer.

**Strategy of data synthesis** For continuous outcomes (pain, anxiety scores), if the studies use the same scale, the mean difference and its 95% confidence interval are calculated; if different scales are used, the standardized mean difference is computed.

• A random-effects model is employed for meta-analysis (assuming heterogeneity of true effects across studies).

• The $I^2$ statistic and p-value of the Q test are used to assess statistical heterogeneity among studies. An $I^2 > 50\%$ is considered to indicate substantial heterogeneity.

• If the number of included studies is sufficient (typically ≥ 10), funnel plots and Egger's regression test will be used to evaluate publication bias.

**Subgroup analysis** Subgroup analyses will be conducted on the following factors to explore sources of heterogeneity: 1. Age group: Preschool children (<7 years) versus school-aged children and adolescents (≥7 years). 2. VR interactivity: Active interactive VR versus passive experiential VR. 3. VR immersion: Fully immersive (HMD) versus non/semi-immersive (screen, tablet). 4. Control type: Usual care versus active non-VR distraction versus passive non-VR distraction. 5. Pain measurement method: Self-report versus observer-report.

**Sensitivity analysis** Several sensitivity analyses will be performed to test the robustness of the review's primary findings:

1. Risk of Bias: Re-analyzing the primary outcome after excluding studies rated as having a 'high' overall risk of bias.
2. Statistical Model: Comparing results from the primary random-effects meta-analysis with those from a fixed-effect model.
3. Small-Study Effects: Assessing the potential impact of small studies by conducting a meta-analysis limited to studies with a sample size larger than the median.
4. Exclusion of Outliers: Examining whether the exclusion of any statistically outlying studies (based on forest plot inspection) substantially changes the overall effect estimate.
5. Specific Population/Intervention: Testing if the removal of studies focused on a specific, potentially influential subgroup (e.g., only adolescents, only passive VR) alters the main conclusion.

These analyses are planned a priori to verify that the conclusions are not unduly dependent on specific methodological choices or a small subset of studies. The results of all sensitivity analyses will be clearly reported.

**Language restriction** No restrictions during search; inclusion limited to English and Chinese studies during eligibility assessment.

**Country(ies) involved** China.

**Other relevant information** This systematic review will be reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. • Any potential conflicts of interest will be declared in the final article. • Anticipated timeline: The search cutoff date is December 17, 2025, and full-text writing is expected to be completed by December 31, 2025.

**Keywords** Virtual Reality; Distraction; Pain Management; Analgesia, Non-Narcotic; Anxiety; Fear; Pediatrics; Child; Adolescent; Venipuncture; Phlebotomy; Randomized Controlled Trial; Meta-Analysis.

**Dissemination plans** The research findings are planned to be disseminated through the following channels: 1. Publication of the full text in peer-reviewed international academic journals. 2. Submission of abstracts for oral/poster presentations at relevant international conferences in pediatrics, pain medicine, or nursing. 3. Distribution of a concise summary of the research results to clinical institutions and professional associations engaged in this field of study. 4. Sharing of publication links on appropriate

academic social media platforms (such as ResearchGate, LinkedIn) to enhance visibility.

## Contributions of each author

Author 1 - Yan Ling - First author drafted the manuscript, designed the study, and conducted data analysis.
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Author 2 - Xueliang Xu - Corresponding author supervised all stages, critically reviewed the manuscript, and acted as the primary contact.
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