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INPLASY

Effectiveness of Virtual Reality Distraction versus Routine Care for Reducing Pain and Anxiety in Children: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

INPLASY2025120051

doi: 10.37766/inplasy2025.12.0051

Received: 14 December 2025

Published: 14 December 2025

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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 14 December 2025.

INTRODUCTION

Review question / Objective Children often experience significant pain and anxiety during invasive medical procedures such as intravenous punctures and dental treatments, which may lead to psychological trauma and non-cooperation with treatment. Virtual Reality (VR) distraction, as an emerging non-pharmacological intervention, diverts children's attention through immersive experiences. However, the conclusions of existing randomized controlled trials regarding its effectiveness compared to conventional care (such as verbal reassurance and parental presence) are inconclusive. Therefore, this study aims to conduct a systematic review and meta-analysis to synthesize the current best evidence and clearly address the following core question: For children aged 0-18 years, is the use of VR distraction more effective than conventional care in reducing pain and anxiety during medical procedures that may cause pain or anxiety?
Specific objectives include:

1. Systematically retrieve and comparatively synthesize randomized controlled trials (RCTs) evaluating the effects of VR distraction versus conventional care on pediatric procedural pain and anxiety.

2. Quantitatively assess the overall effect size of VR intervention in reducing pain (primary outcome) and anxiety (primary outcome).

3. Explore whether the effect varies by subgroup analyses based on children's age groups, procedure types, or differences in VR devices.

4. Evaluate the overall quality of existing evidence and heterogeneity among studies.

This study will provide high-level evidence-based support for whether and how VR technology should be integrated into pediatric clinical practice.

Rationale Pain and anxiety during medical procedures (e.g., venipuncture, dental work, wound care) are highly prevalent and distressing experiences for children. Unmanaged procedural distress can lead to immediate physiological stress, non-cooperation, longer procedure times, and may contribute to the development of needle phobia or long-term healthcare-related anxiety. Current routine care strategies, such as verbal reassurance, topical anesthetics, or passive distraction (e.g., watching television), often provide suboptimal relief.

Virtual Reality (VR) distraction presents a promising, non-pharmacological alternative. By creating an immersive, interactive auditory and visual environment, VR theoretically blocks pain and anxiety pathways by consuming a significant share of the brain's attentional resources. This immersive quality may offer a more potent distraction compared to conventional methods.

In recent years, a growing number of Randomized Controlled Trials (RCTs) have investigated the efficacy of VR distraction in pediatric settings. However, findings are inconsistent. Some studies report significant reductions in self-reported pain, observed distress, and physiological markers, while others show minimal or no benefit compared to active controls. This heterogeneity may stem from variations in study populations (e.g., age groups), procedural contexts, VR hardware/software, and comparator interventions. Narrative reviews and previous meta-analyses exist, but an updated, comprehensive synthesis focusing specifically on the comparison between VR and routine care—the most relevant clinical comparison—is needed. Furthermore, many prior reviews have broad inclusion criteria or do not use the latest rigorous methodological standards (e.g., RoB 2.0 tool).

Therefore, a contemporary, high-quality systematic review and meta-analysis is warranted to integrate this evolving evidence base. This study will quantitatively synthesize data from RCTs to provide a precise estimate of the overall effect of VR distraction versus routine care on pediatric procedural pain and anxiety. By conducting planned subgroup analyses, it will also explore potential moderators of efficacy, such as child age and procedure type. The results of this synthesis will offer clinicians, healthcare administrators, and policymakers a clear, evidence-based conclusion regarding the effectiveness of VR as a tool to improve the procedural experience for children, informing clinical practice guidelines and resource allocation decisions.

Condition being studied The condition under investigation is procedural pain and anxiety in children and adolescents undergoing necessary but distressing medical interventions. This is a highly prevalent, acute condition that occurs regardless of the child's underlying diagnosis. It encompasses the subjective experience of pain and the emotional state of fear or apprehension (anxiety) before, during, and immediately after a wide range of medical procedures. Common eliciting procedures include venipuncture, intravenous cannulation, vaccinations, wound care, burn dressing changes, dental work, and injections.

From a clinical and public health perspective, unmanaged procedural distress is a significant concern. It is estimated that a majority of children experience fear of needles, and many develop anticipatory anxiety. The consequences are multifaceted:

For the child: Acute pain and anxiety activate the stress response, increasing heart rate, blood pressure, and cortisol levels. It can lead to physical resistance, longer procedure times, and first-attempt failure for needle-based procedures. More importantly, repeated negative experiences are a primary risk factor for developing needle phobia, dental phobia, and healthcare-related anxiety, which can persist into adulthood and lead to treatment avoidance.
For healthcare professionals and systems: Managing a distressed child is challenging, can compromise safety, and is time-consuming. It also contributes to occupational stress for clinicians.
Current management often relies on routine care, which varies widely and may include verbal reassurance, topical anesthetics (for needles), parental presence, or passive distraction (e.g., watching a cartoon). However, the efficacy of these methods is often limited, and pharmacological options (e.g., sedatives) carry risks of side effects and require additional monitoring.

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The pathophysiology involves the complex interplay of nociception (pain signal transmission) and psychological factors like attention and expectation. This is where Virtual Reality (VR) distraction intervenes. It is theorized to utilize the limited capacity of attentional resources. By immersing the child in an engaging, multi-sensory virtual environment, VR consumes a significant portion of their attentional "bandwidth," thereby reducing the cognitive resources available to process incoming pain signals and anxious thoughts, a concept known as the gate control theory of pain and distraction.

This systematic review studies this acute condition by synthesizing evidence on whether VR, as a non-pharmacological, attention-capturing intervention, is more effective than the current standard of routine care in mitigating its core symptoms—pain and anxiety—thereby aiming to improve the quality of pediatric healthcare delivery.

METHODS

Search strategy A comprehensive, systematic, and reproducible literature search will be conducted to identify all relevant published and unpublished studies.

1. Search Terms and Strategy Development:

The search strategy will be formulated using the PICO framework and developed by the review team in consultation with an experienced health sciences librarian. It will utilize a combination of controlled vocabulary (e.g., Medical Subject Headings [MeSH] in PubMed, Emtree in Embase) and free-text keywords. The strategy will be designed to maximize sensitivity (completeness) while maintaining acceptable specificity.

The core concepts, with examples of terms to be combined using Boolean operators (AND, OR), are:

• Population: Child*, Pediatric*, Paediatric*, Adolescent*, Infant*, Teen*

• Intervention: Virtual Reality, VR, Distraction, Immersive, Head-Mounted Display

• Outcome: Pain, Anxiety, Distress, Fear, Stress Psychological

• Study Design: Randomized Controlled Trial, RCT, Controlled Clinical Trial

A draft search strategy for PubMed/MEDLINE is presented below as an example. This strategy will be peer-reviewed using the PRESS checklist and then adapted for the specific syntax and subject headings of each of the other databases listed in the "Information sources" section.

PubMed/MEDLINE Search Strategy (Draft Example):

("Virtual Reality"[Mesh] OR "virtual reality"[tiab] OR VR[tiab]) AND
("Distraction"[Mesh] OR distract*[tiab]) AND
("Child"[Mesh] OR "Adolescent"[Mesh] OR child*[tiab] OR pediatric*[tiab] OR paediatric*[tiab] OR adoles*[tiab]) AND
("Pain"[Mesh] OR "Anxiety"[Mesh] OR pain[tiab] OR anxiety[tiab] OR distress[tiab] OR fear[tiab]) AND
("Randomized Controlled Trial"[pt] OR "Controlled Clinical Trial"[pt] OR randomized[tiab] OR randomised[tiab] OR RCT[tiab])

2. Information Sources and Search Execution:

The search will be applied to the electronic databases listed in the "Information sources" section to identify records from their inception to the present (the search will be run in the month of the protocol's submission/execution, e.g., [Date]). No language restrictions will be applied at the database searching stage to capture the global evidence.

3. Supplementary Search Methods:

To ensure literature saturation and identify grey literature, the following steps will be taken:

• Hand-searching: The reference lists of all included studies and relevant systematic reviews identified during the screening process will be manually searched for additional eligible studies.

• Citation Tracking: Forward citation searching for key included articles will be performed using Google Scholar and/or the "Cited by" feature in databases such as Web of Science and Scopus.

• Trial Registries: Clinical trial registries (ClinicalTrials.gov, WHO ICTRP) will be searched to identify completed, ongoing, or unpublished trials. Relevant trial investigators may be contacted to request results or data.

• Contact with Experts: If necessary, authors who are prominent in the field may be contacted to inquire about additional published or unpublished work.

4. Search Record Management and Reporting:

All retrieved records will be imported into the systematic review management software Covidence (or similar). Duplicates will be removed electronically and manually. The exact search date for each database, along with the number of records retrieved, will be documented. The full, final search strategies used for all databases will be provided as an appendix in the published review manuscript to ensure complete transparency and reproducibility, in line with PRISMA guidelines.

5. Language and Publication Status:

While the search itself is unrestricted, the eligibility of studies for final inclusion will be limited to those published in English or Chinese, as resources are available for full translation and critical appraisal in these languages. Both published articles and unpublished manuscripts or theses (with sufficient

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methodological detail and outcome data) will be considered for inclusion.

Participant or population The population of interest for this systematic review is children and adolescents undergoing acutely painful medical procedures.

This is specifically defined as:

Age: Individuals aged 1 to 18 years. Studies including participants outside this range will be included only if the mean age falls within the range or if data for the eligible age subgroup can be extracted separately.
Context: Participants must be undergoing a clearly defined, acutely painful diagnostic or therapeutic procedure. This includes, but is not limited to:
Needle-related procedures: Venipuncture, intravenous (IV) cannulation, vaccination, injections.
Wound care: Burn dressing changes, laceration repair, suture removal, debridement.
Other procedures: Lumbar puncture, dental procedures (e.g., restorative treatment, extractions), fracture reduction, cast removal.
Studies involving patients experiencing chronic pain, those in rehabilitation settings, or those undergoing procedures for which pain is not the primary focus (e.g., routine imaging like MRI) will be excluded. The review will consider studies conducted in various settings, including hospitals, emergency departments, clinics, and dental offices.

Intervention The intervention of interest is the use of virtual reality (VR) distraction during an acutely painful medical procedure. Eligible VR interventions must involve an immersive audiovisual experience designed to divert attention from the procedural context.

Key characteristics include:

Technology: The use of a head-mounted display (HMD), smartphone-based VR viewer (e.g., Google Cardboard), or similar immersive display technology. Studies using non-immersive screens (e.g., standard tablets or TVs) without a stereoscopic, field-of-view-filling display will be excluded.
Interactivity: The VR experience may be either interactive (e.g., a game where the user makes choices or controls elements) or passive (e.g., watching a 360-degree video). Both types are eligible.
Content: The specific VR content (e.g., game genre, virtual environment, video theme) will be recorded but will not be an exclusion criterion, provided its primary purpose is distraction.
Implementation: The intervention must be administered concurrently with the painful procedure. The timing of initiation (e.g., just before needle insertion, throughout dressing change) will be noted.
In summary, the review will adopt an inclusive, function-based definition focused on the core mechanism of immersive sensory distraction, regardless of the specific VR software or hardware brand.

Comparator The comparator in this systematic review refers to the control or alternative intervention against which the efficacy of virtual reality (VR) distraction is evaluated. Specifically, we will include studies that compare VR to:
1. Standard care: This typically involves no specific distraction technique, such as routine medical care without additional interventions, or the use of topical anesthetics alone. This comparator helps isolate the additive effect of VR beyond usual practice.
2. Usual distraction methods: These include common non-VR distractions like watching television, playing with toys, listening to music, or using mobile apps. This comparison assesses whether VR offers superior benefits over established, low-tech distraction strategies.
3. Other non-pharmacological interventions: Examples include guided imagery, breathing exercises, or hypnosis. This allows for evaluating VR's relative effectiveness within the spectrum of psychological interventions for pain management.
The choice of comparators is designed to address key clinical questions: whether VR is better than no intervention, outperforms conventional distractions, or is comparable to other evidence-based techniques. Studies with active comparators (e.g., other distractions) may provide more conservative estimates of effect size but are valuable for contextualizing VR's practical utility. We will note the specific comparator used in each study during data extraction and consider it in subgroup analyses if data permit, as the type of comparator may influence outcome variability. This approach ensures a comprehensive understanding of VR's role relative to current standards and alternatives in pediatric procedural care.

Study designs to be included This systematic review will primarily include Randomized Controlled Trials (RCTs). RCTs are considered the gold standard for evaluating the efficacy of interventions because their design, through random allocation, minimizes selection bias and maximizes the likelihood that outcome differences

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are due to the intervention itself.All identified studies employing non-RCT designs will be documented during the screening phase (e.g., recorded in a "studies excluded at full-text" list with the reason "incorrect study design") to ensure transparency in the selection process.

Eligibility criteria 1. Inclusion Criteria
• Types of Studies: Published and unpublished randomized controlled trials (RCTs) will be included. Cluster-RCTs will be included if appropriate adjustments are made in the analysis. There will be no restrictions on publication year. Only studies published in English and Chinese will be included due to translation resources.
• Types of Participants: Children and adolescents aged 0 to 18 years, undergoing any painful or anxiety-provoking medical procedure (e.g., venipuncture, intravenous cannulation, vaccination, wound care, dental procedures, burn dressing changes) in any healthcare setting (e.g., hospital, clinic, emergency department).
• Types of Interventions: The intervention group must receive Virtual Reality Distraction as the primary non-pharmacological method for managing procedural pain and/or anxiety. The VR intervention can be delivered via any device (e.g., head-mounted displays, desktop systems) and can be of any duration, provided it is administered immediately before and/or during the medical procedure.
• Types of Comparators: The control group must receive routine care or standard care, which may include no specific intervention, verbal reassurance, parental presence, watching a non-immersive video (on a tablet/TV), or other common non-VR distraction techniques (e.g., toys, books). Studies using active comparators that are not considered "routine" (e.g., pharmacological analgesia) will be excluded.
• Types of Outcome Measures:
• Primary Outcomes: (1) Self-reported or observed pain intensity measured by validated scales (e.g., Visual Analogue Scale [VAS], Faces Pain Scale-Revised [FPS-R], Wong-Baker FACES Pain Rating Scale, FLACC Scale for observational pain). (2) Self-reported or observed anxiety levels measured by validated scales (e.g., Visual Analogue Scale-Anxiety [VAS-A], Children's Fear Scale, Modified Yale Preoperative Anxiety Scale [m-YPAS]).
• Secondary Outcomes: (1) Behavioral distress (e.g., percentage of time spent crying, struggling). (2) Physiological parameters (e.g., heart rate, blood pressure, salivary cortisol levels). (3) Procedure duration. (4) Child/parent satisfaction with the procedure. (5) Any reported adverse events related to the VR intervention (e.g., cybersickness, nausea, headache).

2. Exclusion Criteria
Studies will be excluded if they meet any of the following criteria:
• Non-randomized studies, quasi-experimental studies, reviews, meta-analyses, protocols, case reports, and editorials.
• Studies where VR distraction is part of a multimodal intervention package (e.g., VR combined with nitrous oxide or hypnotherapy) and its effect cannot be isolated.
• Studies focusing on chronic pain management, post-operative pain (after the procedure is complete), or anxiety disorders not directly related to an acute medical procedure.
• Studies where the population consists primarily of adults (>18 years) or neonates in the Neonatal Intensive Care Unit (NICU) undergoing procedures, unless the data for children within the 0-18 range can be separately extracted.
• Studies where the full text is unavailable after exhaustive efforts to obtain it.
• Studies published in languages other than English or Chinese.

Information sources The following information sources will be systematically searched to identify relevant published and unpublished studies:

Electronic Databases: Core medical, psychological, and technological databases will be searched, including PubMed/MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials (CENTRAL), PsycINFO, CINAHL, IEEE Xplore, and Web of Science Core Collection.

Grey Literature: Key sources will include clinical trial registries (ClinicalTrials.gov, WHO ICTRP) to identify ongoing and completed but unpublished studies, and ProQuest Dissertations & Theses Global for doctoral theses.

Supplementary Searching: Reference lists of all included studies and relevant systematic reviews will be hand-searched (backward citation tracking). A forward citation search for key articles will be performed using Google Scholar or Web of Science.

No restrictions on publication date or status will be applied during the search. All search strategies will be documented, including the specific search terms, filters, and dates of search execution for each database, to ensure transparency and reproducibility.

Main outcome(s) The primary outcome of this review is the efficacy of VR distraction for reducing procedural pain and anxiety in children and

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adolescents (aged 1-18 years) during acutely painful medical procedures, compared to standard care or other non-pharmacological interventions.

Specifically, we will focus on:

Self-reported pain intensity, measured by validated scales such as the Visual Analogue Scale (VAS), Faces Pain Scale-Revised (FPS-R), or Numeric Rating Scale (NRS), obtained immediately post-procedure.
Self-reported anxiety, measured by validated scales such as the Children's Fear Scale or the State-Trait Anxiety Inventory for Children (STAIC), obtained before and/or after the procedure.
Observer-reported or behavioral distress, measured by validated observational tools such as the Observational Scale of Behavioral Distress (OSBD) or the FLACC scale.
These outcomes will be prioritized for data extraction and will form the core of the evidence synthesis (meta-analysis or narrative summary). The timing of measurement will be noted, with preference given to immediate post-procedural assessment.

Additional outcome(s) In addition to the primary outcomes of pain and anxiety, several secondary or additional outcomes will be considered to provide a comprehensive evaluation of VR distraction's impact. These include:

Physiological measures: Heart rate, blood pressure, cortisol levels, or other biomarkers of stress, which offer objective data complementary to self-reports.
Behavioral outcomes: Duration of crying, need for physical restraint, or observer-rated cooperation scales (e.g., the Procedure Behavior Checklist), capturing real-time reactions.
Procedure-related metrics: Total procedure time, amount of analgesic or sedative medication required, and success rate of the procedure, assessing practical clinical benefits.
Long-term effects: Post-procedural distress, memory of the procedure, or future medical avoidance behaviors, evaluated through follow-up surveys or interviews.
User experience and safety: Participant satisfaction with VR, incidence of cybersickness (e.g., nausea), and any adverse events, ensuring feasibility and acceptability.
These outcomes will be extracted where reported, and if data permit, they may be synthesized narratively or quantitatively to explore broader implications beyond immediate pain relief. This approach aligns with holistic patient-centered care and informs implementation considerations.

Data management Data management will be systematic and documented to ensure accuracy, transparency, and reproducibility.

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 The risk of bias in individual studies will be assessed using the revised Cochrane Risk of Bias tool for randomized trials (RoB 2). It evaluates bias across five domains:

Bias arising from the randomization process.
Bias due to deviations from intended interventions (performance bias).
Bias due to missing outcome data (attrition bias).
Bias in measurement of the outcome (detection bias).
Bias in selection of the reported result (reporting bias).
For each domain, a series of signaling questions will lead to a judgment of "Low," "Some concerns," or "High" risk of bias. An overall risk-of-

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bias judgment for each study will be made based on the worst judgment across all domains.

Due to the nature of the VR intervention (participants and personnel cannot be blinded), special attention will be given to the objectivity of outcome measures. For self-reported outcomes like pain, the risk of detection bias will be considered higher than for observer-reported or physiological outcomes. Two reviewers will independently assess each study, with disagreements resolved through discussion or consultation with a third reviewer.

Results will be presented in a summary table and graphically. The overall findings will be interpreted considering the aggregate risk of bias across the included studies.

Strategy of data synthesis The data synthesis strategy will involve both quantitative and qualitative methods, depending on the availability and homogeneity of the data.

For quantitative synthesis, a meta-analysis will be performed if studies are sufficiently homogeneous in terms of participants, interventions, and outcomes. We will use a random-effects model to account for clinical and methodological heterogeneity. Effect sizes will be calculated as standardized mean differences (SMDs) for continuous outcomes (e.g., pain scores) and risk ratios (RRs) for dichotomous outcomes, with 95% confidence intervals. Heterogeneity will be assessed using the I^2 statistic, with values above 50% indicating substantial heterogeneity.

If meta-analysis is not appropriate due to high heterogeneity or limited data, a narrative synthesis will be conducted. This will involve summarizing findings thematically, discussing patterns, consistencies, and discrepancies across studies.

Software such as RevMan or Stata will be used for statistical analyses. All methods will be pre-specified in the protocol to ensure transparency. We will also consider publication bias through funnel plots and Egger's test if enough studies are available. The synthesis will adhere to PRISMA guidelines for reporting.

Subgroup analysis Planned subgroup analyses aim to explore potential sources of heterogeneity and identify populations or contexts where VR distraction is most effective. Analyses are planned for the primary outcome if sufficient data (≥3 studies per subgroup) are available. The following subgroups will be investigated:

1. Participant Age: (1) Toddlers (1-3 yrs) / Preschoolers (4-7 yrs); (2) School-aged (8-12 yrs); (3) Adolescents (13-18 yrs). This tests if developmental stage moderates effectiveness.
2. VR Technology: (1) High-immersion/high-interactivity systems; (2) Low-immersion/passive VR. This examines if technological sophistication impacts outcomes.
3. Distraction Mode: (1) Interactive (active gaming); (2) Passive (observation). This explores the role of user engagement.
4. Procedure Type: (1) Needle-based procedures; (2) Wound care; (3) Dental procedures. This assesses contextual factors like procedure duration and nature of pain.
5. Pain Measure: (1) Self-report; (2) Observer-report; (3) Physiological. This evaluates consistency across different outcome assessment methods.

Subgroup differences will be tested using formal statistical tests for interaction. Results will be interpreted cautiously as observational, indicating where further targeted research is needed, rather than confirming definitive causal differences.

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.

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Other relevant information Data Management and Synthesis:
All search results will be imported into Covidence or Rayyan systematic review software for deduplication and screening. Data from included studies will be extracted independently by two reviewers using a piloted, standardized form. Discrepancies will be resolved through discussion or consultation with a third reviewer. For continuous outcomes (e.g., pain scores), we will extract means, standard deviations, and sample sizes for each group to calculate mean differences (MD) or standardized mean differences (SMD) with 95% confidence intervals (CIs). For dichotomous outcomes, we will extract event counts and sample sizes to calculate risk ratios (RR). If meta-analysis is feasible (i.e., sufficient clinically and statistically homogeneous studies), a random-effects model will be used due to anticipated variability in populations, VR interventions, and comparators. Statistical heterogeneity will be assessed using the I^2 statistic and the Chi^2 test. Narrative synthesis will be performed if meta-analysis is inappropriate.
2. Subgroup and Sensitivity Analyses:
If sufficient data exist, we plan the following subgroup analyses to explore potential sources of heterogeneity: (a) age groups (e.g., preschool, school-age, adolescents); (b) type of painful procedure (e.g., needle-based vs. wound care); (c) level of VR immersion/interactivity (e.g., passive 360° video vs. interactive game); (d) type of comparator (standard care vs. active distraction). Sensitivity analyses will be conducted to test the robustness of findings by excluding studies with high risk of bias or those employing crossover designs if their analysis is questionable.
3. Risk of Bias Assessment:
The methodological quality of each included RCT will be assessed independently by two reviewers using the revised Cochrane Risk of Bias tool for randomized trials (RoB 2). This tool evaluates bias across five domains: randomization process, deviations from intended interventions, missing outcome data, outcome measurement, and selection of the reported result. Each study will be judged as having "low," "some concerns," or "high" risk of bias. Disagreements will be resolved by consensus. The overall certainty of the evidence for each key outcome will be evaluated using the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach.
4. Reporting and Dissemination:
This review will be conducted and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 statement. The completed review will be submitted for publication in a peer-reviewed journal. Findings will also be disseminated through conference presentations and summaries for relevant clinical audiences (e.g., pediatric nurses, child life specialists, emergency physicians) to maximize practical impact.
5. Protocol Registration:
The detailed protocol for this systematic review has been registered on a publicly accessible platform prior to commencement of the screening. Any deviations from the registered protocol will be explicitly noted and justified in the final publication.

Keywords Virtual Reality Distraction, Routine Care, Pain, Anxiety, Children, Systematic Review, Meta-Analysis, Randomized Controlled Trials.

Dissemination plans The systematic review findings will be disseminated through multiple channels to ensure broad reach and impact. The primary output will be a manuscript submitted for publication in a peer-reviewed, open-access journal in the fields of pediatrics, pain management, or digital health. The study will also be presented at relevant national and international conferences (e.g., pediatric nursing, emergency medicine, or pain research conferences).
To facilitate translation into practice, a one-page policy and practice brief summarizing the key findings and recommendations will be created and distributed to clinical stakeholders, including hospital departments, pediatric nursing associations, and child life specialist networks. All dissemination materials will be based on the final, complete systematic review and will transparently report any funding sources or conflicts of interest.

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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