Systematic Reviews

PROTOCOL

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Barriers and facilitators to using procedural pain treatments in pediatric patients (under 1 year old): protocol for a mixed studies systematic review with a narrative synthesis

Chunji Yan[1†], Jiale Hu[2†], Jiamin Kang[1], Xueyan Xing[3], Shumin Tu[3*†] and Fang Zhou[1*†]

Abstract

Background The management of procedural pain in pediatric patients under 1 year old is crucial but often inadequately addressed in clinical practice. Despite proven evidence-based interventions like skin-to-skin contact, sweet solutions, and breastfeeding, their implementation remains sporadic. This systematic review aims to uncover the barriers and facilitators to adopting these interventions, leveraging the Consolidated Framework for Implementation Research (CFIR) to provide a structured analysis.

Methods This review will examine primary studies identifying barriers or facilitators to the use of procedural pain treatments in pediatric patients under 1 year old, imposing no restrictions on the publication year or language. A thorough search will cover databases such as MEDLINE (Ovid), Embase, CINAHL, PsycINFO, Web of Science, and Scopus. The Mixed Methods Appraisal Tool (MMAT) will be utilized for quality assessment. The CFIR framework will serve to categorize and analyze the identified barriers and facilitators, using narrative synthesis for data integration.

Discussion Applying the CFIR framework allows for a comprehensive and systematic review of the factors influencing the implementation of procedural pain management strategies in pediatric care. By identifying key barriers and facilitators through this lens, the review will guide the development of targeted interventions aimed at enhancing the adoption of evidence-based pain treatments. Such strategic interventions are essential for bridging the gap between research findings and clinical practice, potentially improving the effectiveness and efficiency of pain management for pediatric patients.

Systematic review registration PROSPERO CRD42022322319.

Keywords Barriers, Facilitators, Consolidated Framework for Implementation Research, Pain treatment, Procedural pain, Children, Infants

[†]Chunji Yan and Jiale Hu co-first author and has contributed equally to this work.

[†]Shumin Tu and Fang Zhou co-corresponding author and has contributed equally to this work.

*Correspondence:
Shumin Tu
1182070334@qq.com
Fang Zhou
meadow_zh@hotmail.com
Full list of author information is available at the end of the article

Introduction

The current practices of procedural pain treatment in pediatric patients are inconsistent and evolving. A 2016 systematic review found that during the first 14 days of the neonate life or admission in the unit of care, infants underwent 6832 to 42,413 invasive procedures, with an average of 7.5–17.3 per neonate per day [1]. A study in the NICU of Brazil in 2017 showed that the average newborn underwent 6.6 procedures per day and 27.9 times procedures during hospitalization. A total of 78.6% of these were invasive procedures that caused procedural pain, such as heel lance, and aspiration of the airway [2]. Published articles in recent years have shown that the incidence of procedural pain in hospitalized children is as high as 54–56% [3, 4].

Many studies have identified long-term and short-term adverse effects of pain on infants and young children. Acute pain can influence sleep and recovery in the short term [5]. Early procedural pain in infants may contribute to impaired brain development [6, 7]. The changes in the brain will make infants more sensitive to pain in future life. Early childhood pain can also develop into chronic pain [8]. Repeated pain experiences are associated with behavior and emotions in later childhood and adolescence, including increased anxiety and hyperactivity/attention deficit disorder [9].

Because of the high prevalence of procedural pain and the harm caused by pain, many studies on interventions for the management of procedural pain have been published [10, 11]. Breastfeeding, sweet solutions, and skin-to-skin care are both supported by extensive research. Two systematic reviews of sweet-tasting solutions demonstrated that oral sweet solutions could reduce pain scores and crying time in children from 1 month to 1 year old subjected to procedural pain [12, 13]. Breastfeeding has been reviewed for relief of minor procedural pain in infants and young children, such as immunizations, heel lance, and blood sampling [14, 15]. A systematic review of 25 studies has shown that skin-to-skin care, either in combination with other interventions or alone, can reduce term infants' crying time and improve oxygen saturation during programmed pain [16].

In view of the adverse effects of procedural pain, the management of procedural pain in pediatric patients should be necessary. However, in clinical settings, the implementation of effective procedural pain management is not consistent. A study from Canada found that while 60% of nurses were well-informed about interventions based on evidence, only 12% of nurses implemented them [17]. A survey of neonatal centers in grade III hospitals in Spain showed that only 39% of children were assessed for pain, and even fewer nurses used pain interventions to alleviate procedural pain [18]. A cross-sectional study in China found that of 3886 procedures, only a quarter were assessed for pain, and less than 15% received the intervention [19].

Many factors in complex healthcare systems might influence the process of translating knowledge into action. It takes a long time to translate research into practice or policy through traditional research translation pathways [20], and it is estimated that only half of all research can be translated into routine clinical practice [21]. Applying the framework of implementation science now helps us synthesize barriers and facilitators to implementation [22]. If barriers and facilitators can be synthesized under a framework before taking interventions, the gap between the knowledge and the practice will be shortened [23]. To weaken the barriers and to strengthen the facilitators in advance are conducive to knowledge transformation [24]. Interventions designed based on theoretical frameworks are more effective than direct implementation [25, 26]. Through the theoretical framework, we can systematically find out the barriers and facilitators that affect the intervention.

An integrative review of barriers and facilitators to pediatric pain management in nurses, published in 2018, included factors such as children's and parents' communication with nurses, the knowledge level of health professionals, and the work environment [27]. Barriers to pain management in preterm infants cited in a qualitative meta-ethnography of pain in preterm infants in 2022 include a lack of training and support for pain assessment and intervention in preterm infants [28]. While these reviews identified parents solely as influencers of nursing practices, the study by De Clifford-Faugère et al. underscored the critical role of parents in the management of procedural pain for preterm infants [29]. Eull et al.'s and McNair et al.'s studies similarly highlight the importance of parents as stakeholders in newborn pain management [30, 31]. Therefore, this review will include all stakeholders related to procedural pain in pediatric patients and comprehensively summarize the barriers and facilitators of procedural pain in pediatric patients.

To date, there have been no systematic reviews that synthesize barriers and facilitators to procedural pain treatments in pediatric patients under the guidance of the system framework. The promise of developing effective strategies lies in synthesizing the existing barriers and facilitators to the utilization of procedural pain treatments in pediatric patients [32–34]. Therefore, this systematic review will synthesize barriers and facilitators in the literature under the guidance of implementation science and evaluate the importance of different factors [32]. Findings from this review will help explain why some interventions are more effective than others. This will enable intervention designers to optimize

interventions by targeting the likely causal determinants of procedural pain treatments in pediatric patients.

Objective

The current review will synthesize the barriers/facilitators to procedural pain management in pediatric patients 0–3 years old and assess the relative importance of barriers and facilitators.

Methods and analysis

A mixed studies approach, which appeals to a concomitant examination of qualitative, quantitative, and mixed-methods primary studies, will address the broad purpose of the scope, understanding, and verification of knowledge grounded on all types of empirical research. A mixed studies review with a narrative synthesis is a literature review approach in which the narrative element of qualitative, quantitative, and mixed-methods studies is systematically identified, selected, appraised, and synthesized. Due to the complex and highly context-sensitive nature of interventions, a mixed studies review is particularly relevant to health science [35, 36]. A mixed studies review can provide a better understanding of a health issue than when one type of research approach is used alone. This mixed studies review will have an exploratory purpose where the qualitative component dominates [37, 38].

The protocol has been registered with the PROSPERO (International Prospective Register of Systematic Reviews) database (reference no: CRD42022322319) [39] and adheres to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol (PRISMA-P) guidance.

Study eligibility criteria

The eligibility criteria for studies in this review are adapted to the SPIDER acronym (Sample, Phenomenon of Interest, Design, Evaluation, and Research type), detailed as follows:

Sample

The sample involves direct stakeholders in evidence-based practice for managing procedural pain in pediatric patients aged 0–3 years. This includes pediatric patients aged 0–3 years, healthcare workers, parents, and other health service providers who are directly involved in the pain treatment process.

Phenomenon of interest

The focus is on the barriers/facilitators to evidence-based procedural pain management in pediatric patients, including topical anesthetics, skin-to-skin care, sweet solutions (SS), and breastfeeding (BF) [12–16, 40].

Design

Eligible studies for this review encompass a wide range of research designs, including qualitative methodologies (such as case studies, phenomenology, grounded theory, ethnography, and action research) and quantitative methodologies (including cross-sectional, case–control, cohort, quasi-experimental, and randomized controlled trials), as well as mixed-methods studies that integrate both qualitative and quantitative approaches.

Evaluation

The evaluation focuses on identifying barriers and facilitators to implementing procedural pain management strategies. Barriers are defined as any factors that hinder the implementation process, while facilitators are any factors that support or promote the implementation of pain management strategies.

Research type

The review is inclusive of all primary research studies that meet the defined criteria, regardless of whether they are qualitative, quantitative, or mixed-methods studies. This approach ensures a comprehensive understanding of the procedural pain management phenomenon in pediatric patients within the specified age range.

Search strategies

The search strategy will include database-specific controlled vocabularies, free-text words, synonyms, spelling variants, and truncation. To conduct a comprehensive search with greater sensitivity than specificity, broad search terms will be used to capture potentially eligible studies. We undertook a scoping search to develop an appropriate search strategy, and terms were agreed upon by discussions with the research team. The following electronic databases will be searched: MEDLINE (Ovid), Embase, CINAHL, PsycINFO, Web of Science, and Scopus. To capture relevant information from sources outside the peer-reviewed literature, the review will include gray literature in the search strategy. The main search strategy is listed in Additional file 1: Appendix 1.

The types of gray literature will include government or nongovernmental organization reports, research reports, conference proceedings and abstracts, and theses and dissertations. Sources of gray literature will include Google Scholar, OpenGrey, e-theses online service, ProQuest, WorldCat, Networked Digital Library of Theses and Dissertations, Open Access Theses and Dissertations, and public health organization websites. Based on

the research, we will select the top 200 references sorted by relevance for screening for a systematic review [41].

Study selection

After deleting duplicate studies, two researchers (Y. C. and K. J.) will screen all literature titles and abstracts independently to determine whether the full text needs to be retrieved. Each study will be classified as [1] non-conforming and [2] possibly conforming. We will get the full-text format of all studies which is possibly conforming. After reading the full text, two researchers (Y. C. and K. J.) will screen the papers independently according to pre-established criteria. If differences between the two cannot be resolved through discussion, then we will consult the third reviewer. We will use a flow diagram to report the study selection process which is recommended by the PRISMA guidelines.

Risk-of-bias (quality) assessment

The Mixed Methods Appraisal Tool (MMAT) will be used to assess the quality of the qualitative, quantitative, and mixed-methods studies for this review. The MMAT has been proven great content validity, and it has been piloted in all methodologies [42, 43]. If necessary, we will contact the author of the study for more information. Two researchers (Y. J. and K. J.) will evaluate the quality of all studies. If differences between the two cannot be resolved through discussion, then we will consult the third reviewer. We will not exclude any study based on quality assessment because they may provide different insights.

Data extraction

Data extraction will consist of two steps. In the first step, we will develop a form to extract each study's characteristics, including country/setting, research objective, methodological/theoretical approach (relevant to our review), data collection (relevant to our review), data analysis (relevant to our review), stakeholders (nurses, parents, physicians), and sample size. In the second step, we will extract the statements about factors affecting using procedural pain treatments in pediatric patients (under 3 years old) in qualitative studies. At the same time, we will extract statistically significant factors affecting procedural pain treatments in pediatric patients (under 3 years old) in quantitative studies. As per the narrative synthesis approach [44], code names will be based on a theoretical framework. In our study, we will use the Consolidated Framework for Implementation Research [45]. The CFIR is a research-based framework used to assess multiple contexts and identify factors that might influence the process and effectiveness of implementing a specific intervention [45]. It has been used in multiple studies to identify the perceived barriers and facilitators to using evidence-based practices [46, 47] and guide systematic reviews to synthesize implementation contextual factors [48, 49]. The five major domains are intervention characteristics, inner setting, outer setting, characteristics of individuals involved, and process [45]. Discrepancies in data extraction will be resolved through consensus.

Data synthesis

The synthesis will follow a convergent integrated approach [36, 44, 50]. In this manner, data from all types of evidence will be simultaneously extracted and synthesized into meaningful codes. The integration of these data will be guided by a narrative synthesis approach [44]. The inclusion of the CFIR in the analysis and synthesis phase is very beneficial, as integrating data using a theoretical framework improves the generality and interpretability of the findings and also allows us to conceptualize impediments and facilitators in a more structured way [51]. The extracted quantitative and qualitative data will be deductively encoded into the structure and substructure of the CFIR [52]. This approach is well suited for mixed studies systematic review that utilizes diverse types of evidence and has sample heterogeneity [53–55]. This approach allows for the use of theoretical frameworks to shape the analysis. Popay et al. identified four iterative elements to a narrative synthesis [44].

Element 1: the role of theory in evidence synthesis

We will use the CFIR that are based on theories of change. Study data will be grouped into constructs according to the CFIR domain about the characteristics of the end stakeholders [45]. In this way, theory building and theory testing can be incorporated as a key aspect of the proposed systematic review [44].

Element 2: developing a preliminary synthesis

A preliminary synthesis is conducted to understand the codes identified and summarize the results of included studies. An initial description of the findings will evolve based on similarity in meaning to produce an integrated synthesis. One tool used is grouping and clustering [44]. As per the narrative synthesis approach, we next identify the main, recurrent, and/or most important themes across the aggregated data from multiple studies. Next, we will code the quantitative studies, read the coding summary report to identify salient themes, and add the cumulative description. An outcome of this element is a summary of the salient themes across studies.

Element 3: exploring relationships within and between studies

Exploration of relationships within and between studies will highlight factors facilitating the impact of an intervention or explanations of how or why a component has a particular impact. Patterns of study characteristics and reported findings emerging from the studies will be subject to rigorous evaluation to identify factors that may explain differences in stakeholders' perspectives, revealing any facilitators and barriers to using procedural pain treatments in pediatric patients (under 3 years old). These patterns will be evaluated alongside key aspects reported in other literature. Careful attention will be paid to the heterogeneity, which is the clinical variation in outcomes of research methods, methodologies and participant characteristics, interventions, and other unknown sources across the studies, using narrative synthesis methods. Narrative methods are a valuable tool for investigating heterogeneity across primary studies, highlighting components of an intervention that may account for its success or investigating the possibility that study variation is due to theoretical variables [44].

Element 4: assessing the robustness of the synthesis

The conclusion will include a critical reflection to assess the robustness of the synthesis process. This will involve an assessment of the strength of the evidence for drawing conclusions about the stakeholder's perspectives and an assessment of the transferability of the synthesis findings to different population groups or contexts. The key to ensuring the robustness of the synthesis is the methodological quality of the included studies and the analytical methods employed to develop the narrative synthesis.

Patient and the public involvement

Patients and the public were not involved in designing, conducting, reporting, or disseminating this study.

Discussion

Evidence-based medicine plays an important role in the quality of care and safety of patients [56]. However, it often takes a long time for evidence-based evidence to be implemented in clinical practice [24]. Thus far, it is the first systematic review of barriers and facilitators to using procedural pain treatments in pediatric patients. This systematic review will allow for a more complete and comprehensive understanding of the barriers and facilitators to using procedural pain treatments in pediatric patients. This systematic review aims to amalgamate both the contributing factors and obstacles to the application of procedural pain treatments in pediatric patients. By identifying and addressing key factors for intervention, the aim is to significantly enhance the effectiveness and efficiency of evidence-based clinical practices [23, 57].

CFIR is chosen as the theoretical framework to analyze the factors affecting procedural pain management in this review because it contains rich fields and substructures and can summarize the factors more comprehensively. Using a meta-framework such as the CFIR makes it less likely that the review team will overlook important themes. The rigor of the synthesis and the reliability of coding will be strengthened because of the use of clear consensual definitions for each of the 39 CFIR constructs. CFIR has been used in a wide range of studies, and further use of the CFIR may help advance implementation science [47].

This review will use meta-synthesis to analyze qualitative and quantitative data in the included studies [58]. Meta-synthesis methodology is sensitive to the nature and traditions of qualitative research while being predicated on the systematic review process [59]. We can present the findings of the included studies as intended by the original authors accurately and reliably by using meta-synthesis.

A potential key limitation to this review is that we are relying on reported and interpreted data. Therefore, there is a potential for a "reporting bias" as the studies may present selective findings to fit the stated research question and might not fully report all the findings and data that are relevant to this inquiry. In addition, there may be unchangeable influencing factors related to demographic characteristics, which are difficult for us to improve in clinical work.

In conclusion, this mixed studies systematic review will be the first time to describe and synthesize the barriers and facilitators of evidence-based interventions in pediatric pain management, under the theoretical framework. This review findings will pave the way for more effective, evidence-based interventions in pediatric pain management, ultimately improving clinical outcomes for pediatric patients.

Abbreviations

PRISMA-P	Preferred Reporting Items for Systematic review and Meta-Analysis Protocols
PRISMA	Preferred Reporting Items for Systematic review and Meta-Analysis
CFIR	The Consolidated Framework for Implementation Research
MEDLINE	Medical Literature Analysis and Retrieval System Online
CINAHL	Cumulative Index to Nursing and Allied Health Literature

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13643-024-02713-y.

Additional file 1: Appendix 1. Search strategy for OVID.

Acknowledgements
Not applicable

Authors' contributions
All authors designed the project. YC and JH developed the search strategy. YC and KJ were responsible for searching the literature and data management preliminary. YC and JH drafted the manuscript. All authors reviewed, revised, and edited the manuscript. All authors provided feedback on the manuscript and approved the final manuscript.

Funding
This work was supported by the Jiangsu Province Phase VI 333 high-level talent training project. The contents are solely the responsibility of the authors and do not necessarily represent the official views of the Jiangsu province.

Data availability
Not applicable.

Declarations

Ethics approval and consent to participate
Not applicable.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

Author details
[1]School of Nursing, Xuzhou Medical University, No. 209 Tongshan Road, Xuzhou, Jiangsu, China. [2]Department of Nurse Anesthesia, College of Health Professions, Virginia Commonwealth University, Richmond, USA. [3]Department of Anesthesiology and Perioperative Medicine, Zhengzhou Central Hospital Affiliated to Zhengzhou University, Zhengzhou, China.

Received: 28 February 2023 Accepted: 9 November 2024
Published online: 26 November 2024

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