

Hypnotherapy for Procedural Pain and Distress in Children: A Scoping Review Protocol

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Abstract

Objective. Inadequately treated pain and distress elicited by medical procedures can put children at higher risk of acute and chronic biopsychosocial sequelae. Children can benefit from hypnotherapy, a psychologically tailored intervention, as an adjunct to pharmacological agents to address the multiple components of pain and distress. Despite providing evidence on the effectiveness and potential superiority of hypnotherapy to other psychological interventions, research on hypnotherapy for pediatric procedural pain and distress has been predominantly limited to oncology and needle procedures. Plus, there is a lack of reporting of intervention manuals, factors influencing hypnotic responding, pain unpleasantness outcomes, theoretical frameworks, adverse events, as well as barriers and facilitators to the feasibility of delivering the intervention and study procedures. The proposed review aims to map the range and nature of the evidence on hypnotherapy for procedural pain and distress in children to identify gaps in literature and areas requiring further investigation. **Methods.** This review will follow the Arksey and O'Malley (2005) methodology and incorporate additional scoping review recommendations by the Joanna Briggs Institute and Preferred Reporting Items for Systematic reviews and Meta-Analyses. Relevant studies will be identified through searching published literature databases (PubMed, Cochrane Library, PsycINFO, Embase, CINAHL, Scopus and Web of Science) and grey literature in addition to hand-searching of reference lists and key journals. Two authors will independently screen titles and abstracts of search results followed by full-texts review against eligibility criteria. **Conclusion.** Findings are anticipated to guide future research and inform the development of tailored hypnotic interventions in children.

Key words: Procedural Pain; Distress; Hypnotherapy; Children; Scoping Review

Introduction

Medical procedures are often accompanied by acute pain and distress in children. Distress refers to an individual's response to an unpleasant interior or exterior stimulus [1]. This response is multidimensional and has mainly behavioral (e.g., aggressive behavior), physiological (e.g., changes in pulse and blood pressure) and phenomenological (e.g., anxiety and fear) mechanisms. Pain can be defined as “an unpleasant sensory and emotional

experience associated with, or resembling that associated with, actual or potential tissue damage” [2]. This definition acknowledges the biological, psychological, and social factors that can influence pain [2]. Unaddressed acute pain and distress can lead to the worsening of distress symptoms [3, 4], amplified inflammation [5], delayed healing [6–8], and lack of compliance [3, 9]. These sequelae can increase the need for medications leading to higher healthcare expenses and more

medication side effects. Sustained pain can cause increased pain sensitivity, chronic pain, hyper-metabolic and hyper-inflammatory alterations, psychological disorders, sleep disruption, as well as social and schooling difficulties [5, 10, 11]. In contrast, reducing pain and distress can enhance healing as well as prevent biopsychosocial problems and their effect on families [8, 12, 13]. Treating pain is now considered a fundamental human right and not merely a treatment of a disease symptom [9].

Despite advancements in research and care, more than half of hospitalized children have been reported as not receiving adequate treatment for acute procedural pain and the majority of pediatric pain guidelines have reported the need for improved pain management [14–16]. Pharmacological agents are beneficial and widely used in treating children's procedural pain and distress. However, they are encumbered by adverse effects, high costs, potential ineffectiveness, lack of tailoring as well as ambiguity on the most effective dose and regimen to use in children [17–20]. Optimal treatment of pain and distress in children requires a multimodal approach, including tailored psychological interventions as adjuncts to pharmacological agents to enhance analgesia by addressing mental and emotional processes in addition to physical correlates of pain. A review of systematic reviews of psychological interventions indicated that hypnotherapy and distraction have the strongest evidence of efficacy for reducing pain, including procedural pain and distress [14].

Hypnotherapy is a psychological intervention that has been systematically applied for pediatric pain since 1982 [21]. Hypnotherapy can be tailored to diverse settings and participants with different needs, preferences, and cognitive levels, which can facilitate its application [22]. Several systematic reviews indicate hypnotherapy's effectiveness for children's pain during medical procedures, such as needle-related procedures and cancer treatment procedures (e.g., bone marrow aspiration and lumbar puncture) [23–26], with narrative reviews in pediatric surgery and pediatric procedural pain [27, 28]. The reviews provide evidence of the superiority of hypnotherapy to other psychological interventions and standard medical care or control conditions with medium to large effect in children and adolescents. Although research on hypnotherapy has been predominantly conducted in adults, a meta-analysis on hypnotherapy for procedural distress found larger effect sizes in children [29]. Children's higher suggestibility, imagination capacities, and motivation to learn new skills can increase their responsiveness to hypnotherapy compared with adults [30, 31]. Thus, hypnotherapy appears to be promising in alleviating procedural pain and distress in children.

Despite providing valuable insights on hypnotherapy's effectiveness, existing reviews have not provided a comprehensive evidence base in the broader context of children undergoing painful medical procedures. Reviews of

hypnotherapy's effectiveness in the broad context of pediatric procedural pain do not systematically review the evidence [27, 28]. Plus, no systematic or scoping review has investigated hypnotherapy in the broader context of pediatric procedural pain within the last 10 years as systematic reviews focused on the effectiveness of hypnotherapy in the context of pediatric oncology, omitting other medical procedures. Thus, a scoping review including more recent studies is warranted to map the evidence and guide further research on hypnotherapy.

Our preliminary searches of systematic reviews on hypnotherapy for procedural pain identified that only a few reviews reported on hypnotherapy interventions and factors that can influence hypnotic responding, such as hypnotic suggestibility, despite their importance in therapy outcomes [23, 25, 26, 28, 32]. Plus, there is a lack of reporting of hypnotherapy's effects on the affective component of pain (pain unpleasantness), adverse effects, as well as barriers and facilitators to the feasibility of delivering the intervention and study procedures. A scoping review is warranted to map the evidence on hypnotherapy including interventions, factors influencing hypnotic responding, outcomes (e.g., pain unpleasantness), adverse effects, and barriers and facilitators to the feasibility of delivery and theoretical frameworks. The following sections outline the importance of examining these areas when exploring hypnotherapy in children.

Factors Influencing Hypnotic Responding

Child-related factors that can influence hypnotic responding and subsequent outcomes were identified in current literature as hypnotic suggestibility, absorption ability, fantasy proneness/imaginative capacities, expectations, motivation, and views toward hypnotherapy [33]. Although child-related factors can make children more responsive to hypnotherapy compared with adults [30, 31], there is a lack of evidence on these factors in reviews on hypnotherapy for children's procedural pain [23–26]. Evidence is also lacking regarding social and contextual factors that can influence hypnotic responding, such as rapport with the hypnotherapist, the context in which suggestions are offered, and parental involvement [33].

Hypnotic Suggestibility

Hypnotic suggestibility is a predictor of hypnotic responding and the extent to which children may benefit from hypnotherapy [33]. Meta-analyses involving predominantly adults show the correlation between hypnotic suggestibility and pain outcomes of hypnotherapy. Significant pain reductions were linked to moderate-to-high hypnotic suggestibility and minimal benefits were linked to low suggestibility [34, 35]. Several studies in children also indicate a correlation between the level of hypnotic suggestibility and the magnitude of hypnotherapy outcomes with higher scores of hypnotic suggestibility linked to increased pain and anxiety reductions [28,

36]. Children may be hypnotizable as early as three years of age and generally demonstrate higher hypnotic suggestibility than adults [37]. However, systematic reviews reporting the effect of hypnotic suggestibility on hypnotherapy procedural pain and distress outcomes in children were predominantly conducted in pediatric oncology [23, 26]. Thus, it is important to examine screening for hypnotic suggestibility and reporting of hypnotic suggestibility's relation with hypnotherapy outcomes in a broader pediatric medical context to guide further research.

Absorption and Imaginative Capacities

Variance in hypnotic responding can be partially attributed to differences in absorption (i.e., tendency to be involved in an imaginative, affective, or ideational experience) [38] and imaginative (i.e., cognitive ability to create and experience vivid mental images) capacities [33]. Considering influencing factors of pain, it could be helpful to modulate pain perception, shift the attention away from the painful stimulus, cognitively reframe noxious sensations, and substitute distress symptoms, which could be attained through the imaginative process [39]. Although research is limited in children, early studies indicate that children's absorption and imagination vividness are correlated with hypnotic suggestibility [40–42]. These studies showed mixed results and had methodological limitations, such as the absence of control for baseline non-hypnotic suggestibility. Thus, further research is needed to investigate the role of absorption and imaginative capacities in children's hypnotic responding.

Participants' Age and Cognitive Development

Age is an indicator of children's cognitive development and an essential factor in their experience of pain and hypnotherapy outcomes [39]. Responses to hypnotherapy and the experience of pain can vary according to age due to developmental changes that occur from early childhood to late adolescence. Early studies in the 60's and 70's indicate that hypnotic suggestibility reaches a peak between seven and nine years of age, slightly declines in early adolescence and then remains constant throughout adulthood [30, 43]. Prior studies have shown increased pain intensity and unpleasantness during painful procedures in younger children, which further highlights the differences in the experience of procedural pain according to age [44, 45]. Standards for Research (StaR) in Child Health, an international initiative geared to enhance reliability and relevance of clinical trials in children, advocates the consideration of children's age in randomized controlled trials (RCTs) [46]. In addition, reviews indicate that hypnotherapy can be effective for procedural pain in children aged between two and nineteen years. Yet, there is a paucity of age-based analyses of hypnotherapy procedural pain and distress outcomes and intervention delivery by age in studies [23].

Attitude toward Hypnotherapy

Attitude toward hypnotherapy (including beliefs, perceived self-efficacy, and therapy expectations) is important in responding to hypnotherapy and thereby therapy outcomes [33, 47]. Although children can be more responsive than adults and more motivated to use hypnotherapy to be distracted away from a distressing stimulus, the distress elicited by painful procedures can affect their attitude and compliance [21, 47]. Existing systematic reviews on hypnotherapy for children's procedural pain provide minimal evidence on attitudes toward hypnotherapy [23–26].

Contextual Factors

Parental involvement including negative attitude can adversely influence children's motivation and hypnotherapy outcomes [21]. A study with 505 children aged between three and twenty years showed that parental involvement was linked to health-related issues (acute pain, anxiety, chronic pain, obesity, habit disorders, asthma, enuresis, and encopresis) due to the reduced sense of autonomy needed for the child to attain self-mastery through hypnotherapy [48]. Research on contextual and social factors that can influence hypnotic responding is lacking in systematic reviews on hypnotherapy in children undergoing painful procedures [23–26].

Adverse Effects of Hypnotherapy

Findings on adverse effects of hypnotherapy are limited in children. In a recently conducted RCT, children with acute burns reported no adverse reactions, had less pre-procedural anxiety than those in control conditions, and their parents reported satisfaction with the use of hypnotherapy during dressing changes [49]. Only one systematic review in pediatric oncology examined the occurrence of adverse events with hypnotherapy for procedural pain [23], while other reviews only mentioned the absence of risks in discussion sections [50]. None of the reviews reported on the rate, duration, timing, or severity of adverse events nor factors that contribute to their occurrence (e.g., participants' existing psychiatric disorders).

Pain Unpleasantness

According to a recent systematic review and meta-analysis, hypnotherapy can be effective for treating both pain unpleasantness and intensity [35]. Neurophysiologic studies in adults show that hypnotherapy can reduce pain perception through modulating both the sensory (intensity) and the affective (unpleasantness) components of pain mainly via activating the anterior cingulate cortex [51, 52]. However, reviews examining hypnotherapy for acute procedural pain and distress in children have mainly investigated effects on pain intensity, and no review has examined pain unpleasantness outcomes [25, 27, 28, 49]. Thus, the proposed review will examine pain

unpleasantness as a potentially important outcome that may have previously been overlooked.

Hypnotherapy Interventions

A hypnotherapy intervention involves a pre-hypnosis interview for building rapport followed by a hypnotic session consisting of induction and hypnotic suggestions before emergence from hypnosis [53]. According to guidelines, a treatment manual should be provided to establish a complex intervention as empirically supported [54]. The use of a manual is essential to enhance the fidelity of delivering interventions and to assist researchers in delivering treatment procedures credibly and reliably. Our preliminary searches identified that, since the year 2000, the use of treatment manuals was reported in only one published comprehensive review on hypnotherapy for pediatric procedural pain [28]. An updated review of evidence is essential to add to the body of knowledge on hypnotherapy interventions, including describing their components and assessing the fidelity of their delivery.

Barriers and Facilitators

Elements that can influence the feasibility of delivering an intervention and study procedures include participants' and clinicians' attitudes, the context in which the delivery occurs, and the method of delivery (provider of the intervention) [55]. Potential barriers may be present in the acute medical context, such as the distressing nature of the setting, limited pre-procedural preparatory time, possible interruptions and distractions, and clinicians' attitudes (i.e., mixed opinions and negative attitudes toward hypnotherapy) [22, 38]. Distress elicited by medical procedures may adversely affect children's pain outcomes and attitude [47]. In turn, children's attitude may affect their compliance or willingness to undergo hypnotherapy and thereby the delivery of the intervention [33, 47, 56]. Parental distress and attitude have also been reported to affect children's compliance and thus the feasibility of delivering the intervention [57]. Surveys in adults indicate a lack of patient education and misconceptions about hypnosis [22]. However, data on parental attitudes is limited in acute pediatric medical settings. The assessment of feasibility factors is essential to allow the evaluation of the quality of implementation and to guide the design and planning of future studies [22].

Research Aims and Objectives

The objectives of the review are to map current evidence on hypnotherapy for procedural pain and distress in children, including:

- Perceived and actual factors that influence hypnotic responding (e.g., participants' age and cognitive development, hypnotic suggestibility, and social and contextual factors).
- Primary and secondary outcomes of hypnotherapy (e.g., acute pain unpleasantness and intensity) and their assessment methods.

- Adverse events in the hypnotherapy group that can be attributed to the intervention.
- The hypnotherapy intervention components and treatment gaps (e.g., intervention reporting, availability of treatment manual, and treatment fidelity measures).
- The use of theoretical frameworks to guide the study design; reporting of interventions or barriers and facilitators; and data collection, analysis, interpretation, and dissemination.
- Barriers and facilitators to the feasibility of delivering the intervention and study procedures.

Methods

This protocol follows the recommendations of Arksey, O'Malley [58] and Joanna Briggs Institute (JBI) [59], Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P), [60] and PRISMA for Scoping Reviews (PRISMA-ScR) [61] ([Supplementary Data](#)). The PRISMA-ScR [61] and JBI [59] guidelines will be used for charting and reporting results. The proposed review will be conducted using the following steps: identifying research questions; identifying relevant studies; selecting studies; charting the data; collating, summarizing, and reporting results. Population, Concept, and Context (PCC) elements will be used to guide the scoping review (e.g., inclusion criteria, review questions, charting of data) [59].

Stage 1: Identifying Research Questions

After conducting an initial review of the literature on hypnotherapy for procedural pain and distress in children, the following research questions were identified:

1. What are the factors that influence hypnotic responding (perceived and actual), and is the impact of these factors on hypnotherapy outcomes reported (e.g., is the impact of participants' age and hypnotic suggestibility on hypnotic responding and outcomes reported)?
2. What outcome measures are used to assess the efficacy or effectiveness of hypnotherapy (e.g., acute procedural pain intensity and unpleasantness) and how (e.g., using which assessment tools)?
3. Is the safety of the intervention assessed (are adverse events in the hypnotherapy group that could be attributed to the intervention reported)?
4. What are the components of hypnotherapy interventions that have been delivered and how were these interventions delivered (e.g., via treatment manual to guide the delivery of interventions as assessed by fidelity measures, in person, or using information communication technology from a distance)?
5. What theoretical frameworks are used to design studies, report interventions or barriers and facilitators, or to guide the collection, analysis, and interpretation of data and dissemination of results?
6. What are the barriers and facilitators to the feasibility of delivering hypnotherapy?

Stage 2: Identifying Relevant Studies

Search Strategy

As a first step, an initial limited search was conducted in three relevant online databases (PubMed, Embase, and Google Scholar) using variations of hypnosis/hypnotherapy, child, and pain and distress terms. The search was accompanied by an analysis of the keywords used as index terms and included in the abstracts and the titles of the found articles to identify primary research terms. To identify relevant studies, a comprehensive search strategy will be used, including both published and unpublished (grey) literature on hypnotherapy for children's procedural pain and distress. The search will be conducted using the identified keywords and index terms in the proposed health-focused databases: PubMed, Cochrane Library, PsycINFO, Embase, CINAHL, Scopus, and Web of Science for published literature; ClinicalTrials.gov, The Australian New Zealand Clinical Trials Registry (ANZCTR), MedRxiv, BioRxiv, Open Science Framework, Open Grey for grey literature; the American Psychological Association website (apa.org) will also be searched. [Supplementary Data](#) provides an example of the search conducted for PubMed.

Further Searching. To locate additional citations, further searches will be conducted by searching references of included papers identified through database searching and hand-searching of key journals on hypnotherapy such as the International Journal of Experimental and Clinical Hypnosis [58]. If required, authors of relevant studies or reviews will be approached for [supplementary information](#).

Eligibility Criteria

Study Participants, Concept and Context. The eligibility criteria of the scoping review are based on PCC elements as shown in [Table 1](#) [59]. Participants aged from four to sixteen years will be included in the scoping review to inform a feasibility study involving participants with this age range based on previous studies investigating hypnotherapy with this population.

Sources and Types of Evidence. Studies will be included only if they are published in peer-reviewed journals or in grey literature, which is likely to capture studies with negative results and those that may not have been published. For broader research capture, no language restriction will be used for abstract and title screening. Empirical studies with multiple participants will be included irrespective of design (i.e., RCTs, cohort, cross-sectional, pilot, quasi-experimental, and qualitative studies); case reports and case studies will be excluded. Review articles inclusive of systematic reviews, meta-analysis, and scoping reviews will be included; non-systematic literature reviews will be excluded.

Stage 3: Study Selection

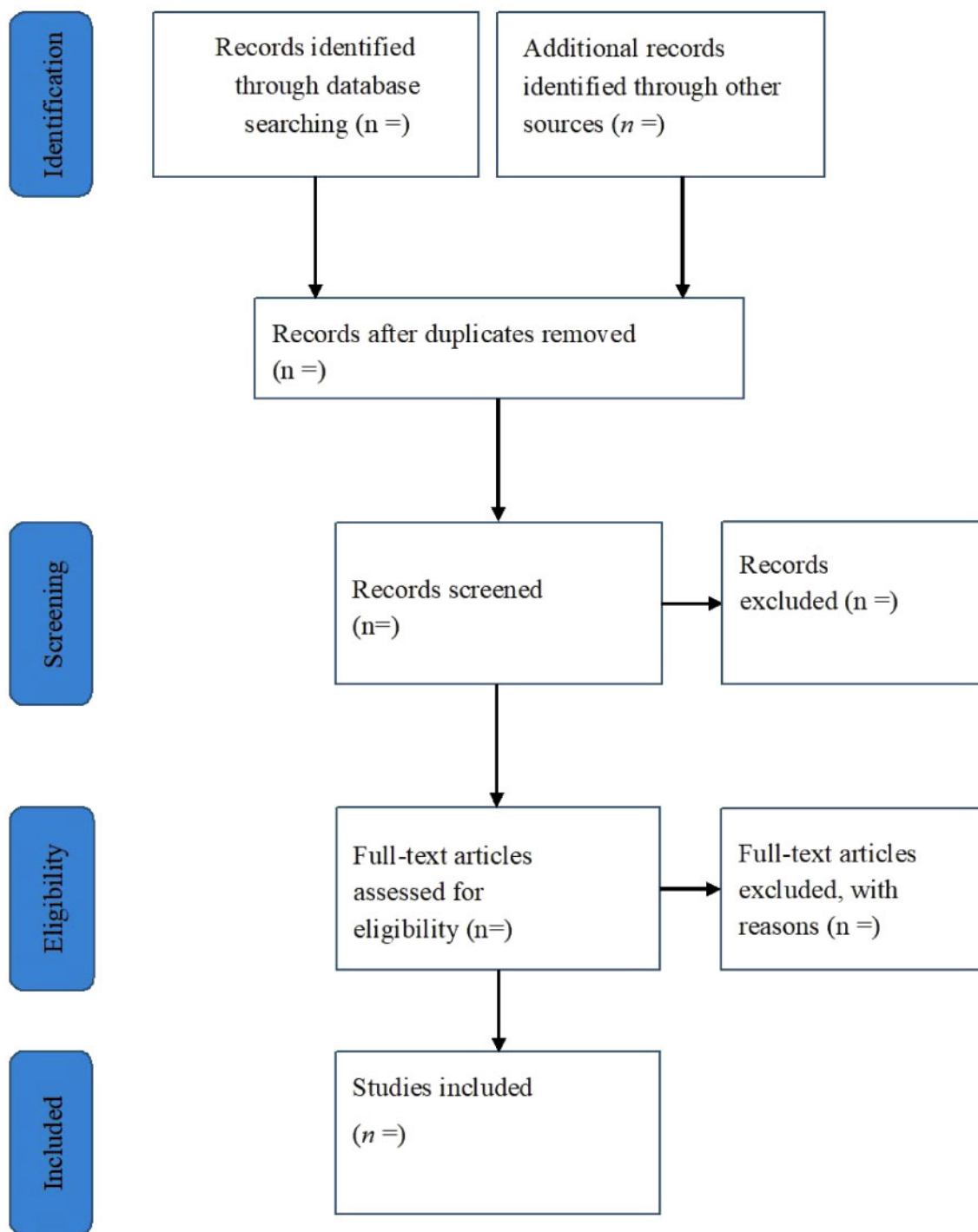
After documenting search strategies, references will be collected and sent to the EndnoteX9 referencing software (Clarivate Analytics, Philadelphia, PA, USA), where a precise database group will be used, and then duplicates will be eliminated. The number of search results and removed duplicates will be recorded. Following the database search and duplicate removal, search results will be sent to Covidence software for transparent data management during the study selection process [62]. Two reviewers will independently screen titles and abstracts using predetermined inclusion and exclusion criteria to identify relevant studies for full-text screening. A study will be selected for full-text review or excluded if both reviewers agree. If the initial screening of abstracts and titles is inconclusive, or in the absence of agreement on inclusion/exclusion of the study, the study will be selected for full-text review where a final decision will be made. The number of included and excluded studies through title and abstract screening will be recorded. Full-text articles that are not available in English, French, German, Italian, Spanish, or Arabic will be excluded if the translation to any of these languages is not possible. In the absence of access to the article, the corresponding author will be contacted to provide access. If the full-text article is not found, the abstract will be used to extract relevant information if it contains sufficient information to be able to assess the paper's eligibility and extract data. The full text of selected studies will be screened for eligibility by two independent reviewers using Covidence software [62]. In the case of disagreement on the selection of a study, a third reviewer will discuss the eligibility of the study in question until reaching an agreement. A PRISMA flow diagram ([Figure 1](#)) will be provided to explain the selection process and flow of papers included and excluded in the review at each stage [63].

Stage 4: Charting the Data

A data-charting form has been developed by the authors to record and extract study characteristics and variables relevant to the review question ([Supplementary Data](#)). Two reviewers will extract at least 20% of the results independently to provide a logical and descriptive summary. The remainder of the data will be extracted by a single reviewer and checked by a second reviewer. The authors' descriptions of interventions will be reported following the Template for Intervention Description and Replication (TIDieR) framework as shown in [Supplementary Data](#) [54]. Barriers and facilitators to the delivery of interventions and study procedures will be mapped to the integrated Promoting Action on Research Implementation in Health Services (i-PARIHS) framework as shown in [Supplementary Data](#) [55]. The extraction process will be iterative; thus, the draft table may be updated and refined during the conduct of the scoping

Table 1. Eligibility criteria mapped to the Population, Concept and Context (PCC) mnemonic

PCC Element	Determinant
Population	Children and adolescents (four to 16 years) undergoing painful procedures and their parent proxies
Concept	Hypnotherapy for procedural pain and distress
Context	Any clinical setting where hypnotherapy is used during painful medical procedures

**Figure 1.** Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram for the scoping review process.

review [59]. Many of the data items to be charted have been previously tested by the authors in systematic reviews of other interventions used in pediatric burns or have been based on the authors' experience in conducting studies on hypnotherapy. Authors of studies included in the review may be contacted to obtain or confirm information (i.e., by contacting the first or last authors of studies by e-mail).

Stage 5: Collating, Summarizing, and Reporting Results

Following the aims, research questions, and scope of the review, quantitative and qualitative data charted from the selected studies will be summarized and presented in a table accompanied by a narrative summary in text. The table will include conceptual categories related to the selected sources of information as in the charting table, such as date of publication, location, study design, study setting, theoretical framework, factors influencing hypnotic responding, intervention components, main findings, and adverse events (Supplementary Data). Quantitative data will be mapped and presented in the table through numerical counts of information based on the PCC elements (e.g., total number of studies with same demographics, country of publication, types of interventions, outcome measures and findings) [59, 61]. Qualitative data will be synthesized and transformed into quantitative counts presented in the table and/or presented as a qualitative narrative summary accompanying the presented findings to describe how the data relates to the research questions and identify gaps that may need further investigation. If unforeseen [supplementary information](#) is charted in the scoping review, the charting table used in the review protocol will be adjusted to include more categories and chart headings will be updated accordingly.

Patient and Public Involvement

Patients or the public were not directly involved in the development of the study. The authors' previous experience with children undergoing medical procedures was used in the development of the scoping review protocol and will be used throughout the review process, including results, analysis, and dissemination.

Discussion

To our knowledge, there is no published synthesis of the literature on hypnotherapy for procedural pain and distress using scoping review methodology. The proposed scoping review is intended to map the extent of evidence on hypnotherapy interventions for paediatric procedural pain and distress, as well as identify critical areas in need of examination and research gaps that can be addressed in future research. The outcomes of the review will be discussed in relation to the proposed questions and

objectives. Among the limitations of the review is examining factors influencing hypnotic responding without other factors related to pain and distress that may influence outcomes. Reviewing factors of pain and distress is beyond the scope of the current review but could be addressed in future reviews.

The scoping review will be initiated in November 2020 and is expected to be completed by March 2021.

Conclusion

The proposed scoping review is part of a larger research project with the ultimate goal of examining the use of hypnotherapy (including suggestibility screening) for procedural pain and distress in children. The findings of the review are anticipated to inform hypnotherapists, researchers, and health providers about research that has already been conducted and guide future research. We believe that the review will provide valuable background information that can be relevant in the development and evaluation of tailored hypnotic interventions to improve the treatment of children's procedural pain and distress in the future.

Ethics and Dissemination

No datasets have been produced in this protocol. The proposed scoping review does not require ethical approval, as it will include information from publicly available sources. The results of the proposed review will be summarized and disseminated in a scientific journal and presented at conference proceedings. Patient consent for publication is not required.

Authors' Contributions

All authors contributed toward the study design. DG drafted the manuscript. Critical review and editing of the final manuscript draft were done by all authors. The final version of this manuscript was read and approved by all the authors.

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Supplementary Data

[Supplementary data](#) are available at *Pain Medicine* online.

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