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

Short Title: Hypnotherapy to alleviate paediatric procedural pain

Authors:

Dr Daly Geagea, PharmD
Centre for Children's Burns and Trauma Research
The University of Queensland
Brisbane, Australia

Dr Zephanie Tyack, PhD
Centre for Children's Burns and Trauma Research
The University of Queensland
Brisbane, Australia

© The Author(s) 2021. Published by Oxford University Press on behalf of the American Academy of Pain Medicine. This is an Open Access article distributed under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs licence (http://creativecommons.org/licenses/by-nc-nd/4.0/), which permits non-commercial reproduction and distribution of the work, in any medium, provided the original work is not altered or transformed in any way, and that the work is properly cited. For commercial re-use, please contact journals.permissions@oup.com
Professor Roy Kimble, MD, PhD
Centre for Children's Burns and Trauma Research
Queensland Children's Hospital
The University of Queensland
Brisbane, Australia

Lars Eriksson, BA
Herston Health Sciences Library
The University of Queensland
Brisbane, Australia

Dr Vince Polito, PhD
Department of Cognitive Science
Macquarie University
Sydney, Australia
Dr Bronwyn Griffin, PhD

Centre for Children's Burns and Trauma Research

Queensland University of Technology

Brisbane, Australia

Correspondence to:

Dr Daly Geagea, PharmD

Postal Address: Centre for Children's Health Research, Level 7, 62 Graham Street, South Brisbane, QLD, Australia, 4101

Email: d.geagea@uq.net.au

Phone: + 61 7 30697428

Disclosures

Acknowledgements

We would like to thank Dr Devin Terhune for his helpful comments.
Competing Interests

The authors have declared no competing interests.

Funding Statement

The proposed research received no specific grant from any funding agency in public, commercial or not-for-profit sectors. The research will be conducted at no cost except for the time of the authors.

Authors' Contributions

All authors contributed towards 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.
Abstract

Objective
Inadequately treated pain and distress elicited by medical procedures can put children at higher risks of acute and chronic biopsychosocial sequelae. Children can benefit from hypnotherapy, a psychological 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 paediatric 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.

**Keywords**

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 and exterior stimulus [1]. This response is multidimensional and has mainly behavioural (e.g., aggressive behaviour), 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 medications' 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 hospitalised children have been reported as not receiving adequate treatment for acute procedural pain and the majority of paediatric 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 paediatric 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 paediatric surgery and paediatric 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 in comparison to 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 paediatric procedural pain do not systematically review the evidence [27,28]. Plus, no systematic or scoping review has investigated hypnotherapy in the broader context of paediatric procedural pain within the last 10 years as systematic reviews focused on the effectiveness of hypnotherapy in the context of paediatric 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, 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 towards hypnotherapy [33]. Although child-related factors can make children more responsive to hypnotherapy in comparison to 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 hypnotisable 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 paediatric 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 paediatric 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, 41, 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 60s and 70s 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 randomised 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 Towards Hypnotherapy

Attitude towards 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 attitude towards 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 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 paediatric 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 paediatric 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 towards 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.

Official Journal of the American Academy of Pain Medicine
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 paediatric 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, 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] (online supplementary file 1). The PRISMA for Scoping Reviews (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, summarising 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, 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, 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) and the American Psychological Association website (apa.org) will also be searched. Online supplementary file 2 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 databases 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 Error! Reference source not found. [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 these 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 is 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 (online supplementary file 3). Two reviewers will extract at least 20 percent 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 online supplementary file 3 [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 online supplementary file 3 [55]. The extraction process will be iterative; thus, the draft table may be updated and refined during the conduct of the scoping 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 paediatric 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 email).

**Stage 5: Collating, Summarising and Reporting Results**
Following the aims, research questions and scope of the review, quantitative and qualitative data charted from the selected studies will be summarised 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 (online supplementary file 3). 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 synthesised 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 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 February 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 summarised and disseminated in a scientific journal and presented at conference proceedings. Patient consent for publication is not required.
References


doi:10.1016/j.burns.2013.09.027


doi:10.1001/archpedi.152.2.147


doi:10.1097/00004583-200108000-00013


doi:10.1097/TA.0b013e3182ab111c


**Word count (excluding title page, abstract, references, disclosure statements):** 3911

**Figure 1 legend:** *Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)* flow diagram for the scoping review process
Table 1. Eligibility criteria mapped to the Population, Concept and Context (PCC) mnemonic

<table>
<thead>
<tr>
<th>PCC element</th>
<th>Determinant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population</td>
<td>Children and adolescents (4 to 16 years) undergoing painful procedures and their parent proxies</td>
</tr>
<tr>
<td>Concept</td>
<td>Hypnotherapy for procedural pain and distress</td>
</tr>
<tr>
<td>Context</td>
<td>Any clinical setting where hypnotherapy is used during painful medical procedures</td>
</tr>
</tbody>
</table>
**Supplementary File 1**

Table displaying the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist

<table>
<thead>
<tr>
<th>Section</th>
<th>#</th>
<th>Checklist item</th>
<th>Information reported</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TITLE</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identification</td>
<td>1</td>
<td>Identify the report as a scoping review</td>
<td>x</td>
</tr>
<tr>
<td><strong>ABSTRACT</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Structured summary</td>
<td>2</td>
<td>Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.</td>
<td>x</td>
</tr>
<tr>
<td><strong>INTRODUCTION</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rationale</td>
<td>3</td>
<td>Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.</td>
<td>x</td>
</tr>
<tr>
<td>Objectives</td>
<td>4</td>
<td>Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.</td>
<td>x</td>
</tr>
<tr>
<td><strong>METHODS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protocol and registration</td>
<td>5</td>
<td>Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.</td>
<td>x</td>
</tr>
<tr>
<td>Eligibility criteria</td>
<td>6</td>
<td>Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a</td>
<td>x</td>
</tr>
<tr>
<td>Task</td>
<td>Number</td>
<td>Description</td>
<td>Complete?</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>--------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-----------</td>
</tr>
<tr>
<td>Information sources*</td>
<td>7</td>
<td>Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.</td>
<td>x</td>
</tr>
<tr>
<td>Search</td>
<td>8</td>
<td>Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.</td>
<td>x</td>
</tr>
<tr>
<td>Selection of sources of evidence**</td>
<td>9</td>
<td>State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.</td>
<td>x</td>
</tr>
<tr>
<td>Data charting Process†</td>
<td>10</td>
<td>Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.</td>
<td>x</td>
</tr>
<tr>
<td>Data items</td>
<td>11</td>
<td>List and define all variables for which data were sought and any assumptions and simplifications made.</td>
<td>x</td>
</tr>
<tr>
<td>Critical appraisal of individual sources of evidence‡</td>
<td>12</td>
<td>If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).</td>
<td>x</td>
</tr>
<tr>
<td>Synthesis of results</td>
<td>13</td>
<td>Describe the methods of handling and summarizing the data that were charted.</td>
<td>x</td>
</tr>
<tr>
<td>RESULTS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Selection of sources of evidence</td>
<td>14</td>
<td>Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.</td>
<td>x</td>
</tr>
<tr>
<td>Characteristic of sources of evidence</td>
<td>15</td>
<td>For each source of evidence, present characteristics for which data were charted and provide the citations.</td>
<td>x</td>
</tr>
<tr>
<td>Critical appraisal within sources of evidence</td>
<td>16</td>
<td>If done, present data on critical appraisal of included sources of evidence (see item 12).</td>
<td>x</td>
</tr>
<tr>
<td>Results of individual sources of evidence</td>
<td>17</td>
<td>For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.</td>
<td>x</td>
</tr>
<tr>
<td>Synthesis of results</td>
<td>18</td>
<td>Summarize and/or present the charting results as they relate to the review questions and objectives.</td>
<td>x</td>
</tr>
</tbody>
</table>

**DISCUSSION**

| Summary of evidence | 19 | Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups. | x |
| Limitations | 20 | Discuss the limitations of the scoping review process. | x |
| Conclusions | 21 | Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps. | x |

**FUNDING**

| Funding | 22 | Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review. | x |

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.

* Where sources of evidence (see the second footnote) are compiled from, such as bibliographic databases, social media platforms and Web sites.

** A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with information sources (see the first footnote).

†The frameworks by Arksey and O’Malley and Levac and colleagues and the JBI guidance refer to the process of data extraction in a scoping review as data charting.

‡The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of “risk of bias” (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g.,
quantitative and/or qualitative research, expert opinion, and policy document).


**References**


Official Journal of the American Academy of Pain Medicine
## Supplementary File 2

PubMed keyword search terms

<table>
<thead>
<tr>
<th>Key concept</th>
<th>Keywords searched</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AND</td>
</tr>
<tr>
<td></td>
<td>AND</td>
</tr>
</tbody>
</table>
## Draft data charting fields

<table>
<thead>
<tr>
<th>Data item</th>
<th>Description/components</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DOCUMENT DETAILS</strong></td>
<td></td>
</tr>
<tr>
<td>Document type</td>
<td>Include published or unpublished primary research, e.g., reviews, experimental study.</td>
</tr>
<tr>
<td>Author(s)</td>
<td>List of all the authors of the document</td>
</tr>
<tr>
<td>Title</td>
<td>Title of the document</td>
</tr>
<tr>
<td>Journal</td>
<td>Title of the journal (for published documents)</td>
</tr>
<tr>
<td>Year of publication</td>
<td>Year of publication</td>
</tr>
<tr>
<td>Country of origin</td>
<td>The country where the study was published or conducted</td>
</tr>
<tr>
<td><strong>STUDY CHARACTERISTICS</strong></td>
<td></td>
</tr>
<tr>
<td>Study design</td>
<td>The type of the study as reported in the paper (e.g., randomised controlled trials, quasi-experimental, cohort, cross-sectional, pilot and qualitative studies)</td>
</tr>
<tr>
<td>Methodological framework</td>
<td>Theoretical framework guiding the study conduct such as data collection, analysis and synthesis of data (e.g., qualitative, quantitative or mixed methods); reporting of the intervention and choice of outcome measurements.</td>
</tr>
<tr>
<td>Context or setting</td>
<td>The physical setting is open to clinical settings involving painful medical procedures in which the intervention is provided and research is conducted (e.g., outpatient clinics and inpatient wards). The setting may include one or more of these settings.</td>
</tr>
<tr>
<td>Aims/objectives</td>
<td>Summary of the aims and objectives of the document</td>
</tr>
<tr>
<td>Study population</td>
<td>Sample size</td>
</tr>
<tr>
<td>Participants' age</td>
<td>Participants' age</td>
</tr>
<tr>
<td>------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>Demographic data</td>
<td>Demographic data</td>
</tr>
</tbody>
</table>

**METHODOLOGY**

<table>
<thead>
<tr>
<th>Intervention Descriptors [1]</th>
<th>Name of the intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rationale and goals</td>
<td></td>
</tr>
<tr>
<td>Materials (e.g., treatment manual) and procedures</td>
<td></td>
</tr>
<tr>
<td>Delivery mode</td>
<td></td>
</tr>
<tr>
<td>Provider of the intervention</td>
<td></td>
</tr>
<tr>
<td>Duration of the intervention and frequency</td>
<td></td>
</tr>
<tr>
<td>Tailoring</td>
<td></td>
</tr>
<tr>
<td>Modifications</td>
<td></td>
</tr>
<tr>
<td>Assessment of the fidelity of delivery</td>
<td>Yes □ No □</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Comparator(s)</th>
<th>Type of comparator</th>
</tr>
</thead>
</table>

**Outcome measures**

<table>
<thead>
<tr>
<th>Primary outcomes</th>
<th>Outcome measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measurement method</td>
<td></td>
</tr>
<tr>
<td>Measurement time-point</td>
<td></td>
</tr>
<tr>
<td>Assessor</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Secondary outcomes</th>
<th>Outcome measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measurement method</td>
<td></td>
</tr>
<tr>
<td>Measurement time-point</td>
<td></td>
</tr>
<tr>
<td>FINDINGS</td>
<td>Rate</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>------</td>
</tr>
<tr>
<td>Adverse events in the intervention group</td>
<td></td>
</tr>
</tbody>
</table>

**Primary Findings**

**Secondary Findings**

Factors: Barriers and facilitators to the delivery of the intervention and study procedures [2]

<table>
<thead>
<tr>
<th>Related to the context</th>
<th>Related to participants</th>
<th>Related to clinicians</th>
<th>Related to the facilitator</th>
</tr>
</thead>
</table>

Factors linked to hypnotic responses

<table>
<thead>
<tr>
<th>Hypnotic suggestibility screening</th>
<th>Assessment</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessment tool</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reporting on the relation with study outcomes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contextual factors</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attitude towards hypnotherapy</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
References
