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ADMINISTRATIVE INFORMATION**Support** - York Research Chair Research Grant to Senior Author (Rebecca Pillai Riddell, York University).**Review Stage at time of this submission** - Formal screening of search results against eligibility criteria.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202470099**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 July 2024 and was last updated on 11 June 2025.**INTRODUCTION**

Review question / Objective The primary goal is to examine the effectiveness of skin-to-skin contact for acute pain in very and extremely preterm infants (gestational age < 32 weeks, 6 days). The secondary goal of this review is to elicit from these articles any features of the skin-to-skin contact intervention or infant or parent associated with greater effectiveness (i.e. infant: gestational age, age at study, sex of infant, pain history, days in NICU, type of acute pain stimulus applied to infant; parent: duration of skin-to-skin prior to lance, type of caregiver, average age of parent, emotional state of parent, delivery method; intervention: duration of skin-to-skin contact prior to painful procedure).

Rationale In a 2023 call to action released by the World Health Organization, experts advocated for a fundamental re-organization of NICU care to accommodate 100% of preterm infants receiving

skin-to-skin care (NICU infant held at least 8 hours of skin-to-skin with parent a day) due to its positive impact on preterm outcomes. Distinct from skin-to-skin care is the recommended practice of skin-to-skin contact for acutely painful procedures. This is where an infant wearing only a diaper is held upright on the caregiver's bare chest, providing maximal skin-to-skin contact between the baby and parent during acutely painful procedures (e.g., heel lance, vaccine needle).

A cursory review of the literature focused on very and extremely preterm infants (i.e., <32 weeks) demonstrated that of 14 trials found, less than half showed efficacy. Very and extremely preterm infants face more painful procedures over longer hospitalizations. Very and extremely preterm infants are also less physiologically stable than older preterm infants, parents are less able to do general skin-to-skin care in the period following birth due to infant physiological instability, and there is a higher prevalence of infant support devices that make skin-to-skin contact for acute

pain more challenging (e.g., ventilation and feeding support equipment). Thus, the effectiveness of skin-to-skin contact for painful procedures in very and extremely preterm infants must be systematically examined. The aim of the present study is to conduct a meta-analysis to examine the effectiveness of skin-to-skin contact for acute pain in the youngest of preterm infants (<32 weeks 6 days) as well as identify potential variables that may impact the effectiveness of skin-to-skin contact.

Condition being studied Painful procedures and acute pain in the youngest of premature infants.

METHODS

Search strategy In collaboration with a hospital librarian, a search strategy was created. The MEDLINE, Embase, CINAHL, Cochrane, and APA PsycInfo databases were searched for terms related to skin-to-skin/kangaroo care, pain, and premature infants.

Participant or population The youngest of preterm infants (gestational age < 32 weeks, 6 days) experiencing procedural pain or other acute pain.

Intervention Skin-to-skin care (also known as Kangaroo care).

Comparator Standard care, sucrose, other pain management intervention (e.g., music therapy, swaddling, etc.).

Study designs to be included Observational studies and randomized controlled trials.

Eligibility criteria Exclusion criteria: 1) non-human studies; 2) review papers, book chapters, commentaries, case studies, conference proceedings; 3) mean participant gestational age > 32 week, 6 days; 4) no skin-to-skin intervention; 5) no acute pain; 6) no infant pain measure.

Information sources MEDLINE, Embase, CINAHL, Cochrane, and APA PsycInfo databases.

Main outcome(s) Four outcomes will be meta-analyzed: Premature Infant Pain Profile, heart rate, oxygen saturation, and cry duration. These outcomes will be examined across four time points: Baseline (pre-procedure), During the procedure, Immediate-after (within the first two minutes after the painful procedure has been completed), and Distal-after (longer than two

minutes after the painful procedure has been completed).

Data management Abstracts, full-text extraction and risk of bias will be managed using the COVIDENCE software package.

Quality assessment / Risk of bias analysis Risk of bias will be assessed using the Cochrane tool for assessing risk of bias.

Strategy of data synthesis A meta-analysis will be performed to examine effectiveness of the skin-to-skin intervention used compared to standard care control and compared to interventions using sweet-tasting solutions.

When quantitative analysis is not possible, a narrative strategy will be taken.

Subgroup analysis We will attempt to conduct a subgroup analysis based on post-menstrual age at time of study. Groupings will be based on an analysis of age distribution of included articles.

Sensitivity analysis Sensitivity analysis will be performed to assess the contribution of each study by excluding one study at a time to observe their impact on the meta-analysis.

Country(ies) involved Canada.

Keywords Preterm infant, acute pain, procedural pain, skin-to-skin, systematic review, meta-analysis.

Dissemination plans We plan to publish in an open access, peer-reviewed journal.

Contributions of each author

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