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Paediatric intensive care unit (PICU) trials: a scoping review protocol

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Corresponding author:
Kristen Gibbons

k.gibbons@uq.edu.au

Author Affiliation:
Children's Intensive Care Research Program, Faculty of Health, Medicine, and Behavioural Sciences, The University of Queensland.

Gibbons, KS; Gilholm, P; Le Marsney, R; McNally, D; O'Hearn, K.

ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2025100087

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 October 2025 and was last updated on 24 October 2025.

INTRODUCTION

Review question / Objective The objective of this scoping review is to identify all randomised controlled trials (RCTs) within the field of paediatric critical care published since July 2023, adding to an existing database of paediatric intensive care unit (PICU) trials from inception (1986) to June 2023.

Background While randomised controlled trials are important in all areas of paediatrics, they are particularly important in paediatric critical care as death and chronic lifelong morbidity are well established consequences of critical illness in children. Comparing and quantifying the relative benefits and risks of different approaches to diagnosis and management is essential for patients, their families and the health care system.

A database of all PICU trials from inception was established in 2013 (1). This database has been updated regularly from 2013 to the end of June 2023 (2, 3), based on rigorous methodology for searching, screening and including trials that meet well defined eligibility criteria. Review strategies have evolved over time to incorporate advancements to recommendations for search terms as well as technologies to facilitate screening.

References:
1) Duffett M, Choong K, Hartling L, Menon K, Thabane L, Cook DJ. Randomized controlled trials in pediatric critical care: a scoping review. Critical care. 2013 Oct 29;17(5):R256
2) Gilholm P, Ergetu E, Gelbart B, Raman S, Festa M, Schlapbach LJ, Long D, Gibbons KS. Adaptive clinical trials in pediatric critical care: a systematic review. Pediatric Critical Care Medicine. 2023 Sep 1;24(9):738-49

3) Schlapbach LJ, Ramnarayan P, Gibbons KS, Morrow BM, Napolitano N, Tume LN, Argent AC, Deep A, Lee JH, Peters MJ, Agus MS. Building global collaborative research networks in paediatric critical care: a roadmap. The Lancet Child & Adolescent Health. 2025 Feb 1;9(2):138-50.

Rationale An ongoing effort to update and maintain this database of PICU trials is required to capture evidence that is clinically relevant, methodologically robust, and in alignment with evolving priorities for PICU patients, families, and health care providers. Expanding the database of PICU trials will also increase the inclusion of more diverse populations and settings, ensuring greater equity in evidence synthesis.

METHODS

Strategy of data synthesis MEDLINE (Ovid), EMBASE, LILACS and CENTRAL will be searched from 1st July 2023. The below search terms and filters will be used for each database:

MEDLINE (ovid)
1. Exp intensive care units/ or ((critical$ or intensive) adj2 (care or ill$)).mp. or (picu or icu or pccu).mp.
2. (child$ or adolescen$ or infan$ or pediatric$ or paediatric$).mp.
3. (exp randomized controlled trial/ OR controlled clinical trial.pt. OR randomized.ab. OR randomised.ab. OR placebo.ab. OR drug therapy.fs. OR randomly.ab. OR trial.ab. OR groups.ab. NOT (exp animals/ not humans.sh.))
4. 1 AND 2 AND 3
5. (neonat$ or newborn or NICU or "low birth$" or VLBW or LBW or birthweight or preterm or "pre-term" or prematur$).ti.
6. 4 NOT 5
7. (202307* or 202308* or 202309* or 202310* or 202311* or 202312* or 2024* or 2025*).dt.
8. ("2023" or "2024" or "2025").yr.
9. 6 AND 7 AND 8

EMBASE
1. 'intensive care unit'/exp OR 'intensive care'/exp OR ((critical* OR intensive) NEAR/2 (care OR ill*)):ti,ab,oa,tt,de,kw,ok,aid,ii,uiOR ((picu OR icu OR pccu)):ti,ab,oa,tt,de,kw,ok,aid,ii,ui
2. (child* OR adolescen* OR infan* OR pediatric* OR paediatric*):ti,ab,oa,tt,de,kw,ok,aid,ii,ui
3. ('randomized controlled trial'/de OR 'controlled clinical trial'/de OR random*:ti,ab,tt OR 'randomization'/de OR 'intermethod comparison'/de OR 'crossover procedure'/de OR 'double-blind procedure'/de OR 'single-blind procedure'/de OR (random* OR factorial* OR crossover* OR cross NEXT/1 over* OR placebo* OR doubl* NEAR/1 blind* OR singl* NEAR/1 blind* OR assign* OR allocat* OR volunteer*):ab,ti NOT (('animal experiment'/de OR animal/exp) NOT ('human experiment'/de OR 'human'/exp)))
4. #1 AND #2 AND #3
5. (neonat* OR newborn OR NICU OR 'low birth*' OR VLBW OR LBW OR birthweight OR preterm OR 'pre-term' OR prematur*):ti
6. #4 NOT #5
7. [01-07-2023]/sd
8. [2023-2025]/py
9. #6 AND #7 AND #8

CENTRAL
1. [mh "intensive care units"] OR ((critical* OR intensive) NEAR/2 (care OR ill*)) OR (picu OR icu OR pccu)
2. (child* OR adolescen* OR infan* OR pediatric* OR paediatric*)
3. #1 AND #2
4. (neonat*:ti OR newborn:ti OR NICU:ti OR ("low" NEXT birth*):ti OR VLBW:ti OR LBW:ti OR birthweight:ti OR preterm:ti OR "pre-term":ti OR prematur*:ti)
5. #3 NOT #4
6. Filter for added to CENTRAL from 01/07/2023
7. Filter for publication year from 2023 to 2025

LILACS
1. mh:("Intensive Care Units") OR ("Cuidados Críticos" OR "Cuidados Intensivos" OR "Intensive care" OR "Critical care" OR "critically ill" OR "critical illness" OR PICU OR "UTI pediatrica" OR "Unidade de Terapia Intensiva")
2. Child OR adolescent* OR adolescence OR infan* OR pediatric* or paediatric* OR Pré-Escolar* OR Niño* OR Criança* OR Infant* OR Lactante*
3. 1 AND 2 [search under title, abstract subject]
4. Filter for publication year from 2023 to 2025
5. Filter for type of study: controlled clinical trial.

Eligibility criteria Inclusion criteria:
• Eligible population - Trial includes children admitted to a paediatric intensive care unit (PICU) or paediatric critical care unit (PCCU) or a specialised centre including burn, trauma, and/or cardiovascular intensive care or critical care units, or families of PICU patients. The trial may also include other populations (e.g., adults, emergency department) as long as children admitted to an intensive or critical care unit are also included. The intervention could be delivered to the PICU patients and/or family of PICU patients and outcomes measured in the patient and/or family.
• Eligible Study Design - Randomised controlled trial (may also be called a randomised clinical trial),

quasi-randomised trial or individual patient/cluster cross-over trial.
• Eligible Study Setting - We will consider a unit to be an intensive or critical care unit if the authors described it as such, or if likely to be a pediatric intensive or critical care unit, even if not explicitly stated (e.g. if it had the capacity to provide mechanical ventilation for long periods).
• Eligible Language - We will accept articles in any language.

Exclusion Criteria:
• Ineligible Population - We will exclude studies that exclusively enrolled adult patients. Neonatal Intensive Care Unit (NICU) trials are not considered pediatric ICU, therefore studies that exclusively enrolled patients admitted to a NICU will also be excluded.
• Ineligible Study Design - All study designs other than RCTs will be excluded. Examples of study designs that are excluded include observational studies, retrospective studies, database studies, systematic or scoping reviews, meta-analyses, commentaries, editorials, survey studies.
• Ineligible Study Setting - Study does not include any children admitted to an intensive or critical care unit.
• Ineligible Intervention/comparators - No part of the intervention, control, and/or placebo occurs while patients are admitted to an intensive or critical care unit.
• Ineligible Study Article - Studies that present a secondary analysis or substudy of an RCT will be excluded. Study protocols (i.e. no results reported) will be excluded. However, we will flag these studies during screening and verify whether the trial has been published. Conference abstracts and retracted articles will be excluded.

Source of evidence screening and selection Seach results from the four databases will be uploaded to InsightScope. A machine learning (ML) algorithm will be used to semiautomate citation screening at the title and abstract stage, which is consistent with previously described approaches (4, 5, 6). The ML algorithm ranks each citation by relevance based on the eligibility criteria, project overview, and example true positive citations, with the highest-ranking citations being retained based upon a threshold of 70% (i.e., a threshold of 70% retains the 30% highest-ranking citations). Two reviewers will independently screen the title and abstracts of the highest-ranking citations against the eligibility criteria in InsightScope and any conflicts will be resolved by a third reviewer or through team discussion. The title and abstracts of citations meeting a ML algorithm threshold of 30-70% will be screened independently by one reviewer only, and those meeting a threshold of ≤30% will have machine review only. For eligible title and abstracts, the full text article will then be reviewed independently by two reviewers and any conflicts resolved by a third reviewer or through team discussion. Reasons for exclusion of studies at title and abstract and full text screening that do not meet the eligibility criteria will be recorded.

References:
4) Zorko D, McNally JD, Rochwerg B, Pinto N, Couban R, O'Hearn K, Choong K. Pediatric chronic critical illness: Protocol for a scoping review. JMIR Research Protocols. 2021 Oct 1;10(10):e30582.
5) Hay RE, O'Hearn K, Zorko DJ, Lee LA, Mooney S, McQuaid C, Albrecht L, Henshall DE, Dannenberg VC, Flamenghi V, Thibault C, Lee WK, Shi Min Ko M, Cree M, St Louis J, Heneghan JA, Leung KKY, Wood A, López-Barón E, Temsah MH, Almazyad M, Retallack J, Reddy M, Aldairi N, Palomino REL, Choong K, Du Pont-Thibodeau G, Ducharme-Crevier L, Tsampalieros A, Hayawi L, McNally JDM, Garcia Guerra G. Systematic Review and Meta-Analysis of Prevalence and Population-Level Factors Contributing to Posttraumatic Stress Disorder in Pediatric Intensive Care Survivors. Pediatr Crit Care Med. 2025 Apr 1;26(4):e531-e543.
6) Hay RE, Zorko DJ, O'Hearn K, McQuaid C, Thibodeau GDP, Garcia Guerra G, Olivier J, Ducharme-Crevier L, Lee L, Del Bel MJ, Choong K, McNally JD. Child and Family Outcomes After PICU Admission: Creation of an Open Access Literature Database Using a Global Team of PICU Specialists Integrated With Machine Learning. Pediatr Crit Care Med. 2025 Aug 1;26(8):e1017-e1023.

Data management We will import search results into EndNote (Clarivate, Chandler, AZ) where duplicates will be removed. All remaining studies will be imported into InsightScope for review. Data on trial characteristics from included trials will be extracted in InsightScope using a data extraction template designed for the review. Data will be extracted and recorded by one reviewer, checked by a second reviewer, and disagreements resolved by a third reviewer.

Reporting results / Analysis of the evidence Trial characteristics for included studies will be summarised using descriptive statistics. Continuous data will be summarized as medians (interquartile range (IQR), and binary data as count (percent).

Presentation of the results Search results will be presented using the Preferred Reporting Items for

Systematic Review and Meta-Analysis (PRISMA) flow diagram. Descriptive results of trial characteristics will be presented in tables and figures.

Language restriction None.

Country(ies) involved Australia, Canada, India, Switzerland.

Other relevant information None

Keywords clinical trial, critical care, pediatric, intensive care, scoping review.

Dissemination plans The results of this scoping review will be disseminated through intensive care networks, published in peer-reviewed journals and presented at national and international critical care conferences. The PICU trials database will also be hosted on an accessible web-based platform.

Contributions of each author

Author 1 - Patricia Gilholm - Study design, review of articles, data synthesis, manuscript preparation.
Email: p.gilholm@uq.edu.au
Author 2 - Renate Le Marsney - Study design, review of articles, data synthesis, manuscript preparation.
Email: r.lemarsney@uq.edu.au
Author 3 - Dayre McNally - Study design, review of articles, manuscript preparation.
Email: dmcnally@cheo.on.ca
Author 4 - Katie O'Hearn - Study design, review of articles, manuscript preparation.
Email: kohearn@cheo.on.ca