

Effectiveness of ear protectors in maintaining physiological stability in hospitalized preterm newborns: systematic review protocol

Eficácia do protetor auricular na estabilidade fisiológica de recém-nascidos prematuros hospitalizados: protocolo de revisão sistemática

Eficacia de protectores auditivos en la estabilidad fisiológica de los recién nacidos prematuros hospitalizados: protocolo de revisión sistemática

 Luana Trindade dos Santos Mascarenhas¹

 Paloma Santos Machado Silva²

 Max Douglas de Jesus Carmo³

 Adriele Almeida Santos de Jesus⁴

 Beatriz Ferreira Santos Oliveira⁵

 Andreia Cristina Feitosa do Carmo⁶

 Maria Cristina de Camargo⁷

 Luciano Marques dos Santos⁸

^{1,2,3,4,5,7,8}State University of Feira de Santana. Feira de Santana (BA), Brazil.

⁶Federal University of Sao Paulo. São Paulo (SP), Brazil.

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Corresponding Author

Name: Luana Trindade dos Santos Mascarenhas

E-mail: luatrindade25@gmail.com

ABSTRACT

Objective: to develop a systematic review protocol addressing the effectiveness of ear protectors in maintaining physiological stability in hospitalized preterm newborns (PTNBs) admitted to Neonatal Intensive Care Units (NICUs), compared to standard care. **Method:** systematic review protocol guided by the methodology recommended by the Joanna Briggs Institute (JBI) and the 2020 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA-2020). This protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO) under registration number CRD42023409081. Studies indexed in PubMed, Embase, LILACS, Scopus, CINAHL, and Web of Science will be selected using controlled descriptors. Reference management will be conducted using Rayyan software. The JBI evidence quality checklists will be applied to assess the included studies. **Results:** the systematic review is currently in progress. Data will be summarized in tables according to the defined methodology. **Conclusion:** this protocol aims to guide the systematic review process and synthesize evidence regarding the use and effectiveness of ear protectors in reducing noise exposure in NICU environments.

Keywords: *Infant; Premature; Intensive care units; Neonatal; Noise; Physiology; Ear protective devices.*

RESUMO

Objetivo: construir um protocolo de revisão sistemática relacionada à eficácia do uso de protetores auriculares na estabilidade fisiológica de recém-nascidos prematuros (RNPT) hospitalizados em Unidade de Terapia Intensiva Neonatal (UTIN), quando comparado ao cuidado habitual. **Método:** protocolo de revisão sistemática, orientado conforme a metodologia recomendada pelo Joanna Briggs Institute (JBI) e Preferred Reporting Items for Systematic Reviews and Meta-Analyses 2020 (PRISMA-2020). Este protocolo foi registrado na International Prospective Register of Systematic Reviews (PROSPERO) sob o número CRD42023409081. Serão selecionadas pesquisas indexadas no PubMed, Embase, LILACS, Scopus, CINAHL e Web of Science utilizando os descritores controlados. Será utilizado o software Rayyan para o gerenciamento de referências. Foram utilizadas listas das qualidades das evidências para avaliar os estudos, segundo o JBI. **Resultados:** esta revisão sistemática está em desenvolvimento. Os dados serão apresentados em quadros-resumo, de acordo com a metodologia descrita. **Conclusão:** espera-se que este protocolo possa conduzir a construção da revisão sistemática e sintetizar evidências sobre o uso e eficácia dos protetores auriculares na redução dos ruídos em ambiente de UTIN.

Descritores: *Recém-nascido prematuro; Unidades de terapia intensiva neonatal; Ruído; Fisiologia; Dispositivos de proteção das orelhas.*

RESUMEN

Objetivo: construir un protocolo de revisión sistemática relacionado con la eficacia del uso de orejeras en la estabilidad fisiológica de los recién nacidos prematuros (RNPT) hospitalizados en la Unidad de Cuidados Intensivos Neonatales (UCIN), en comparación con los cuidados habituales.

Método: protocolo de revisión sistemática, orientado según la metodología recomendada por el Joanna Briggs Institute (JBI) y Preferred Reporting Items for Systematic Reviews and Meta-Analyses 2020 (PRISMA-2020). Este protocolo ha sido registrado en Prospective Register of Systematic Reviews (PROSPERO) con el número CRD42023409081. Las búsquedas indexadas en PubMed, Embase, LILACS, Scopus, CINAHL y Web of Science se seleccionarán utilizando los descriptores controlados. Se utilizará el software Rayyan para gestionar las referencias. Para evaluar los estudios se utilizaron listas de las cualidades de la evidencia, según el JBI. **Resultados:** esta revisión sistemática está en desarrollo. Los datos se presentarán en tablas resumen según la metodología descrita. **Conclusión:** se espera que este protocolo conduzca a la construcción de la revisión sistemática y sintetice la evidencia sobre el uso y la efectividad de los protectores auditivos para reducir el ruido en el entorno de la UCIN.

Descriptores: *Recién nacido prematuro; Unidades de cuidado intensivo neonatal; Ruido; Fisiología; Dispositivos de protección auditiva.*

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Introduction

Prematurity is defined as birth occurring before the thirty-seventh gestational week¹ with an estimated 30 million preterm births annually, constituting a global public health concern.²

Due to early delivery, preterm newborns (PTNBs) present delayed organ and system maturation, which may lead to metabolic imbalances, systemic dysfunctions, and infections. Given their clinical characteristics and the complexity of required care, specialized support is essential, making NICU admission indispensable.³

The clinical condition and physiological immaturity of preterm infants expose them to various harmful and stressful stimuli in NICU environments, particularly high-intensity sounds.⁴ The American Academy of Pediatrics recommends a maximum noise level of 45 dB.⁵ However, studies report significantly higher levels,⁶⁻⁷ with NICU noise reaching more than twice the recommended threshold during daytime and nearly triple at night.⁷

Excessive noise may trigger apnea, hypoxemia, fluctuations in oxygen saturation, and increased oxygen consumption due to elevated heart and respiratory rates, ultimately reducing available caloric energy for growth.⁴ Elevated sound levels also disrupt sleep cycles⁸ and may delay proper auditory cortex development in hospitalized PTNBs.⁹

Some studies show that exposure to loud noise alters sleep–wake states in PTNBs, and sudden peaks during rest periods may hinder development. Conversely, during quieter periods, total sleep time increases.¹⁰

Primary noise sources include routine team activities: shift changes,⁷ staff conversations^{7,11} near incubators¹¹ leading to continuous or intermittent sound elevation,⁷ operation of life-support equipment, furniture handling,⁷ open incubator access ports, water flow from ventilators, and device alarms.¹¹

This indicates that, even inside incubators, sound levels remain high.^{6,9,12-13} Consequently, prolonged NICU stays contribute to adverse auditory outcomes in developing preterm infants.

Given the constant exposure to elevated sound and its harmful impact on neonatal health, using ear protectors may help mitigate auditory damage in NICU settings. A national study showed that ear protectors increased active sleep duration, essential for neurosensory development. Brazilian researchers recommend these devices.¹⁴

However, a small high-quality trial comparing silicone earplugs to no protection in 34 PTNBs reported insufficient evidence for clinical recommendations due to limited sample size, highlighting the need for larger, well-designed trials.⁴ The effectiveness of ear protectors in reducing physiological impacts remains unclear.

After this review, new trials have been published, but their findings have yet to be synthesized to determine the protective effect of ear protectors on preterm auditory health, justifying the need for systematic reviews.

A preliminary search in the Cochrane Library, JBI, and PROSPERO databases revealed no protocols aimed at evaluating the effectiveness of ear protectors in PTNBs.

Thus, this review aims to develop a systematic review protocol focused on assessing whether ear protectors help maintain physiological stability in hospitalized PTNBs compared to standard NICU care.

Method

Type of study

This protocol outlines a systematic review focused on evaluating the effectiveness of ear protectors, following the methodology recommended by the Joanna Briggs Institute¹⁵ and the 2020 Preferred Reporting Items for Systematic Reviews and Meta-Analyses checklist.¹⁶ The protocol is registered in PROSPERO under the number CRD42023409081. The review seeks to answer the following question: Are ear protectors effective in maintaining physiological stability in hospitalized preterm newborns in NICUs compared to standard care?

Information sources

Eligible studies will be selected from the following electronic databases: National Library of Medicine and National Institutes of Health (PUBMED), Cumulative Index to Nursing and Allied Health Literature (CINAHL), *Literatura Latino-Americana e do Caribe em Ciências da Saúde* (LILACS), Embase, Web of Science and Scopus.

Search strategies will be tailored to each database to maximize retrieval of relevant studies. Reference lists from included articles and previous reviews will also be screened.

Research strategy

Initial search strategies were developed based on the unique features of each database, with assistance from a librarian specialized in literature reviews. Controlled vocabulary terms were identified using Medical Subject Headings (MeSH), Health Sciences Descriptors (DeCS), and Embase Subject Headings (Emtree). Preliminary searches in each database helped identify the most commonly used keywords and descriptors related to the review topic, which were included in the construction of the research strategies.

Different combinations of keywords and controlled terms were created, using the Boolean operators AND and OR. Table 1 presents the complete search syntaxes used for each database.

Table 1 - Research strategy and database. Feira de Santana (BA), Brazil, 2024.

DATA SOURCES	STRATEGY
PUBMED	("premature*" [All Fields] OR ("infant, newborn" [MeSH Terms] OR ("infant" [All Fields] AND "newborn" [All Fields]) OR "newborn infant" [All Fields] OR "newborn" [All Fields] OR "newborns" [All Fields] OR "newborn s" [All Fields]) OR "preterm*" [All Fields] OR ("baby s" [All Fields] OR "babys" [All Fields] OR "infant" [MeSH Terms] OR "infant" [All Fields] OR "babies" [All Fields]) OR ("infant, newborn" [MeSH Terms] OR ("infant" [All Fields] AND "newborn" [All Fields]) OR "newborn infant" [All Fields] OR "baby" [All Fields] OR "infant" [MeSH Terms] OR "infant" [All Fields]) OR ("infant, newborn" [MeSH Terms] OR ("infant" [All Fields] AND "newborn" [All Fields]) OR "newborn infant" [All Fields] OR "neonatal" [All Fields] OR "neonate" [All Fields] OR "neonates" [All Fields] OR "neonatality" [All Fields] OR "neonats" [All Fields] OR "neonate s" [All Fields]) OR ("infant, newborn" [MeSH Terms] OR ("infant" [All Fields] AND "newborn" [All Fields]) OR "newborn infant" [All Fields] OR "neonatal" [All Fields] OR "neonate" [All Fields] OR "neonates" [All Fields] OR "neonatality" [All Fields] OR "neonats" [All Fields] OR "neonate s" [All Fields])) AND ("ear protective devices" [MeSH Terms] OR ("ear" [All Fields] AND "protective" [All Fields] AND "devices" [All Fields]) OR "ear protective devices" [All Fields] OR ("ear" [All Fields] AND "protective" [All Fields] AND "device" [All Fields]) OR "ear protective device" [All Fields])
CINAHL	(MH "premature"* OR newborn OR infant OR baby OR babies OR neonat*) AND (MH "ear protective device" OR "devices, hearing protective" OR "ear occluder" OR "ear protecting device" OR "ear protection device" OR "ear protective device" OR "ear protective devices" OR "ear protector" OR "hearing protecting device" OR "hearing protection" OR "hearing protective device" OR "hearing protective devices" OR "hearing protector")
LILACS	(premature* OR newborn OR infant OR baby OR babies OR neonat*) ("ear protective device" OR "devices, hearing protective" OR "ear occluder" OR "ear protecting device" OR "ear protection device" OR "ear protective device" OR "ear protective devices" OR "ear protector" OR "hearing protecting device" OR "hearing protection" OR "hearing protective device" OR "hearing protective devices" OR "hearing protector") AND (db:("LILACS"))
Embase	('prematurity'/exp OR 'extremely premature infant' OR 'infant, extremely premature' OR 'infant, premature' OR 'infant, premature, diseases' OR

'neonate, premature' OR 'pre-mature infant' OR 'pre-term baby' OR 'pre-term child' OR 'pre-term infant' OR 'pre-term neonate' OR 'pre-term newborn' OR 'premature' OR 'premature baby' OR 'premature birth' OR 'premature child' OR 'premature childbirth' OR 'premature infant' OR 'premature infant disease' OR 'premature infant diseases' OR 'premature neonate' OR 'premature newborn' OR 'premature syndrome' OR 'prematuritas' OR 'prematurity' OR 'preterm baby' OR 'preterm child' OR 'preterm infant' OR 'preterm neonate' OR 'preterm newborn' OR 'newborn'/exp OR 'animals, newborn' OR 'child, newborn' OR 'full term infant' OR 'human neonate' OR 'human newborn' OR 'infant, newborn' OR 'neonatal animal' OR 'neonate' OR 'neonate animal' OR 'neonatus' OR 'newborn' OR 'newborn animal' OR 'newborn animals' OR 'newborn baby' OR 'newborn child' OR 'newborn infant' OR 'newly born animal' OR 'newly born baby' OR 'newly born child' OR 'newly born infant' OR 'infant'/exp OR 'infant') AND ('ear protective device'/exp OR 'device, ear protective' OR 'device, hearing protective' OR 'devices, ear protective' OR 'devices, hearing protective' OR 'ear occluder' OR 'ear protecting device' OR 'ear protection device' OR 'ear protective device' OR 'ear protective devices' OR 'ear protector' OR 'hearing protecting device' OR 'hearing protection' OR 'hearing protective device' OR 'hearing protective devices' OR 'hearing protector')

Scopus and Web of Science

(premature* OR newborn OR infant OR baby OR babies OR neonat*) AND ("ear protective device" OR "devices, hearing protective" OR "ear occluder" OR "ear protecting device" OR "ear protection device" OR "ear protective device" OR "ear protective devices" OR "ear protector" OR "hearing protecting device" OR "hearing protection" OR "hearing protective device" OR "hearing protective devices" OR "hearing protector")

Eligibility Criteria

This review will include original analytical studies, particularly randomized clinical trials, regardless of publication date or language. Editorials, letters to the editor, pilot studies, and meta-analyses addressing the effectiveness of any ear protector will be excluded. Only studies available in full text will be considered. Reference lists from retrieved articles and previous reviews will also be screened.

The PICO framework (Population, Intervention, Comparison, Outcome) was used to formulate the review question and guide data collection and extraction.

Eligible studies must involve PTNBs with gestational age between 24 and 36 weeks and 6 days, admitted to NICUs. Infants must be breathing room air, without continuous sedatives or vasoactive drugs, and placed in incubators, radiant warmers, or open cribs. Studies involving PTNBs who underwent surgical procedures will be excluded.

Any type of ear protector will be accepted as an intervention. Studies involving multifaceted interventions will be excluded to prevent bias in determining which component contributed most to stability. Likewise, studies combining thermal blankets or pain-reducing interventions with ear protection will be excluded, due to their potential influence on physiological outcomes.

Control groups may include any standard care approach, such as continuous NICU noise exposure, environmental sound management, incubator cover use, or the absence of protective devices over the ears. Any of these approaches will be referred to in this review as standard care. Studies using thermal blankets alongside standard care will be excluded.

Eligible studies must evaluate ear protector effectiveness in maintaining physiological stability in PTNBs, measured by vital signs such as respiratory rate, heart rate, body temperature, blood pressure, and oxygen saturation. Studies using inadequate hypothesis testing methods for group comparisons, regardless of binary or continuous outcomes, will be excluded.

Results

Study selection

References retrieved through the search strategies will be imported into Rayyan software,¹⁷ which will be used to identify duplicates and facilitate the screening of titles, abstracts, and full texts.

Two independent reviewers trained in systematic review methodology will initially assess duplicates. Their findings will then be compared to confirm accurate exclusion of ineligible references.

Next, the reviewers will evaluate the remaining studies in two phases. In the first phase, titles and abstracts will be screened. In the second, full texts will be assessed for inclusion based on the eligibility criteria. Any disagreements during the selection process will be resolved through discussion with a third reviewer to reach consensus.

The number of studies selected, included, and excluded, along with reasons for exclusion and ineligibility, will be documented in a flowchart aligned with PRISMA 2020 recommendations.

Data extraction

Following full-text review in Rayyan Software,¹⁷ two independent reviewers will extract data from eligible studies. Extracted information will include publication details (title,

authors, journal, year, country, publication language, and objective), methodological characteristics (study design, setting, eligibility criteria, sample, intervention and control, implementation procedures, and outcomes), key results, and study limitations.

This process will support structured organization and synthesis of findings, in accordance with JBI methodology,¹⁵ using adapted tables to ensure a high-quality systematic review. If discrepancies arise between extracted data, they will be discussed among the review team to reach agreement.

Risk of bias assessment

To evaluate the reliability, relevance, and results of the included studies, the JBI checklists for randomized controlled trials and quasi-experimental studies will be applied.¹⁸

Methodological quality assessment

The JBI Critical Appraisal Checklist for Randomized Controlled Trials and the JBI Checklist for Quasi-Experimental Studies will be used to assess methodological quality.¹⁸

Data synthesis

Data will be analyzed quantitatively. Clinical heterogeneity, including differences in sample characteristics, interventions, evaluation timing, and outcome measures, along with methodological heterogeneity related to bias risk, will be reported in the synthesis.

Quantitative outcomes will be analyzed using mean differences and corresponding 95 percent confidence intervals. Dichotomous variables will be assessed using relative risk, with estimates of risk increase or reduction and their respective 95 percent confidence intervals.

A summary table will present the review findings, including study characteristics, methodological quality, methods, results, conclusions, and synthesized evidence.

Conclusion

Technological strategies aimed at reducing excessive noise exposure in preterm newborns primarily seek to preserve sleep cycles, support appropriate growth and development, and maintain stable physiological parameters.⁶

This protocol is expected to guide the development of a systematic review capable of providing evidence to inform NICU management and support healthcare professionals involved in preterm care. It also aims to raise awareness about the importance of minimizing environmental noise and its consequences for physiological stability in PTNBs.

Additionally, the review may offer scientific insight regarding the effectiveness of ear protectors in NICU settings and support the design of targeted strategies for their implementation in controlled environments.

The synthesized findings may further contribute to the development of clinical guidelines and public health policies focused on the use of ear protectors to promote neurodevelopment in hospitalized PTNBs, helping to clarify lingering questions regarding their effectiveness.

Any protocol amendments, if necessary, will be registered in PROSPERO with detailed justifications following discussion among the review team.

Authors Contributions

Study Design: Luana Trindade dos Santos Mascarenhas, Paloma Santos Machado Silva, Max Douglas de Jesus Carmo, Adriele Almeida Santos de Jesus, Beatriz Ferreira Santos Oliveira, Luciano Marques dos Santos, Maria Cristina de Camargo. **Data Collection:** Luana Trindade dos Santos Mascarenhas, Paloma Santos Machado Silva, Max Douglas de Jesus Carmo, Adriele Almeida Santos de Jesus, Beatriz Ferreira Santos Oliveira. **Data analysis and interpretation:** Luana Trindade dos Santos Mascarenhas, Paloma Santos Machado Silva, Max Douglas de Jesus Carmo, Adriele Almeida Santos de Jesus, Beatriz Ferreira Santos Oliveira, Luciano Marques dos Santos, Maria Cristina de Camargo. **Manuscript Writing:** Luana Trindade dos Santos Mascarenhas, Paloma Santos Machado Silva, Max Douglas de Jesus Carmo, Luciano Marques dos Santos, Maria Cristina de Camargo. **Critical review of the manuscript:** Luana Trindade dos Santos Mascarenhas, Paloma Santos Machado Silva, Max Douglas de Jesus Carmo, Luciano Marques dos Santos, Maria Cristina de Camargo. **Approval of the final version of the text:** Luciano Marques dos Santos, Maria Cristina de Camargo.

Conflict of interest

This systematic review protocol has no declared conflicts of interest.

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