EFFECTIVENESS OF EYE PROTECTION IN PHYSIOLOGICAL STABILITY OF HOSPITALIZED PREMATURE NEWBORNS: A SYSTEMATIC REVIEW **PROTOCOL**

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ABSTRACT

Introduction: The premature newborn (PTNB) hospitalized in the Neonatal Intensive Care Unit (NICU) can be exposed to high levels of fluorescent lights that can impact their development, change their sleep pattern, and interfere with the circadian cycle. Objective: Evaluating the effectiveness of eye protectors in the physiological stability of PTNBs hospitalized in NICU, compared to usual care. Method: This is a systematic review protocol developed according to the recommendations of the Joanna Briggs Institute and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses 2020 (PRISMA-2020). The protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO). The search of documents will be performed in PubMed, Embase, Cochrane Library, LILACS, Scopus, CINAHL and Web of Science, combining the controlled descriptors. Only random and guasi-experimental clinical trials published in any language and without a temporal cut will be included. Results management will be performed in the Rayyan software. Result: This study is in progress and the data obtained from the searches will be presented in summary tables, based on the methodology adopted. Conclusion: It is expected that this protocol can guide the development of the review to highlight the effectiveness of eye protectors in reducing the effects of environmental luminosity of NICU in clinical parameters of PTNB.

Keywords: Infant. Premature. Sleep-wake transition disorders. Intensive care units. Neonatal. Lighting. Eye protective devices.

INTRODUCTION

The global neonatal mortality rate fell from 31 deaths per thousand live births in 2000 to 18 deaths per thousand live births in 2017 (1). Nevertheless, prematurity, defined as birth with gestational age below 37 weeks (2,3), is still worrying due to the high global prevalence of almost 11% (2) and the strict relationship with perinatal asphyxia.

In this context, prematurity remains a global public health problem, affecting almost 15 million babies annually (4), accounting for 35% of all deaths among newborns and 18% of all deaths among children under five years old (3).

In addition, every year, worldwide, 30 million newborns are hospitalized (1) and, in the case of premature newborn (PTNB), this event occurs more frequently in the Neonatal Intensive Care Unit (NICU)⁽⁵⁾ due to its organic immaturity and clinical instability.

Technological and scientific advances, as well as the care provided to the newborn in NICU, have enabled more than 95% of these children to receive modern care and survive to adulthood (2); however, they may present a risk of neurological deficiencies in the long term (6-7), in view of the possibility of adverse neonatal

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outcomes (7).

The child is susceptible to numerous risks during the neonatal period, becoming essential the integral care ⁽⁸⁾. It is emphasized that the adverse results are due to several environmental stimuli such as excessive illumination of the environment, which causes stress and disturbances in the behavior and sleep of the PTNB ^(9,10).

Sleep interruption may have a negative effect on clinical outcomes, growth, and development, and may delay hospital discharge (11). Sleep and continuous cycle of sleep states are necessary for sensorineural processing, learning and brain plasticity (10).

Environments of unfavorable care for neurodevelopment and initial experiences of PTNB directly and in the long term impact their brain development, as well as lay the foundations for health, learning, productivity, and well-being throughout life ⁽¹⁾.

Thus, the risk management in NICU demands efforts for a quality and safe assistance and needs to be seen in an individualized way through systematic, resolution and continuous preventive actions (12).

Therefore, it is important to provide low levels of luminosity in the NICU, emphasizing the better structural organization of sleep and neurodevelopment of the PTNB ⁽¹³⁾, aiming at reducing the exposure of this newborn ⁽¹⁴⁾.

Therefore, neonatologist nurses should implement interventions that can reduce exposure to excessive light ^(15,16), such as the use of eye protectors. The exposure of PTNB to this type of measure for the promotion of the light-dark cycle can contribute to improvements in its physiological development, favoring earlier weight gain and, consequently, the reduction of hospitalization time ⁽¹⁷⁾.

However, there are records that the use of this technology causes more response to stress in the newborn, due to the increase in heart rate ⁽¹⁸⁾, not being clear, therefore, its effectiveness in reducing the impact of environmental light on neonatal health, which requires reviews of published studies.

Thus, this review aims to evaluate the effectiveness of eye protectors in the physiological stability of PTNBs hospitalized in NICU, compared to usual care. Physiological

stability and usual care will be described in the method of this protocol.

MATERIALS AND METHOD

Type of study

This is a protocol for systematic review of evidence of efficacy, which will be conducted according to the methodology recommended by the Joanna Briggs Institute (JBI) ⁽¹⁹⁾. This review was chosen because it provides an integral and impartial synthesis of several relevant studies in only one document, with a clear method, in addition to making it possible to summarize existing knowledge related to a certain content, thus discovering considerable evidence for the question elaborated by the researchers.

The reporting of this systematic review protocol followed the recommendations of the Preferred Reporting Items for Systematic reviews and Meta-Analyses 2020 (PRISMA-2020) checklist ⁽²⁰⁾ and is registered in the International Prospective Register of Systematic Reviews (PROSPERO) under number CRD42023392946.

In this sense, it is intended to obtain answers to the following question: is the use of eye protectors effective in the physiological stability of PTNBs hospitalized in the NICU compared to the absence of this care?

Sources of information

The studies will be retrieved through electronic searches in the following electronic databases: National Library of Medicine and National Institutes of Health (PUBMED), Cumulative Index to Nursing and Allied Health Literature (CINAHL), Latin American and Caribbean Literature in Health Sciences (LILACS), Embase, Cochrane Central Register of Controlled Trials (CENTRAL), Web of Science and Scopus. Specific search strategies will be considered for each data source.

To give greater scope to the recovery of potential studies, the list of references of the recovered studies and previous review articles will be examined.

Search strategy

The syntaxes of the initial searches will be elaborated according to specific characteristics of the sources of electronic databases consulted and with the support of a librarian specialized in literature review, through consultation of controlled terms in the Medical Subject Headings (MeSH), in the Health Sciences Descriptors (DeCS) and in the Embase Subject Headings (Emtree).

In addition, an initial consultation will be conducted in each data source to identify the descriptors and keywords most used in articles on the theme of the review, which were included in the preparation of research strategies.

A comprehensive list of controlled terms and keywords will be incorporated and combined for each part of PICO (Population - PTNB; Intervention - use of eye protection; Comparison - PTNB exposed to usual care; Outcomes - physiological stability)described in the eligibility criteria.

Several combinations of keywords and controlled terms were developed, applying the Boolean operators AND and OR. Tables 1 and 2 show the syntaxes that will be applied for the recovery of the studies according to the electronic database.

Table 1. Search strategy according to data source: PUBMED, CINAHL, LILACS. 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 "newborns"[All Fields] OR "newborns"[All Fields] OR "infant"[MeSH Terms] OR "infant"[All Fields] OR "babies"[All Fields] OR "infant"[MeSH Terms] OR ("infant"[All Fields] OR "babies"[All Fields]) OR ("infant, newborn"[MeSH Terms] OR ("infant"[All Fields] OR "newborn"[All Fields]) OR "newborn infant"[All Fields] OR "infant"[MeSH Terms] OR ("infant, newborn"[MeSH Terms] OR ("infant"[All Fields]) OR "newborn infant"[All Fields] OR "neonatal"[All Fields] OR "neonates"[All Fields] OR "neonates"[All Fields] OR "neonates"[All Fields]) OR ("infant, newborn"[MeSH Terms] OR ("infant, newborn"[MeSH Terms] OR ("infant, newborn"[MeSH Terms] OR ("infant"[All Fields] OR "neonates"[All Fields]) OR "newborn infant"[All Fields] OR "neonatal"[All Fields] OR "neonates"[All Fields]) OR "neonates"[All Fields] OR "neonates"[All Fields] OR "neonates"[All Fields]) OR "neonates"[All Fields] OR "neonates"[All Fields] OR "neonates"[All Fields])) OR "neonatal"[All Fields] OR "neonates"[All Fields])) OR "neonatall"[All Fields] OR "neonates"[All Fields])) OR "neonatall"[All Fields] OR "neonates"[All Fields])) OR "neonatall"[All Fields]))
CINAHL	(premature* OR newborn OR infant OR baby OR babies OR neonate*) AND ("eye protective device" OR "eye protection shield" OR "eye protective devices" OR "eye protective shield" OR "eye protective wear" OR "eye protector" OR "eye splash shield" OR "eyesight protection appliance" OR "laser beam eye protector" OR "laser beam eye protector" OR "laser beam eye protector" OR "ocular protection devices" OR "ocular protection shield" OR "ocular protective devices" OR "ocular protection" OR "optic protector" OR "optical protection" OR "optical protection" OR "patient laser beam eye protector" OR "protective eye-wear" OR "protective eyewear" OR "staff laser beam eye protector")
LILACS	(premature* OR newborn OR infant OR baby OR babies OR neonate*) AND ("eye protective device" OR "eye protection shield" OR "eye protective devices" OR "eye protective shield" OR "eye protective wear" OR "eye protector" OR "eye splash shield" OR "eyesight protection appliance" OR "laser beam eye protector" OR "laser beam eye protector" OR "laser beam eye protector" OR "ocular protection devices" OR "ocular protection shield" OR "ocular protective devices" OR "ocular protector" OR "optic protection" OR "optic protector" OR "optical protection" OR "optical protection" OR "optical protective shield" OR "patient laser beam eye protector" OR "protective eye-wear" OR "protective eyewear" OR "staff laser beam eye protector") AND (db:("LILACS"))

Source: Prepared by the authors, 2024.

Study eligibility criteria

The studies selected for this systematic review will be selected by the eligibility criteria,

described below, according to the study design (including publication, language, and year), participants, interventions, comparators, and results.

Table 2. Search strategy according to data source: Embase, SCOPUS and Web of science. Feira de Santana, BA, Brazil, 2024.

DATA SOURCES	STRATEGY
Embase	('prematurity'/exp OR 'extremely premature infant' OR 'infant, extremely premature' OR 'infant, premature' OR 'infant, premature' 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 infant diseases' OR 'premature infant diseases' OR 'premature infant diseases' OR 'premature infant' 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 'neonate on 'neonate' OR 'neonate' OR 'neonate' OR 'newborn' OR 'newborn animal' OR 'neonate' OR 'neonate animal' OR 'neonates' OR 'newborn or infant' OR 'newborn animal' OR 'newborn animal' OR 'newborn baby' OR 'newborn child' OR 'newborn infant' OR 'infant'/exp OR 'infant') AND ('eye protective device'/exp OR 'eye protection device' OR 'eye protection shield' OR 'eye protective device' OR 'eye protective devices' OR 'eye protective shield' OR 'eye protective wear' OR 'eye protection devices' OR 'ocular protection shield' OR 'ocular protection devices' OR 'ocular protection shield' OR 'optical protection' OR 'optical protection' OR 'optical protection' OR 'optical protection' OR 'protective shield' OR 'protective eye-wear' OR 'protective eye-wear' OR 'staff laser beam eye protector')
	(premature OR newborn OR infant OR baby OR babies OR neonate*) AND ("eye protective device" OR "eye protection shield" OR "eye protective devices" OR "eye protective shield" OR "eye protective wear" OR "eye protector" OR "eye splash shield" OR "eyesight protection appliance" OR "laser beam eye protector" OR "laser beam eye protector" OR "laser beam eye protector" OR "ocular protection devices" OR "ocular protection shield" OR "ocular protective devices" OR "ocular protector" OR "optic protection" OR "optical protection" OR "optical protection" OR "patient laser beam eye protector" OR "protective eye-wear" OR "protective eyewear" OR "staff laser beam eye protector")

Source: Prepared by the authors, 2024.

Study design

Original clinical, randomized and controlled or quasi-experimental crossover, Stepped Wedge, and interrupted time series articles, available in full, will be included in this review.

Research of the type of almost experimental drawings without control group, with control but without pre-test, and those with pre-tests will be excluded. These designs are weak in establishing the causal relationship (21,22). Letters to the editor, editorials, pilot studies and meta-analyses related

to intervention studies that assessed the effectiveness of some eye protection will also be excluded. Such types of publications will not be considered for analysis because they do not provide data on the effectiveness of the intervention of interest.

In addition, there will be no time and language restrictions on the search strategy.

Participants

Studies including PTNB with gestational age

between 28 and 36 weeks and hospitalized in NICU will be considered for review. These newborns should have been included in the study when breathing in ambient air, without support of continuous sedatives or vasoactive drugs, and inside incubators.

Studies with PTNBs that presented surgical problems in any body segment will be excluded.

Interventions

Any type of eye protection applied in PTNB will be considered intervention. Multifaceted interventions will be excluded from this review, as it will be difficult to estimate which component was most effective in promoting newborn stability. Studies will also be excluded in which the thermal blanket and interventions aimed at reducing pain were used in conjunction with eye protection, due to its effects on the physiological stability of PTNB.

Comparator

All types of comparator groups, such as the control group exposed to the constant light of the NICU, the management of ambient luminosity, the application of blankets on the incubator dome and the absence of any artifact on the eyes of the newly born, will be included in this systematic review. The application of any of the interventions described for the control group will be called in this review of usual care.

In addition, studies in which the thermal blanket was used in conjunction with usual care will be excluded.

RESULTS

Will be selected studies that report the physiological stability of PTNB, measured by the effect of eye protection on vital signs (heart rate, respiratory, oxygen saturation, temperature, and blood pressure), behavior, sleep, weight gain, and diet progression.

Likewise, studies that measure the behavior and sleep of the PTNB through the application of some instrument (scales, scores, or inventories) validated and appropriate to the PTNB. The measurement instruments will not be delimited in this review.

Studies that, after data extraction, do not present the difference in means as a measure used in the analysis of the associations between exposure and outcome will be excluded. Will also be excluded studies that, after trying to contact the corresponding author for clarification of potential questions, is not obtained answer.

Selection of studies

The references selected by applying the research strategies will be exported to the Rayyan Software, because through this feature it will be possible to identify duplicates, title screening, abstract and full text.

Three reviewers duly qualified for the application of this review protocol will analyze the duplicates initially and independently, which will be compared a posteriori to confirm the appropriate exclusion of recovered studies that do not meet the eligibility criteria.

The three reviewers will then carefully examine the remaining studies in two stages. In the first stage, the titles and abstracts will be read, and in the second, a thorough review of the full text will be performed to assess their suitability for inclusion in the systematic review.

If there are disagreements between the three reviewers in any of the stages of study selection, a fourth reviewer will be triggered to resolve them through discussion and consensus.

The number of studies selected, included, and excluded, as well as the reasons for ineligibility and exclusion, will be documented in a flowchart.

Data Extraction

After selection, the eligible studies will be transported to the MaxQDA Software, since, with this feature, it is possible to decode the most varied types of files, adding more reliability to the review.

The data will be extracted independently by the three reviewers and then the review team will compare the results. Thus, a pilot test for data extraction in ten studies will be necessary to identify groupings of information.

In case of discrepancies in the data extracted by the reviewers, discussion among the review team will be necessary to achieve consensus. In addition, the following information will be extracted from the selected references: data for the characterization of the publication (title, journal, year and language of publication, country of origin and objective), method (research design, gestational age of newborns, type of eye protector used, intervention used in the control group, main and secondary outcome, instruments used to measure the physiological stability of PTNB), main results, limitations of research and conclusion.

In the presence of insufficient data, reviewers will contact the corresponding authors of the publication to clarify doubts.

Risk of Bias Assessment

To evaluate the reliability, relevance and results of the published articles, the checklists proposed for random and quasi-experimental tests proposed by JBI will be applied.

Evaluation of methodological quality

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) will be used to assess the following items: Methodological limitations (risk of bias); Inconsistency; Indirect Evidence; Inaccuracy; Publication bias; Factors that increase the quality of evidence; and Considerations regarding raising the level of evidence (23).

Data synthesis

The data will be analyzed qualitatively and quantitatively. Clinical heterogeneity (samples, interventions, time of evaluation and measurement of results) and methodological (risk of bias) in the synthesis of data will be described.

The quantitative outcomes will be compared by means of mean difference and their respective 95% confidence intervals (CI); the dichotomous qualitative variables will be presented by relative risks (RR) with 95% CI.

The data will be presented in a summary table based on the review report, describing the methodological quality, the characterization of the studies, the method, the results, the completion of the eligible studies and the synthesis.

DISCUSSION

The results of this systematic review may provide guidance to NICU managers, local policymakers and health professionals involved in PTNB care.

The synthesis may support the development of policies and clinical guidelines for the use of eye protection in the promotion of neurodevelopment of PTNB in the NICU, since it will contribute to the elucidation of uncertainties related to its effectiveness.

In addition, it will provide robust scientific evidence that can be implemented in clinical practice, avoiding variations in care aimed at reducing the effect of the luminosity of the NICU environment on the physiological stability of PTNB, and may optimize its neurodevelopment.

CONCLUSION

The results of this systematic review will also highlight the state of knowledge about the use of eye protectors in PTNBs in the NICU, as well as may point out gaps that will require completion by conducting future research.

Finally, if there is a need for changes in this protocol, after discussion among the members of the review team, the modifications, and the respective justifications, these will be documented in PROSPERO.

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ABSTRACT

Introduction: The premature newborn (PTNB) hospitalized in the Neonatal Intensive Care Unit (NICU) can be exposed to high levels of fluorescent lights that can impact their development, change their sleep pattern, and interfere with the circadian cycle. **Objective:** Evaluating the effectiveness of eye protectors in the physiological stability of PTNBs hospitalized in NICU, compared to usual care. **Method:** This is a systematic review protocol developed according to the recommendations of the Joanna Briggs Institute and reported according to the

Preferred Reporting Items for Systematic Reviews and Meta-Analyses 2020 (PRISMA-2020). The protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO). The search of documents will be performed in PubMed, Embase, Cochrane Library, LILACS, Scopus, CINAHL and Web of Science, combining the controlled descriptors. Only random and quasi-experimental clinical trials published in any language and without a temporal cut will be included. Results management will be performed in the Rayyan software. **Result:** This study is in progress and the data obtained from the searches will be presented in summary tables, based on the methodology adopted. **Conclusion:** It is expected that this protocol can guide the development of the review to highlight the effectiveness of eye protectors in reducing the effects of environmental luminosity of NICU in clinical parameters of PTNB.

Keywords: Infant. Premature. Sleep-wake transition disorders. Intensive care units. Neonatal. Lighting. Eye protective devices.

EFICACIA DEL PROTECTOR OCULAR EN LA ESTABILIDAD FISIOLÓGICA DE LOS RECIÉN NACIDOS PREMATUROS HOSPITALIZADOS: PROTOCOLO DE REVISIÓN SISTEMÁTICA

RESUMEN

Introducción: el recién nacido prematuro (RNPT) hospitalizado en Unidad de Cuidados Intensivos Neonatales (UCIN) puede estar expuesto a altos niveles de luces fluorescentes que pueden impactar en su desarrollo, alterar su patrón de sueño e interferir en el ritmo circadiano. Objetivo: evaluar la eficacia de protectores oculares en la estabilidad fisiológica de RNPTs hospitalizados en UCIN, comparado al cuidado habitual. Método: se trata de un protocolo de revisión sistemática elaborado conforme recomendaciones de Joanna Briggs Institute y reportado según el Preferred Reporting Items for Systematic Reviews and Meta-Analyses 2020 (PRISMA-2020). El protocolo fue registrado en el International Prospective Register of Systematic Reviews (PROSPERO). La búsqueda de documentos se realizará en PubMed, Embase, Cochrane Library, LILACS, Scopus, CINAHL y Web of Science, combinando los descriptores controlados. Se incluirán solo ensayos clínicos aleatorizados y cuasiexperimentales, publicados en cualquier idioma y sin recorte temporal. La gestión de los resultados se llevará a cabo en el software Rayyan. Resultado: este estudio se encuentra en marcha y los datos obtenidos a partir de las búsquedas serán presentados en cuadros resumen, con base en la metodología adoptada. Conclusión: se espera que este protocolo pueda orientar el desarrollo de la revisión para evidenciar la eficacia de protectores oculares en la reducción de los efectos de la luminosidad ambiental de UCIN en los parámetros clínicos de RNPT.

Palabras clave: Recién nacidos prematuros. Trastornos de la transición sueño-vigilia. Unidades de cuidados intensivos neonatales. Iluminación. Dispositivos de protección de los ojos.

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