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The effects of the introduction of the single-family room in neonatal intensive care and paediatric intensive care on the outcomes of paediatric patients, families, staff, and organizations: a mixed method systematic review protocol

Gli effetti dell'introduzione delle single family room in terapia intensiva neonatale e pediatrica sugli esiti dei pazienti pediatrici, delle famiglie, del personale e delle organizzazioni: un protocollo di revisione sistematica a metodo misto

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ABSTRACT

Introduction: the design of neonatal and paediatric neonatal intensive care significantly impacts the outcomes of the families, workers, and organizations. The aim of this review is to identify the effects of the introduction of the single-family room in neonatal intensive care and paediatric intensive care on the outcomes of paediatric patients, families, staff, and organizations.
Materials and Methods: we structured this work as a systematic review, registered on PROSPERO (CRD42024501520). This review has been developed using Joanna Briggs Institute recommendations. The database search will include PubMed, CINAHL, SCOPUS, EMBASE, PsycINFO, Web of Science. Documents published in English, Italian and Spanish from 2009 will be included.
Results: the results of this review will provide insights on the effects of the introduction of single-family room assessment. This could help nursing stakeholders to effectively evaluate and eventually plan the transition to single-family room assessment to ensure quality of care, user and staff satisfaction.
Discussion: the introduction of single-family room structure plays a pivotal role in family involvement and active participation in their child's care. Also, this requires modifications in healthcare professionals' way of approaching and planning patient care. Considering the importance and the substantial changes that single-family room could bring to patients, families, staff and organizational outcomes, this review may provide important insights for the introduction of single-family room on patients, families, staff, and organizations building a rationale on the introduction of this new organizational structure.

Key words: single-family room; NICU; PICU; outcome; review.

RIASSUNTO

Introduzione: la progettazione della terapia intensiva neonatale e pediatrica ha un impatto significativo sugli esiti delle famiglie, degli operatori e delle organizzazioni. Lo scopo di questa revisione è identificare gli effetti dell'introduzione delle single family room nelle terapie intensive neonatali e pediatriche sugli esiti dei pazienti pediatrici, delle famiglie, del personale e delle organizzazioni.
Materiali e metodi: abbiamo strutturato questo lavoro come una revisione sistematica, registrata su PROSPERO (CRD42024501520). Questa revisione è stata sviluppata utilizzando le raccomandazioni del Joanna Briggs Institute. La ricerca nelle banche dati comprende PubMed, CINAHL, SCOPUS, EMBASE, PsycINFO, Web of Science. Saranno inclusi i documenti pubblicati in inglese, italiano e spagnolo a partire dal 2009.
Risultati: i risultati di questa revisione forniranno approfondimenti sugli effetti dell'introduzione delle single family room. Ciò potrebbe aiutare gli operatori del settore infermieristico a valutare efficacemente ed eventualmente a strutturare il passaggio alla single family room per garantire la qualità dell'assistenza, la soddisfazione degli utenti e del personale.
Discussione: l'introduzione delle single family room gioca un ruolo fondamentale nel coinvolgimento e nella partecipazione attiva della famiglia nella cura del proprio figlio. Inoltre, ciò richiede modifiche nel modo in cui gli operatori sanitari approcciano e pianificano l'assistenza ai pazienti. Considerando l'importanza e i cambiamenti sostanziali che la single family room potrebbe apportare ai pazienti, alle famiglie, al personale e ai risultati organizzativi, questa revisione può fornire importanti spunti per l'introduzione della single family room e i suoi esiti su pazienti, famiglie, personale e organizzazioni, costruendo un razionale sull'introduzione di questa nuova struttura organizzativa.

Parole chiave: single family room; NICU; PICU; risultati; revisione.

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Introduction

Over the last 15-20 years, much attention has been paid to the physical environment of Neonatal Intensive Care Units (NICU) and paediatric units with a view increasingly focused on patient and family-centred care with the aim of providing focused and personalized care for children and their families. The term Single-Family Room (SFR) refers to a welcoming and familiar space within hospitals, in which parents can remain next to their child twenty-four hours a day for the entire hospital stay.[1] Starting from 2009, the single-room structure was officially introduced in some NICUs, while there are fewer experiences in the literature regarding the context of paediatric intensive care.[2,3] Inside these rooms the family is offered all the necessary comforts: from the dining room to the kitchen, to a place to sleep and a place for games. This model distinguishes itself from the structure mainly present in hospitals, i.e. the Open Bay, as it allows the creation of an individualized treatment plan, respect for privacy and family comfort and to encourage the creation of a bond between parents and child, guaranteeing the family involvement in the treatment process[4] and better control of the environment (fewer inappropriate stimulations such as high levels of noise and lighting).

Background

The design of neonatal and paediatric neonatal intensive care significantly impacts the outcomes of the families, workers, and organizations,[5,6,7] as mentioned before. The design of these units could also have an impact on how family-centred care is provided. Family-centred care can determine several effects on patients, families, staff, and organizations both on a short- and long-term time period. For example, it could determine shorter length of stay, increased rates of breastfeeding, and increased weight gain for the neonates, while parents/caregivers see increased bonding and parent-infant attachment and decreased stress and anxiety.[8] Although family-centred care in intensive care can be implemented in any logistical context, an architectural structure that promotes privacy and is able to protect from stress, both visual and auditory, significantly enhances the health benefits resulting from the daily presence of parents. Facilitating the presence of parents to stay with their child without any restrictions is an action that is still little used and widespread with a view to improving the experience of hospitalization. The single-family room setting is a highly complex environment with specific design features that have not been sufficiently studied as to how they might support family presence in combination with other behaviours and perceptions relevant to active family involvement.

Aim

The aim of this review is to identify the effects of the introduction of the SFR in neonatal intensive care and paediatric intensive care on the clinical-care outcomes of paediatric patients (premature infants, newborns, infants, children and adolescents), on the outcomes of families (intended as parents /caregiver in reference to the figures connected to the child who are physically in the room together with the patient),[9] on the outcomes of the clinical, care and rehabilitation staff, and on the organizational outcomes.

Materials and Methods

This is a mixed methods systematic review protocol that has been registered in PROSPERO (International Prospective Register of Systematic Reviews) with the following registration number CRD42024501520. The systematic review protocol is developed according to the mixed methods systematic reviews guidelines of the Johanna Briggs Institute.[10]

In the review, the transparency of the study selection process will be based on the PRISMA statement for systematic reviews[11]. The protocol outlines the review question, inclusion criteria, search strategy, study selection, data extraction, quality assessment and data synthesis.

Review question

"What are the effects of the introduction of SFR in paediatric intensive care units and neonatal intensive care units on the clinical-care outcomes of paediatric patients (0-18 years), on family outcomes, on staff outcomes, and on organizational outcomes?"

Inclusion and/or exclusion criteria

Type of participants

The review will include all studies that present the outcomes of the presence of the SFR setup in the neonatal and paediatric intensive care units on patients, or on families, or on healthcare staff or on the organization. Studies will be included in which the possible outcomes of the presence of SFR introduced in paediatric and neonatal intensive departments are identified and evaluated with different tools.

Type of studies

This review includes primary studies that adopted quantitative, qualitative, or mixed-methods study designs. In order to achieve a comprehensive systematic review, quantitative studies will include: Randomized Controlled Trials (RCTs), observational studies such as prospective and retrospective cohort studies, case-control studies and cross-sectional studies. Qualitative studies will include phenomenological studies, ethnographic studies, and grounded theory studies. Mixed methods studies will be considered if data from quantitative or qualitative studies can be clearly extrapolated.

The search will consider studies published by commercial and academic publishers, as well as studies published non-commercially (grey literature).

Non-primary studies will be excluded, therefore all types of literature reviews and meta-analyses. Language restrictions will be applied to include studies in English, Italian and Spanish, as these are the languages spoken and understood by the members of the research team.

Articles published from 2009, the year in which the single-family room structure for neonatal and paediatric intensive care was introduced, to today will be included.[2,3]

Search strategy

The development of the search strategy took place in collaboration with a librarian.

A systematic search for documents relevant to the review will take place on six databases appropriate to the research question: PubMed, CINAHL, SCOPUS, EMBASE, PsycINFO, Web of Science (Table 1). Reference lists of relevant systematic reviews and other review types will be examined to find any further studies of interest for our review question that may not have been previously obtained.

Search for other resources

For this purpose, the Open Gray and Google Scholar databases will be consulted. If there are completed and unpublished studies, the RCT trial registries included in the World Health Organization's International Clinical Trials Registry Platform (ICTRP) will be

consulted (https://www.who.int/clinical-trials-registry-platform) and (International Standard Randomized Controlled Trial Number) ISRCTN registry (https://www.isrctn.com).

The search terms used will be: *"single-family room*", "single family room", "single room*", "private room*", "intensive care unit *", "intensive care", "paediatric intensive care unit*" "neonatal intensive care unit*", "newborn intensive care unit*", "PICU", "NICU"*.

The "text words" contained in the titles and abstracts of relevant articles and the indexed terms used to describe the articles will be used to develop a comprehensive search strategy for each database. The search strategy, including all identified keywords and indexed terms, will be adapted for each information source included. The reference list of all studies selected for critical appraisal will be screened for additional studies. After carrying out the search, all citations to be included in the review process will be uploaded into EndNote Web after eliminating all duplicates. Then, screening of title and abstract of references retrieved will be performed by reviewers. The full text of documents for possible inclusion in the review will be assessed by the screening team at a reviewers' meeting. Reasons for exclusion of sources of evidence at full text will be logged and then stated in the review itself. Any difference of opinion in the review team at any point will be resolved through discussion within the team.

Quality appraisal

To establish the internal validity and risk of bias of studies meeting the review's inclusion criteria, tools developed and made available by JBI will be used to assess the quality of included studies. The critical evaluation will be conducted by two reviewers independently. The reviewers will meet to discuss the results of their critical evaluation for their final evaluation. If the two reviewers disagree on the final critical assessment and the disagreement is not resolved through discussion, an evaluation by a third reviewer may be necessary. The critical evaluation tools that will be used for the different study designs are: i) JBI Critical Appraisal Checklist for Prevalence Studies ii) JBI Critical Appraisal Checklist for Cohort Studies; iii) JBI Critical Appraisal Checklist for Case Control

Table 1. Search strategy.

DATABASE	Search Strategy
PubMed	(("single family room*"[Title/Abstract] OR "single family room*"[All Fields] OR "single room*"[Title/Abstract] OR "private room*"[Title/Abstract]) AND ("intensive care"[Title/Abstract] OR "intensive care unit*"[Text Word] OR "ICU"[Title/Abstract] OR "pediatric intensive care unit"[All Fields] OR "PICU"[Title/Abstract] OR "neonatal intensive care unit"[All Fields] OR "NICU"[Title/Abstract]) AND ((english[Filter] OR italian[Filter] OR spanish[Filter]) AND (allchild[Filter] OR newborn[Filter] OR allinfant[Filter] OR infant[Filter] OR preschoolchild[Filter] OR child[Filter] OR adolescent[Filter]) AND (2009:2024[pdat]))
CINAHL	AB (single family room OR single-family room OR single room OR private room)) AND AB (intensive care OR intensive care unit OR ICU OR pediatric intensive care unit OR PICU OR neonatal intensive care unit OR NICU) Limiters - Publication Date: 20090101-20241231 Expanders - Apply related words; Apply equivalent subjects Narrow by Language: - english Narrow by SubjectAge: - child, preschool: 2-5 years Narrow by SubjectAge: - child: 6-12 years Narrow by SubjectAge: - adolescent: 13-18 years Narrow by SubjectAge: - infant: 1-23 months Narrow by SubjectAge: - infant, newborn: birth-1 month Narrow by SubjectAge: - all infant Narrow by SubjectAge: - all child Search modes - Boolean/Phrase
PsychInfo	(single family room* or single-family room* or single room* or private room*) AND (intensive care or intensive care unit or ICU or pediatric intensive care unit or PICU or neonatal intensive care unit or NICU).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh word] limit 3 to (human and english language and (100 childhood <birth to age 12 yrs> or 120 neonatal <birth to age 1 mo> or 140 infancy <2 to 23 mo> or 160 preschool age <age 2 to 5 yrs> or 180 school age <age 6 to 12 yrs> or 200 adolescence <age 13 to 17 yrs>) and yr="2009 - 2024")
Embase	('single family room*':ab,ti OR 'single-family room':ab,ti OR 'single room':ab,ti OR 'private room':ab,ti) AND ('intensive care':ab,ti OR 'intensive care unit*':ab,ti OR 'pediatric intensive care unit*':ab,ti OR 'neonatal intensive care unit*':ab,ti OR picu:ab,ti OR nicu:ab,ti) AND ([newborn]/lim OR [infant]/lim OR [child]/lim OR [preschool]/lim OR [school]/lim OR [adolescent]/lim) AND [2009-2023]/py AND ([english]/lim OR [italian]/lim OR [spanish]/lim)
Scopus	(TITLE-ABS-KEY ("single family room*" OR "single- family room" OR "single room" OR "private room") AND TITLE-ABS KEY ("intensive care" OR "intensive care unit" OR "ICU" OR "pediatric intensive care unit" OR "PICU" OR "neonatal intensive care unit" OR "NICU")) AND PUBYEAR > 2008 AND PUBYEAR < 2024 AND (LIMIT-TO (EXACTKEYWORD , "Infant, Premature") OR LIMIT-TO (EXACTKEYWORD , "Child") OR LIMIT-TO (EXACTKEYWORD , "Infant Care") OR LIMIT-TO (EXACTKEYWORD , "Nursing Staff, Hospital") OR LIMIT-TO (EXACTKEYWORD , "Health Care Personnel")) AND (LIMIT TO (LANGUAGE , "English"))
Web of Science (WoS)	(TS=("single family room*" OR "single- family room*" OR "single room" OR "private room")) AND TS=("intensive care" OR "intensive care unit" OR ICU OR PICU OR NICU) Refined by: languages English Publication date: 2009-2024

Studies; iv) JBI Critical Appraisal Checklist for Case Series; v) JBI Critical Appraisal Checklist for Case Reports; vi) JBI Critical Appraisal Checklist for Analytical Cross-Sectional Studies; vii) JBI Critical Appraisal Checklist for Qualitative Research; viii) JBI Critical Appraisal Checklist for Randomized Controlled Trials; ix) JBI Critical Appraisal Checklist for Quasi-Experimental Studies (non-randomized experimental studies)

Data extraction

A data extraction sheet will be developed to extract relevant data from the papers that will be included in the review, according to guidelines provided by the Institute of Medicine (US) Committee on Standards for Systematic Reviews of Comparative Effectiveness Research.[12] The following data will be collected in a standardized data extraction tool to describe the included articles with the following elements: title, authors, year, study design/methodology, aim/objectives, research questions/hypotheses, study context (setting) and country in which it was conducted, description of the sample, sample size, outcome measurement tools, results, data analysis methods, conclusions, comments and issues raised by the reviewer, quality assessment, reviewer initials. Furthermore, to answer the research question, data relating to the outcomes measured will also be collected to explore the impact of the single-family room, on which population the outcomes were measured (premature infants, newborns, infants, children and adolescents, families, professionals). Screening for full-text inclusion will be performed by five groups of researchers divided into couples. After this, data from included articles will be extracted separately by three researchers with experience with the review method using a data extraction Excel® sheet. The extraction sheet will be tested to assess whether it is appropriate for collecting the data needed to answer the review questions. Any disagreements between researchers will be resolved together with an additional expert researcher and all modifications made will be explained fully in the final review.

Data synthesis

The final review for this study will be summarized according to Mixed Methods Systematic Review of the Johanna Briggs Institute (JBI) and PRISMA Preferred Reporting Items for Systematic Reviews and Meta-Analysis) by following the systematic review process through the main phases of a systematic review consisting of identification, screening, assessment of eligibility and selection of the studies.[11] To combine the results of multiple primary studies into a single overall summary estimate, we will proceed with meta-analysis with a random effects model,[13] where this is possible (at least two studies, homogeneous outcomes). The heterogeneity between the estimates resulting from the different studies will be assessed using the I2 index.[14]

In cases where meta-analysis is not possible, researchers will resort to narrative synthesis of the results of the included studies. Narrative synthesis will rely primarily on the use of words and text to summarize and explain the findings of the synthesis process including description of study characteristics, context, quality, and findings. To highlight the characteristics of the studies and data extracted and allow their comparison, tables, graphs, and other diagrams will be used.[15] This narrative synthesis will present quantitative data drawn from individual studies and, where available, point estimates (a value representing the best estimate of effects) and interval estimates (an estimated range of effects, presented as a 95% confidence interval).

The presence of publication bias will be assessed by producing funnel plots.[16]

Discussion

This review will seek to comprehensively synthesize the existing body of research related to the effects of the introduction of SFR for NICU and PICU settings on patients, families, staff, and organizations. We expect that this review would provide an overview and insights and information on all published outcomes related to SFR introduction. This is important to report the outcomes of SFR introduction of SFR introduction in neonatal and paediatric intensive care settings providing supportive data that help healthcare professionals and stakeholders in deciding to approach and start this change.

The background for this protocol provides clear identification of the problem and purpose of gathering the data. The method describes the process of study selection and steps to gather, identify and synthesize results from included studies and to evaluate the evidence in a way that is sufficiently robust to enable a meaningful outcome and replicable review.

By considering different study designs quantitative, qualitative, and mixed method studies, we aim to produce a comprehensive review and recommendations that could be relevant for policy makers and healthcare professionals when thinking of introducing SFR in NICU and PICU settings.

This systematic review protocol considers both qualitative and quantitative empirical studies. These review types are still evolving, and certain issues arise for both reviewers and users of reviews in terms of their robustness and the transparency of outcomes.[17] In response to this, this review protocol presents a clear systematic process and the methodology used has been adapted from the JBI guidelines.

From a preliminary search, we found out those articles are predominantly related to SFR in NICU settings rather that PICU ones. We aim that with this review, more studies exploring SFR outcomes on PICU settings will be found and described to provide a better overview on the effect of SFR in two different paediatric contexts.

Findings from this review could help in providing relevant information for evaluating the opportunity of introducing SFR assessment and subsequently preparing staff, patients, and families to this transition.

Limitations

This review protocol could present some shortcomings. First, the study type would probably not allow us to do a meta-analysis considering data heterogeneity and variability, wide variations in the primary aim of included studies, inclusion of both quantitative and qualitative studies as well as the inclusion of grey literature in the analysis. Also, language restrictions have been applied for studies written in English, Italian or Spanish meaning that some studies may have been omitted from the review. Bias inherent to individual studies would be reflected in our analysis such as different healthcare contexts that could affect study results. Finally, quality appraisal of included studies when including quantitative and qualitative studies can be challenging, as very few critical appraisal tools for mixed studies review are available and this limits the choice of quality appraisal checklists.

Conclusions

This systematic review will provide evidence on the impact of SFR introduction in NICU and PICU settings on patients, families, staff, and organizations. Overall, the review will complement the

the existing evidence on the current understanding of the effects of SFR introduction in NICU and PICU settings on patients, families, staff, and organizations.

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