

The Effectiveness of Developmental Care Bundle for Late Preterm Neonates and Their Parents: A Systematic Review

Christy Suthasini N¹, Manjubala Dash², Jeyastrikurushev³, Muthamizhselvi⁴

¹Ph.D Scholar, Mother Theresa Post Graduate and Research Institute of Health Sciences, Puducherry.

²Professor cum HOD (Dept. of OBG), Mother Theresa Post Graduate and Research Institute of Health Sciences, Puducherry.

³Professor cum HOD (Dept. of Mental Health Nursing), Mother Theresa Post Graduate and Research Institute of Health Sciences, Puducherry.

⁴ Principal Sri Manakula Vinayagar Nursing College (SMVNC), Kalitheerthalkuppam, Puducherry.

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Corresponding Author: Mrs. Christy Suthasini N*

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Abstract:

Background: Neonatal early supported transfer to home interventions aim to facilitate the transition of preterm infants from hospital to home care. This systematic review evaluates their effectiveness compared to routine NICU care.

Methods: A comprehensive search was conducted, encompassing studies that compared early supported transfer to home interventions with standard NICU care. Key outcomes included duration of hospital stay, hospital re-admission, parental wellbeing, parental confidence, breastfeeding, and infant weight gain.

Results: Ten studies with 12,821 participants were included. Early supported transfer to home interventions were associated with a reduction in hospital stay by an average of 11 days ($P < 0.001$). There was no significant increase in hospital re-admissions (RR 0.91, 95% CI 0.65–1.26, $P = 0.57$). No conclusive evidence was found regarding improvements in parental wellbeing or confidence. The interventions did not significantly affect weight gain or breastfeeding rates.

Conclusion: Early supported transfer to home interventions may reduce hospital stays for preterm infants without increasing re-admission rates. However, their impact on parental outcomes needs further investigation. The moderate to serious risk of bias in the included studies suggests that these findings should be interpreted with caution.

Keywords: Preterm infants, Neonatal care, Early discharge, Parental wellbeing, Hospital readmission, NICU, Systematic review.

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Introduction

The journey of a neonate, particularly those born preterm, is fraught with complexities that impact not only their immediate health outcomes but also their long-term developmental trajectory. As healthcare continues to advance, the focus has expanded from mere survival of these fragile individuals to ensuring their optimal development and minimizing the stress experienced by their families. In this context, developmental care bundles for late preterm neonates emerge as a critical area of investigation. This systematic review aims to evaluate the effectiveness of developmental care bundles in improving the outcomes for late preterm neonates and their parents, synthesizing evidence from a range of studies to provide a comprehensive overview.

Late preterm neonates, defined as infants born between 34 0/7 weeks and 36 6/7 weeks of gestation, represent a significant portion of preterm births [1]. Despite being closer to term, these infants are at a heightened risk for respiratory distress, thermal instability, feeding difficulties, and developmental delays compared to their full-term counterparts [2,3]. Furthermore, the psychological impact on parents, who often grapple with anxiety, stress, and the challenges of caregiving, cannot be underestimated [4].

Developmental care, as a concept in neonatology, emphasizes the provision of a supportive environment that caters to the developmental needs of neonates. It involves interventions designed to minimize stress and pain, support neurodevelopment, and promote parent-infant

interaction [5]. The bundling of these interventions into a structured program is a relatively recent approach that has garnered attention in neonatal care [6].

The effectiveness of developmental care bundles is a subject of ongoing research. Previous studies have demonstrated varied outcomes, ranging from improved neurodevelopmental scores to reduced length of hospital stay and enhanced parental satisfaction [7,8]. However, the specific impact on late preterm neonates and their parents remains less explored, necessitating a focused systematic review.

This review will meticulously analyze available literature, sourced from reputable medical databases like PubMed, to ascertain the impact of developmental care bundles on late preterm neonates. The primary outcomes of interest include neurodevelopmental progress, physiological stability (such as reduced incidence of apnea, improved feeding, and weight gain), and length of hospital stay. Secondary outcomes focus on parental factors, including stress reduction, increased confidence in caregiving, and overall satisfaction with neonatal care [9].

It is important to acknowledge the inherent challenges in synthesizing data from diverse studies. Variability in developmental care interventions, differences in healthcare settings, and the heterogeneity of study populations pose significant challenges in drawing generalized conclusions [10]. Furthermore, the evolving nature of neonatal care and the continuous emergence of new evidence necessitate a dynamic approach to reviewing and interpreting findings.

This systematic review endeavors to shed light on the effectiveness of developmental care bundles for late preterm neonates and their parents. By systematically evaluating the evidence, this study aims to inform clinical practice, contribute to policy formulation, and guide future research in this vital area of neonatal care. The ultimate goal is to enhance the care quality and outcomes for this vulnerable population and provide a framework for supportive parental involvement.

Methodology

Study Design This systematic review was designed to assess the effectiveness of developmental care bundles for late preterm neonates and their parents. It followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

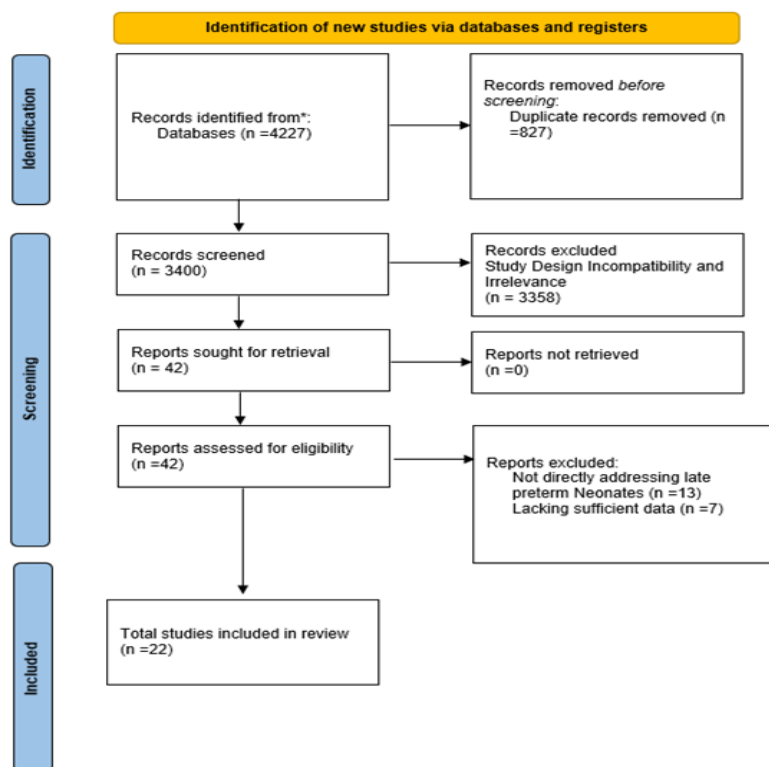
Search Strategy A comprehensive search was conducted across six databases: Cochrane Central Register of Controlled Trials (CENTRAL), World Health Organization International Clinical Trials Registry Platform, EMBASE, Medline, CINAHL, and PsychInfo. The search covered all records from inception to February 2023. Additional searches included clinical trials from the Cochrane Airways Trials Register and CENTRAL. Reference lists of primary studies and review articles were checked for additional studies.

Inclusion and Exclusion Criteria: Included were randomized controlled trials (RCTs), non-randomized intervention studies, and observational studies focusing on developmental care bundles for late preterm neonates and their parents. Studies in full text and abstract form were considered. Studies not in English or without a comparator/control group were excluded.

Data Extraction Process: Data were extracted independently by three reviewers using a pre-planned and piloted form. A fourth reviewer checked the extractions. Disagreements were resolved through consultation with a fifth reviewer.

Quality Assessment of Included Studies: The risk of bias in included RCTs was appraised using the Cochrane risk-of-bias 2 tool (RoB2), while non-randomized studies were assessed with the Risk of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool.

Statistical Analysis: Data were synthesized using a random effects model for meta-analysis where applicable, employing Jamovi software (version 2.3.13). Where meta-analysis was not feasible, data were synthesized and ordered according to the guidelines of Synthesis Without Meta-analysis (SWiM).



Results

Study Selection

- **Identification:** Database searches and trial registries yielded 4227 citations.
- **Screening:** Titles and abstracts were screened for relevance.
- **Eligibility:** Full texts of 42 potentially eligible studies were assessed.
- **Included:** Finally, 22 papers were included.

Characteristics of Included Studies The studies encompassed 12821 participants, with a majority in the control groups. The mean gestational age ranged from 24 to 36 weeks. The studies spanned from 1995 to 2023, conducted across various countries and predominantly in hospital settings. Study designs included observational studies, intervention studies, and RCTs.

Characteristics of Included Studies

The total number of participants across all 10 studies was 12821 [11]. There were substantially higher numbers of participants receiving the control (routine care) compared to those receiving the intervention. The mean age of preterm infants in the studies ranges from 24 to 36 weeks [12]; [13]. The year of publication ranged from 1995 to 2019, with seven studies published on, or after 2008 [14]; [15]; [16]; [17]; [18]; [19]; [20]; [21]; [22]; [23]. Studies were conducted in seven countries: four in Spain [17];

[18]; [22]; [23], one in New Zealand [20], one in Australia [14], one in the Netherlands [14], one in England [13], one in Sweden [19], and one in the United States of America [15]. All studies were conducted in hospital settings and ranged in duration from 12 months to 12 years [17]; [22]. Across the studies, follow up ranges from 8 days to 12 months [19]; [17].

Intervention Components

Early supported transfer to home interventions of pre-term infants varied across all studies but typically aimed to reduce the length of hospital stay, improve parents' preparedness to take their infant home and teach parents about caretaking of their child [11]. Interventions were delivered by specialist neonatology nurses [17]; [19], home-care nurses [19]; [13]; [15], research nurses [20], primary care paediatricians [17], nursing specialist programme managers [17]; [18]; [20]; [15] or members of the outreach team [17]; [18]; [23]; [22]; [16].

Across the studies, interventions had several components such as home visits, educational sessions and support which varied in frequency/intensity [24]. The most common component within the interventions were home visits which featured in seven studies [16]; [23]; [19]; [15]; [20]; [18]; [17]. Home visits were conducted at least weekly in all seven studies and in addition, conducted daily (for the first week) following discharge in two studies [20]; [15]. The mean number of home visits was reported in three studies ranging between 3.35 and 5.9 per infant

[18]; [19]; [16]. Two studies indicated that home visits lasted on average between 28 and 47 min in length [18]; [16]. Six of the 10 interventions studies included parental educational sessions that provided information and training on breastfeeding, kangaroo care (method of holding an infant involving skin-to-skin contact), preparation for discharge and arrival at home [17]; [18]; [19]; [23]; [16]; [13]. It was unclear how many education sessions parents received but the emphasis of the sessions was largely on pre-discharge planning and preparedness for the transfer home [16]. Two studies also provided parents with takeaway information (i.e. leaflets) on feeding, growth, temperature and sleeping [17]; [13]. Of the 10 intervention studies, six included 24-h telephone support where parents had a direct line to a healthcare professional [25]. One study increased parental visits to the NICU prior to discharge [15].

Five intervention studies provided guidance as part of the interventions which recommended that infants not be discharged until they reached a body weight of at least 750g [17]. Most studies recommended a body weight discharge range between 1.6 and 2.5 kg [17]; [14]; [22]. That said, weight was not always used as a criterion for discharge but instead an infant was judged to be eligible by a senior clinician [15].

Most studies did not provide details relating to the duration of the intervention, but three indicated a range from three to 11 months [13]; [15]; [22]. The comparator (control) group of each study involved usual neonatal intensive care with standard discharge times [11].

Methodological Quality of Included Studies

The 10 studies included in this review were judged to have moderate to serious concerns of bias [16]; [23]; [22]; [19]; [14]; [15]; [20]; [18]; [17]; [13]. The risk of bias in the two RCT's were judged to be of some concerns [20]; [22]. The risk of bias in four non-RCT studies was judged to be moderate [18]; [13]; [23]; [16], whilst the other four non-RCT studies were judged to be serious [17]; [14]; [15]; [19]. Largely, less rigorous study designs (e.g., non-randomised observational study) were associated with a higher risk of bias [14]; [19].

The methods of measuring the outcomes were appropriate in all studies with low risk of measurement or detection bias. The outcomes were reported according to those detailed in the protocol or methods in 90% of the included studies [17]; [18]; [13]; [15]; [14]; [19]; [23]; [20]; [22]. Eight studies had low risk of bias regarding missing data as they reported low attrition rates or used appropriate methods to impute missing data [17]; [18]; [13]; [15]; [23]; [16]; [20]; [22]. There was little to no reporting bias (outcomes), and the risk of bias in selection of the reported result was low in all but one study [16]. Blinding and selection bias was a risk in 60% of included studies as parents or staff were not blinded

and confounding differences were observed between intervention and control groups [17]; [13]; [15]; [14]; [20]; [22]. Allocation bias was a risk in most studies due to a lack of randomisation and the absence of description relating to the concealment process of treatment allocation [17]; [13]; [15]; [14]; [20]; [22].

Duration of Hospital Stay

Ten studies reported on duration of hospital stay [16]; [23]; [22]; [19]; [14]; [15]; [20]; [18]; [17]; [13]. Nine of the 10 studies indicated that early supported transfer to home interventions reduced duration of hospital stay for pre-term infants under 37 weeks gestational age [16]; [23]; [22]; [19]; [14]; [15]; [20]; [18]; [17]. A meta-analysis of four studies ($n = 1038$) showed that early supported transfer home enabled pre-term infants to be discharged 10.4 days (95% CI -13.8; -7.1, $P < 0.001$, RoB = Non-RCT: three serious & one moderate) earlier compared to those receiving standard care [17]; [15]; [19]; [23]. There was no evidence of heterogeneity between the four studies ($P = 0.602$).

Out of the six studies which could not be meta-analysed, four studies reported duration of hospital stay comparing median days between intervention and control groups and two described any differences narratively [22]; [16]; [23]; [13]. Two of the four studies showed that early supported transfer to home enabled pre-term infants to be discharged 10.5 median days ($p < 0.001$) and 6 median days ($p =$ not reported) earlier than those receiving standard care, respectively [22]; [16] (RoB = RCT: one some concerns, Non-RCT: one serious).

One study ($n = 245$) indicated that standard care enabled pre-term infants to be discharged a median of 4 days earlier compared to the intervention group [13] (RoB = non-RCT: one serious). However, this difference was not statistically significant between groups ($P = 0.32$). One further study ($n = 182$) indicated that standard care enabled pre-term infants aged 30–33 and 34–35 weeks to be discharged earlier compared to early supported discharge, but this difference was not statistically significant [16] (RoB = non-RCT: one moderate).

Two studies descriptively reported differences in duration of hospital stay between intervention and control groups [18]; [14] (RoB = non-RCT: one serious & one moderate). One study reported earlier discharge of 11 days, whilst another study stated that the total length of stay was always shorter in the early supported discharge group [18]; [14].

One study ($n = 308$) indicated that early supported discharge enabled pre-term infants to be discharged on average, 1.7 mean days earlier than those receiving standard care ($P < 0.001$) [20] (RoB = RCT: one some concerns). This study was not included in the meta-analysis because duration of hospital stay was

recorded at the point of full oral feeding and not from infant birth (therefore, not directly comparable with other studies included in this review) [20]

Parental Confidence

Two studies reported parental confidence as an outcome [19]; [13] (RoB = non-RCT: one serious & one moderate). In one study, changes in parental confidence were measured using the Perceived Maternal Parenting Self-Efficacy (PMPS-E) [13], and the Borg scale CR-10 was used in the other study [19]. In both studies (n = 302), no significant difference in parental confidence scores were observed between early supported discharge and the standard care groups (measurements at baseline, discharge, home, or one-year follow-up) (P= >0.05) [19]; [13].

Secondary Outcomes 4 – Infant Weight Gain

A pooled analysis of three studies (n = 574) using a random effects model indicated that there was no evidence of difference observed in weight gain of preterm infants between early supported discharge intervention compared to those who received standard care (Mean difference = 1.150 g per day. 95% CI: 1.85 - 4.15, Std. Error 1.53, P = 0.454) [11]; [20]; [19] (RoB = RCT: one Some concerns, Non-RCT: two serious). Values indicated that there was a statistically significant heterogeneity (I² = 91.67%, P= <0.001).

Breastfeeding

A total of five studies reported breastfeeding as an outcome [18]; [20]; [19]; [17]; [16]. In four studies, no significant difference in rates of exclusive infant breastfeeding, rates of partial infant breastfeeding, or duration of breastfeeding were observed between early supported discharge and standard care groups (at three weeks, six weeks, or six-month follow-up; P= >0.05) [20]; [19]; [17]; [16]. One study indicated that breastfeeding was more frequent in the infants receiving early supported discharge support compared to control (statistical significance not reported) [18].

Discussion

This systematic review aimed to assess the effectiveness of early supported transfer to home interventions for parents of preterm infants in NICU compared to routine care. The studies included in this review explored outcomes such as the duration of hospital stay, hospital re-admission, and various parental and infant health factors [26-35].

The evidence suggests that early supported transfer to home interventions for pre-term infants (<37 weeks GA) may reduce the duration of hospital stay by up to 11 days compared to standard NICU care. This reduction does not seem to significantly increase hospital re-admission rates, although the findings are limited by methodological weaknesses in the studies [26, 29]. This aligns with earlier

research showing no significant difference in re-admissions between early transfer to home and routine care [36, 37]. Additionally, no significant differences were found in weight gain or breastfeeding outcomes between the intervention and control groups, which supports findings from previous studies [38, 39].

Contrary to some existing literature [40], this review did not find evidence that early supported transfer to home interventions significantly enhance parental confidence or wellbeing compared to standard care [29, 31]. The moderate to serious risk of bias and the heterogeneity among the reviewed studies necessitate a cautious interpretation of these findings. The current evidence's limitations highlight the need for high-quality research in this area.

Early supported transfer to home interventions often incorporate elements like education, home visits, and 24-hour telephone support [27, 30, 32, 35, 42]. However, given the limitations of the current evidence, no definitive recommendations for clinical practice can be made.

Future research should focus on standardizing outcome measures and addressing methodological shortcomings in existing studies. However, conducting high-quality RCTs in NICU settings involves ethical and practical challenges.

The review also points out that the mean gestational age of infants in the studies was 33 weeks, suggesting that the findings may be more applicable to late or moderate preterm infants [38]. Further research is needed to evaluate these interventions' effectiveness in early preterm infants (<32 weeks GA).

One limitation of this review is its exclusion of studies published in non-English languages, which might have led to relevant research being omitted. Additionally, publication bias was not assessed due to the small number of studies, and inconsistencies in reporting limited the inclusion of some studies in the meta-analysis.

Conclusion

This systematic review underscores the potential benefits of neonatal early supported transfer to home interventions for preterm infants. Notably, the interventions show a promising reduction in the duration of hospital stay by up to 11 days compared to standard NICU care, without significantly increasing hospital re-admission rates. However, the evidence concerning the impact on parental wellbeing and confidence remains inconclusive. Despite methodological limitations in the included studies, these findings hint at the possibility of enhanced parent-infant interactions and a more efficient use of healthcare resources.

It's imperative to approach these findings with caution due to the moderate to serious risk of bias observed in the studies. The transition from hospital to home for parents of preterm infants is complex and requires careful planning and support. Future research should focus on robust, randomized control trials to establish clear, evidence-based guidelines for the implementation of these interventions.

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