



## Effects of early intervention on feeding behavior in preterm infants: A randomized controlled trial<sup>☆</sup>



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### ABSTRACT

**Background:** Although highly beneficial, human milk feeding is challenging in preterm infants due to adverse NICU factors for the infant and mother.

**Aim:** To investigate the effects of an early intervention in promoting infant's human milk feeding and acquisition of full oral feeding.

**Methods:** This study is part of a RCT. We included preterm infants born between 25<sup>+0</sup> and 29<sup>+6</sup> weeks of gestational age (GA) without severe morbidities, and their parents. Infants were randomized to either receive early intervention (EI) or standard care (SC). EI included PremieStart and parental training to promote infant massage and visual attention according to a detailed protocol. SC, in line with NICU protocols, included Kangaroo Mother Care. The time of acquisition of full oral feeding and human milk consumption at discharge were recorded.

**Results:** Seventy preterm (EI n = 34, SC n = 36) infants were enrolled. Thirteen were excluded according to the protocol. Fifty-seven (EI n = 29, SC n = 28) infants were evaluated at discharge. The two groups were comparable for parent and infant characteristics. A significantly higher rate of infants fed with any human milk was observed in the EI group (75.9%) compared with the SC group (32.1%) (p = 0.001), and EI infants were four times more likely to be fed exclusively with human milk. Full oral feeding was achieved almost one week earlier in EI infants (mean postmenstrual age 36.8 ± 1.6 vs 37.9 ± 2.4 weeks in EI vs SC, p = 0.04).

**Conclusions:** Early interventions promoting mother self-efficacy and involvement in multisensory stimulation have beneficial effects on human milk feeding in preterm infants.

### 1. Background

Preterm birth is the leading cause of infant mortality worldwide [1] and it is associated with several neonatal morbidities, the main ones including sepsis, bronchopulmonary dysplasia (BPD), necrotizing enterocolitis (NEC) and brain lesions [2]. Infants' life quality may also be negatively affected by long-term neurodevelopmental delays [3,4].

In premature infants, breast milk plays a key role with several studies reporting a significant decrease of sepsis and NEC or lower rates of retinopathy of prematurity (ROP) [5–7]. Similarly, it has been demonstrated to positively affect neurodevelopment in the long term,

with benefits in motor and cognitive outcomes and neurobehavioral organization [8,9].

Therefore, exclusive human milk is recommended by the American Academy of Pediatrics as the first choice for preterm infants' enteral nutrition, especially during the first six months of life [10].

However, preterm birth and admission to a Neonatal Intensive Care Unit (NICU) are the strongest predictors of not being exclusively breastfed at discharge [11]. Vohr et al. reported that 78% of mothers initiate human milk feeding in the NICU, but only 31% provide it at discharge [12].

Human milk feeding is particularly challenging for preterm infants

**Abbreviations:** BPD, bronchopulmonary dysplasia; CRIB, Clinical Risk Index for Babies; cPVL, cystic periventricular leukomalacia; cUS, cranial ultrasound; EI, early intervention; GA, gestational age; GMH, IVH Germinal Matrix Hemorrhage-Intraventricular Hemorrhage; KMC, Kangaroo Mother Care; NCPAP, nasal continuous positive airway pressure; NEC, necrotizing enterocolitis; NICU, Neonatal Intensive Care Unit; NIDCAP, Newborn Individualized Developmental Care Assessment Program; ROP, retinopathy of prematurity; SC, standard care; SES, socio economic status; SGA, small for gestational age

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and their mothers because of the negative factors they are exposed to, such as the NICU environment, neonatal morbidities, the paucity of parental contact, delayed breastfeeding, and other factors [13]. All of these factors can affect the mother-infant relationship, which is essential for starting and continuing lactation [14,15]. An established practice to improve the mother-infant relationship in NICU is Kangaroo Mother Care (KMC), and its benefits on breastfeeding are well-known [16]. Skin-to-skin contact promotes a greater closeness between infant and mother, helping her to interpret infant cues [17]. The potential beneficial effects of a more active tactile contact, such as preterm baby massage, have been recently suggested to have a positive impact on infant neurodevelopment [18,19] and duration of hospital stay [20], although the reported evidence related to the latter issue are still inconsistent [21,22]. Moreover, early intervention strategies, including infant massage, have been proved to be effective on sensitive and responsive interactions between preterm infants and their mothers [22,23], as documented by recently published RCTs [22,23].

However, the effects of an early multisensory intervention that includes preterm baby massage and early mother-infant interaction on infant's feeding behavior have not yet been investigated.

The present study is part of an RCT aimed at assessing the effectiveness of an early intervention program in promoting visual function and neurodevelopment in preterm infants. Within this context, further analyses have been performed, with the exploratory purpose of investigating the effect of the early intervention in promoting infants' milk feeding and acquisition of full oral feeding.

## 2. Methods

### 2.1. Subjects

The trial was approved by the Ethics Committee Milano Area B on the 14th of March 2014. Written parental informed consent was obtained from the parents.

All of the preterm babies, consecutively born between 25<sup>+0</sup> and 29<sup>+6</sup> weeks gestational age (GA) from April 2014 to January 2017 at the same institution, were eligible for the study. Exclusion criteria were as follows: multiple pregnancy (triplets or higher); genetic syndromes and/or major congenital malformations; NEC stage III according to Bell [24]; and major brain lesions, including Germinal Matrix Intraventricular Hemorrhage (GMH-IVH) > 2° grade according to Papile [25], documented by early cranial ultrasound (cUS). Infants who developed stage II NEC were also excluded from the present exploratory study due to the potential adverse effect of any stage of NEC on oral feeding acquisition related to the protracted suspension of oral feeding.

Mothers were selected according to the following inclusion criteria: age over 18 years, good comprehension of the Italian language, no single-parent families, no obvious cognitive impairments or psychiatric disorders, and no drug addictions.

Infants were recruited after the first week of life and if clinically stable (no need for invasive mechanical ventilation and no active sepsis).

### 2.2. Study design

This study is part of a larger RCT (Trial Registration Number: NCT02983513).

Infants were randomized either to receive early intervention (EI) or standard care (SC) using sealed envelopes prepared in groups of 10 through computer-generated randomization. Twins were considered together for the randomization, as the EI program was mainly parent-based.

The EI program was delivered in addition to routine care during the NICU stay by the same investigator, according to the PremieStart Protocol [26], to train parents to: recognize signs of infant stress and alert-available behavior to promote mother-infant interaction; adopt

principles of graded stimulation; and optimize interactions and avoid overwhelming infants through facilitation strategies (for example, engage and support the visual attention of the newborn). The program was held in eight main sessions and one additional post-discharge session. In addition, parents were trained and invited daily to promote preterm baby massage therapy and visual attention when babies were in an alert or active behavioral state according to Brazelton [27]. A daily diary was given to parents to register the interventions. Preterm baby massage therapy was performed twice a day by parents after receiving two training sessions and not before both 30 weeks post-menstrual age and 10 days of postnatal life. Each massage session consisted on 10 min of slow tactile stimulation of the back, applying moderate-pressure stroking with both hands. During the massage, the infant was placed in the prone position. Each session was performed at least 2 h after the previous one.

Parents promoted visual attention at least once a day using either a black and white toy or the parent's face. This interaction took place when the baby was in an alert behavioral state and not before 34 weeks of postmenstrual age. Infants were supine, either on the parent's lap or in their crib, and were nested with a blanket to avoid excessive stimulation.

SC, according to the NICU protocols, included KMC, nesting and minimal handling. During the study period, no specific interventions to decrease stress (e.g., Newborn Individualized Developmental Care Assessment Program - NIDCAP) were in use.

KMC was part of the clinical routine practice for both groups and it was started as soon as infants were weaned from mechanical ventilation regardless of the randomization group.

The baseline characteristics of the two groups were collected from hospital charts. Recorded data included: gender, birth weight and GA, small for gestational age (SGA) [28], twin birth, mode of delivery, Apgar scores at 1 and 5 min, Clinical Risk Index for Babies (CRIB) [29], number of days on invasive mechanical ventilation or on nasal continuous positive airway pressure (NCPAP) or high-flow nasal cannula, duration of hospital stay and postmenstrual age at discharge.

The following neonatal morbidities were considered: ROP [30], BPD [31], GMH-IVH [25] and sepsis (increased plasma levels of C-reactive protein associated with a positive blood culture).

Family socio-economic status (SES) was calculated and classified according to Hollingshead's criteria [32].

The feeding protocol of the unit was the same during the study period, and all mothers were provided with a pump and encouraged to start pumping on day 1 after birth and to increase the pumping interval to every 3 h.

In case of unavailable or insufficient human milk, formula feeding was started. Infants' human milk intake at discharge was calculated from the infants' computerized medical chart, completed by nurses blinded to group allocation and expressed as a percentage of the total milk intake. When infants were breast fed, mothers were asked to weigh their baby before and after each feeding so that the volumes consumed by the baby could be calculated. Infants were categorized as receiving exclusive formula, exclusive human milk and human milk plus formula, and the data are presented accordingly.

For further analysis, infants fed any extent of human milk, irrespective of the quantity or the exclusivity, were categorized as fed any human milk [10].

Fortification of human milk was started when the enteral intake reached 90 ml/kg/day. The volume of enteral feeding was increased based on the infants' cardio-respiratory stability and gastrointestinal tolerance. Human milk was fortified with a target fortification to comply with the guidelines from the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN). The target levels of the human milk macronutrients were as follows: 3 g/100 ml of protein, 8.8 g/100 ml of carbohydrate and 4.4 g/100 ml of fat [33].

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