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Parental engagement and early interactions with preterm infants during the stay in the NICU: protocol of a mixed-method and longitudinal study

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Parental engagement and early interactions with preterm infants during the stay in the NICU: protocol of a mixed-method and longitudinal study

ABSTRACT

Introduction: The preterm infants' developmental outcomes depends on both biological and environmental risk factors. The environmental factors include prolonged parental separation, less exposure to early mother/father-infant interactions and the parents' ability to respond to the trauma of premature birth. In the case of premature birth, the father's ability to take an active part in the care of the child from the start is essential. The parents' emotional closeness to the preterm infant hospitalized in the NICU—through touch, affectionate talk, visual contact, etc.—may be crucial to the well-being of the newborn, the development of mutual regulation, the establishment of a functioning parent-infant affective relationship, and the parents' confidence in their ability to provide care for their baby.

Methods and analysis: This is a mixed-methods, observational and longitudinal study. The methodological strategy will include: (1) ethnographic observation in a level III NICU located in Northern Italy for a duration of 18 months; (2) one 3 minute video recording of mother-infant and father-infant face-to-face interaction in NICU; (3) a single semi-structured interview with fathers during the infants' hospital stay; (4) one 5 minute video recording of mother-infant and father-infant face-to-face interaction in the laboratory at 4 months corrected age; (5) a parent self-report questionnaire on depression and couple relationship quality questionnaire at the approximate times of video recording sessions.

Ethics and dissemination: The study protocol was approved by the Ethical Committee for Clinical Trials of the Verona and Rovigo Provinces. Results aim to be published in an international peer-reviewed journal, and presented at relevant national and international conferences. This research project will develop research relevant to (A) the quality and modalities of maternal and paternal communication with the preterm infant in the NICU; (B) the influence of maternal/paternal social stimulation on infant states; (C) the quality and modalities of paternal support to the partner, and how this influences the mother-infant relationship.

Strengths and limitations of this study:

- This is the first study focused on maternal/paternal communicative behaviors addressed spontaneously to the preterm infant hospitalized in the NICU, and their effects on the infant's behavioral states.
- Results from this project will increase the very scant knowledge about the presence of early interactive contingencies between mother/father and very preterm infant in the NICU, and their possible predictive role of positive outcomes in mother-infant and father-infant relationship.
- Findings will be limited to the experiences of Italian parents.

INTRODUCTION

The preterm birth is a physiologically traumatic event in which infants' healthy neurological and emotional development is threatened.¹⁻⁵ The preterm infants' developmental outcomes depend on both biological and environmental risk factors.⁶⁻¹⁰ During the period of hospitalization in the Neonatal Intensive Care Unit (NICU), environmental factors include physical (e.g. excessive noise and light levels, painful procedures) and psychosocial (e.g. prolonged parental separation) stressors.^{11,12} Furthermore, preterm infants in incubators cannot experience the earliest mother-infant interactions which play a crucial role in early regulation of the stress response^{13,14} and provides a foundations for the development of mutual regulation.¹⁵ These skills are known to have a long term impact on the functioning of affective relationships and healthy developmental outcomes.⁶ The immature brain of a preterm infant is particularly vulnerable to the quality of these experiences.¹⁶

When a baby is born prior to the physiological term of 39 weeks, the process of preparation for parenthood is also interrupted ahead of time.^{17,18} In this way, parents are also premature.¹⁹ In this situation, the parent is required to adjust their emotional structures in order to respond to the trauma of premature birth.²⁰ This process is exceptionally important as the inability to respond to the trauma may have negative consequences on infant development.^{21,22} Often, mothers require a recovery period after the premature birth. As a result, the father's ability to take an active part in the care of the child from birth may be crucial.²³ However, fathers' can face many obstacles that can impact their roles as partner and father,²⁴⁻²⁶ with possible negative consequences on partners' affective states (e.g., depression, anxiety),²⁷⁻²⁹ and on the development of parental relationships with the infants'.^{28,30} In the literature to date, few studies have focused their investigations on fathers' role in preterm birth.

Past studies exploring the quality of care given to preterm infants in the NICUs have shown that parent-preterm infant closeness during hospitalization, particularly skin-to-skin contact with the mother, and interventions aimed at supporting parental involvement in infant care can enhance neurobehavioral outcomes.³¹⁻³³ Other recent studies have shown that exposure to recorded or live maternal/parental voice has beneficial effects on physiological and behavioral states of preterm infants,³⁴⁻³⁶ and predicts infants' vocalizations more than the voices of other adults.³⁷ However, very few studies have focused on mothers'³⁸⁻⁴⁰ or both parents'²⁸ spontaneous behaviors with their infants in the NICU. There has also been little research directed at observing caregiving routines before discharge or when the baby was allowed to spend some time out of the incubator. To our knowledge, no study has focused on maternal and/or paternal communicative behaviors addressed spontaneously to the preterm infant hospitalized in a level III NICU, and how this may impact the infant's behavioral states.

It is important to acknowledge that parents of very preterm infants are at great risk of psychological distress and depressive symptoms^{27,41,42} that may interfere with their sensitivity to infant cues.^{28,43} For instance, parental depression – as an inhibitory factor of good parent-child

1 interactions – has a negative impact on the early neurobehavioral⁴⁴ and socio-emotional⁴⁵
2 development of the child. Nevertheless, the parents' emotional closeness to the preterm infant in
3 the incubator – through touch, affectionate talk, visual contact, and other sensorimotor
4 interactions – may be crucial to the well-being of the newborn (physiological and behavioral
5 benefits),^{34,46} the establishment of parent-infant relationship,⁴⁷ and the parents' sense of
6 confidence in providing care for their baby.³³ In addition, other studies have found that a
7 nurturing home environment, in which basic and psychological needs are met, is associated with
8 better cognitive and social-emotional development in children born preterm and very
9 preterm.^{10,22,48}

16 **Objectives**

17 The first objective of this study is to explore the presence of interactive contingency. Interactive
18 contingency is defined as the predictability of each partner's behavior from that of the other,
19 over time.⁴⁹ In other words, 'how I affect you', and 'how you affect me'. The study aimed to
20 examine the presence of interactive contingency between parental communicative behaviors
21 with the hospitalized infant and infant behavioral states and gaze direction.

22 The second objective of the study is to assess whether early interactive contingency between
23 mother/father and preterm infant in the NICU predicts positive outcomes in the mother-
24 infant/father-infant relationship and infant development at 4 months corrected age.

25 The third objective of the study is to investigate the emotional impact of the premature birth of a
26 son/daughter on the fathers. This objective will be explored by examining a number of factors
27 namely, the way in which the perception of the fathers' role (or absence of role) influences the
28 care of the baby, the support to the partner, and the mother-infant relationship.

37 **METHODS AND ANALYSIS**

38 This is a mixed-methods, observational and longitudinal study. The methodological strategy
39 will include: (1) ethnographic observation in a level III NICU located in Northern Italy for a
40 duration of 18 months; (2) one 3 minute video recording of mother-infant and father-infant face-
41 to-face interaction in NICU between 34/35+6 weeks of post-conception age; (3) a single semi-
42 structured interview to the fathers during the infants' hospital stay; (4) one 5 minute video
43 recording of mother-infant and father-infant face-to-face interaction in the Social and Language
44 Development Lab of Verona University at 4 months corrected age; (5) a parent self-report
45 questionnaire on depression and couple relationship quality undertaken at the approximate times
46 of video recording sessions.

54 **Selection criteria**

55 *Inclusion criteria*

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Infants are eligible to be included in the study if they meet the following criteria: (1) birth at less than 34 weeks.

Mothers and fathers are eligible to be included in the study if they meet the following criteria: (1) born and raised in Italy; (2) both members of the couple must give consent to participate in the study.

Exclusion criteria

Infants will be excluded from the study if: (1) they have perinatal asphyxia; (2) they have neurologic pathologies (periventricular leukomalacia up to stage I and/or intraventricular hemorrhage up to stage II); (3) they experience malformation syndromes and/or major malformations; (4) they have sensory deficits; (5) they present with metabolic or genetic disease.

Mothers and fathers will be excluded from the study if: (1) they have a psychiatric illness; (2) they have issues with drug or substance abuse; (3) they are not living together.

To participate in the study it is necessary that both parents and infants must meet the inclusion and exclusion criteria.

Procedures

Recruitment

All parents (couples: mothers and fathers) of preterm infants born between 17 September 2015 and 31 March 2017 and hospitalized at level III NICU of the Borgo Roma Hospital - Azienda Ospedaliera Universitaria Integrata Verona (northern Italy) will be invited to participate in the study. Researcher will invite the parents to participate during the hospital stay, when the infant's medical condition has been stabilized. The recruitment of the study participants will take place from 32 to 34+6 weeks after conception. According to the calculation of sample sizes, a minimum of 25 dyads mother-infant and father-infant will be recruited.

Ethnographic observation

In order to minimize the potentially negative and invasive risks associated with having an observing researcher, the researcher will have a familiarization period with the parents in the NICU. The researcher will observe the interactions between (1) parents and infant, (2) mothers and fathers, (3) parents and staff (nurses, neonatologist and psychologist) and (4) infant and nurses. The researcher will attend meetings between neonatologists, and observe conversations between staff and parents. The researcher will hold individual and/or couple informal talks with mothers and fathers. The researcher will present the research project to the parents who meet inclusion/exclusion criteria.

Parent-infant interaction in NICU

Between 34 and 35+6 weeks of post-conception age, the mother's spontaneous social stimulation with the neonate on a radiant warmer (an open bed with an overhead heating source) and the neonate's responses will be videotaped during a 3-minute interaction. Subsequently, the neonate will be let rest for at least 5 minutes. Afterwards, the father's social stimulation with the neonate on a radiant warmer and the neonate's responses will be videotaped over a 3-minute interaction. The date the video will be recorded depends on: (1) the infant's medical conditions, (2) the mother's and father's restrictions on the time available to stay in the NICU, (3) the infant's behavioral states (for instance, if the infant is sleeping or crying the video recording will be postponed).

Qualitative interviews in NICU

Before the infant's discharge from the NICU, fathers will be contacted to participate in a single semi-structured interview. The interviews will allow for a deeper and fuller understanding of the emotional impact that the premature birth has on fathers. The topic guide will include the following areas: the first time that the father saw and/or touched their baby; the technical aspects of recovery; the bond with the baby; the caregiving activities; the feelings associated with seeing their partner care for, feed, or cuddle their baby; space for one's own emotions when supporting and assisting their partner; work and management of the responsibilities in the external world during the period of hospitalization in NICU; the couple's relationship quality during the pregnancy and the period of hospitalization in NICU; how the feelings towards the baby change from the moment of his/her birth and the discharge moment; amongst other topics. In addition to fathers who will participate in the parent-infant interaction, we will recruit additional fathers who met the inclusion criteria for parents and infants. These additional participants do not need to meet the infants' exclusion criteria. This will allow the study to have a more representative sample of daily clinical reality.

Interviews will be carried out in a private room at NICU, and will be digitally recorded.

Questionnaires in NICU

In approximate times with videotaping, parents will be asked to complete the Center for Epidemiologic Studies Depression Scale (CES-D)⁵⁰ to assess symptoms of depression, and the Dyadic Adjustment Scale (DAS)⁵¹ to assess couple relationship quality.

Parent-infant interaction after discharge

At 4 months corrected age, 5 minutes of mother-infant and father-infant face-to-face spontaneous interaction will be videotaped in the Social and Language Development Laboratory at the University of Verona.

Questionnaires after discharge

Parents will also be asked to complete the CES-D Scale and the DAS Scale at 4 months corrected age in order to assess depression and relationship quality at this time point.

Parents and infants data

Data on parents' demographic and socioeconomic characteristics (age, marital status, years of formal education, occupation, family composition, and subjective social network), gynecological and obstetric history, infant's neonatal characteristics (gestational age, weight, height and head circumference) and information about severity of the perinatal problems (evaluated using the Perinatal Risk Inventory; PERI)⁵² will be collected. Information will also be collected regarding the infant's hospitalization and developmental outcomes (assessed after discharge in a follow-up based on a pediatric examination including a somatic and neurological status assessment).

Data Analysis

Video coding

Parent and infant behaviors from videotaped interactions will be coded micro-analytically, using units of 1 second.⁵³⁻⁵⁶ Behaviors will be coded using ordinal scales.

Features of parent's social stimulation in the NICU will be coded including Gaze Direction, Facial Affect, Vocal Stimulation, and Touch, and the composite Maternal Affiliative Behavior³⁹ – including the sum proportions of Gaze at infant face, Positive Affect, ID-Speech and Affectionate Touch – will be computed as macro-category of maternal/paternal sensitive behavior. Neonate's responses will be measured in terms of behavioral states (Brazelton's Neonatal Behavioral Assessment Scale adapted by Als³¹ for preterm infants), Face Expression, and Gaze Direction.

Parents' and infants' behaviors during face-to-face interaction at 4 months will be coded in categories of parent interactive behaviors (Affectionate Talk/Touch, Playful Talk/Touch, Mirroring, Following, Stimulating, Demanding, Disrupting) and infant joint states of gaze direction and expressive configurations (Unengaged, Simple Attention, Active Attention, Smile, Cooing, Fussy/Crying) adapted from Lavelli and Fogel^{15,57}, and Beebe et al.⁵⁸

The inter-rater reliability for maternal/paternal/infant behaviors will be calculated on 15% of videotapes, which will be coded by a second researcher who is blind to the aims of the study.

Quantitative data

To explore the possible presence of early interactive contingency between parental communicative behaviors and neonate's behavioral states, a co-occurrence and sequential analysis will be run between parental behaviors grouped according to their quality (Maternal/Paternal Affiliative Behavior vs. Other communicative behaviors vs. No

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communicative behaviors) and neonate's behavioral states grouped for readiness for social stimulation (Alert state vs. Other states). Furthermore, to assess possible associations between study variables (neonatal risk score evaluated using the PERI⁵², Maternal/Paternal Affiliative Behavior, neonate's Alertness, early interactive contingency, maternal/paternal depression, couple relationship quality), a bi-variate correlation analysis will be performed.

With regard to the follow-up of mother/father-infant interaction at a corrected age of 4 months, a sequential analysis (GSEQ)⁵⁹ will be performed on the infant's behaviors as target and maternal/paternal behaviors as given, and vice versa, to assess any significant transitional probability – i.e., interactive contingency – between dyads' behaviors. The analysis will be run on each mother-infant and father-infant dyad separately, to allow for the calculation of a measure of Mutual Engagement¹⁵ indexed by the duration of sequences of bidirectional links between all categories of infant's positive engagement and maternal Mirroring/Affectionate/Playful behaviors.

To create indices of self-contingency (autocorrelation) and interactive contingency (cross-correlation), a multilevel time-series analysis⁶⁰ will be performed. This allows for the assessment of whether early interactive contingency in the NICU can predict later Mutual Engagement. The self-contingency occurs when the individual's moment by moment behavior adjusts to his/her own prior behavior; while interactive contingency occurs when the individual's moment by moment behaviors adjusts to his/her partner's prior behavior.^{58,61} In a bi-variate series, it is expected that each partner's behavior may predict the other dyad member's current behavior (bidirectional influence), or only one partner's behavior may predict the other partner's behavior (unidirectional influence). Through the assessment of interactive process we will differentiate the direction of influence for both partners.

Qualitative data

All transcripts will be verified by one researcher before data analysis by listening to the audio recording and checking for accuracy of the written transcript. The transcripts will be analyzed using thematic content analysis⁶² for each question in the interview. Thematic analysis is a qualitative analytic method for identifying, analyzing, and reporting themes within data.⁶³ Transcripts will be read and re-read so as to become familiarized with the data. Data will be managed using NVivo 11 (QSR International, USA). The first author will use an initial open coding to allow for the emergence of recurrent themes across fathers. Response patterns that will be relevant across all fathers will be coded and organized in structured thematic categories (along with verbatim quotes which illustrate each theme).^{63,64} All codes will be compared and contrasted, and then they will be examined and discussed by the first author and two other researchers to identify meaningful categories or emergent themes. Codes will be removed if they have a single occurrence. Coding reliability and face validity achieved by remaining codes will be checked. A final coding schedule (defining each theme, with examples of verbatim

quotes which illustrate each theme) will be collated. All transcripts will be re-coded by the first author using the coding schedule. The inter-rater reliability will be calculated on 15% of transcriptions, which will be coded by a second researcher.

Each father's interview responses will be correlated to the results of the questionnaires and to perinatal risk inventory (PERI)⁵².

ETHICS AND DISSEMINATION

Ethical principles

Ethics approval of the study protocol was obtained from the Ethical Committee for Clinical Trials of the Verona and Rovigo Provinces (reference no. 569CESC).

Description of risks

There will be no risks associated with participation in any aspect of the described study.

Informed consent

Previous to study participation all mothers and fathers will receive written and oral information about the content and extent of the study. If they are willing to participate, they will sign the informed consent form. They will be able to withdraw from the study at any time without explanation, without any consequences to the care of the family at the Azienda Ospedaliera Universitaria Integrata Verona.

Data protection

All the video files, coding sheets, audio files, audio transcriptions, questionnaires and documents, will be provided with a special alphanumeric code and will not contain any identifying information. The electronic data will be stored on a computer that is password protected. The paper materials will be stored in a locked archive. Only members of the internal study team will have access to the data.

Scientific, clinical and social impact

To our knowledge, this is the first research project focused on maternal/paternal communicative behaviors addressed spontaneously to the preterm infant hospitalized in the NICU, and their effects on the infant's behavioral states. Therefore, this research project will provide new knowledge relevant to the (a) quality and modalities of maternal and paternal communication with the preterm infant in the NICU when the infant is on a radiant warmer; (b) influence of maternal/paternal social stimulation on infant's states, and the associated potential benefits for the preterm infant; (c) quality and modalities of paternal support to the mother/partner, and the manner by which this influences the mother-infant relationship. In addition, results from this project will increase the very scant knowledge about the presence of early interactive

contingencies between mother/father and very preterm infant in the NICU, and their possible predictive role of positive outcomes in mother-infant and father-infant relationship.

This knowledge highlights possible factors on which early intervention programs in the NICU should focus in order to support the development of a healthy mother-father, mother-infant and father-infant relationship. Additionally, analyzing the quality of maternal/paternal communication with the preterm infant on radiant warmer allows for the identification of early indexes of risk in the developing mother/father-preterm infant relationship. This may in turn help to improve the identification of mother/father-infant dyads who are at-risk and who might benefit from early preventive intervention. With regard to this, staff members in the NICU might become more aware of individual differences in mothers and fathers that may facilitate or interfere with the parents' ability to provide sensitive care for their preterm infants.

Dissemination

The results of this study will be published in international peer-reviewed journal. Additionally, key results will be presented at relevant national and international conferences. Finally, the results of this study will form the first author's PhD thesis.

Contributors AS was involved in the general study design. ML drafted the quantitative aspects of the study protocol. AS and ML were involved in the writing of the manuscript.

Competing interests None

REFERENCES

1. Doyle LW, Anderson PJ. Adult outcome of extremely preterm infants. *Pediatrics*. 2010;126(2):342-351. doi:10.1542/peds.2010-0710.
2. Johnson S, Fawke J, Hennessy E, et al. Neurodevelopmental disability through 11 years of age in children born before 26 weeks of gestation. 2009;124(2). doi:10.1542/peds.2008-3743.
3. Marlow N, Wolke D, Bracewell MA, Samara M. Neurologic and developmental disability at six years of age after extremely preterm birth. *N Engl J Med*. 2005;352(1):9-19. doi:10.1056/NEJMoa041367.
4. Mwaniki MK, Atieno M, Lawn JE, Newton CRJC. Long-term neurodevelopmental outcomes after intrauterine and neonatal insults: A systematic review. *Lancet*. 2012;379:445-452. doi:10.1016/S0140-6736(11)61577-8.
5. Talge NM, Holzman C, Wang J, Lucia V, Gardiner J, Breslau N. Late-preterm birth and its association with cognitive and socioemotional outcomes at 6 years of age. *Pediatrics*. 2010;126(6):1124-1131. doi:10.1542/peds.2010-1536.
6. Feldman R. Parent-infant synchrony and the construction of shared timing; physiological precursors, developmental outcomes, and risk conditions. *J Child Psychol Psychiatry*. 2007;48(3-

- 4):329-354. doi:10.1111/j.1469-7610.2006.01701.x.
7. Feldman R, Eidelman AI. Neonatal state organization, neuromaturation, mother-infant interaction, and cognitive development in small-for-gestational-age premature infants. *Pediatrics*. 2006;118(3):e869-e878. doi:10.1542/peds.2005-2040.
8. Greenberg MT, Crnic KA. Longitudinal predictors of developmental status and social interaction in premature and full-term infants at age two. *Child Dev*. 1988;59(3):554-570. <http://www.scopus.com/inward/record.url?eid=2-s2.0-0024022307&partnerID=tZOtx3y1>.
9. Minde K. Prematurity and serious medical conditions in infancy: Implications for development, behaviour, and intervention. In: Zeanah CH, ed. *Handbook of Infant Mental Health*. Vol New York: Guilford; 2000:176-194.
10. Treyvaud K, Inder TE, Lee KJ, Northam EA, Doyle LW, Anderson PJ. Can the home environment promote resilience for children born very preterm in the context of social and medical risk? *J Exp Child Psychol*. 2012;112(3):326-337. doi:10.1016/j.jecp.2012.02.009.
11. Maroney DI. Recognizing the Potential Effect of Stress and Trauma on Premature Infants in the NICU: How are Outcomes Affected? *J Perinatol*. 2003;23(8):679-683. doi:10.1038/sj.jp.7211010.
12. Montirosso R, Provenzi L. Implications of epigenetics and stress regulation on research and developmental care of preterm infants. 2015;44(2):174-182. doi:10.1111/1552-6909.12559.
13. Meaney MJ, Szyf M. Maternal care as a model for experience-dependent chromatin plasticity? 2005;28(9):456-463. doi:10.1016/j.tins.2005.07.006.
14. Mendelsohn A. Recovering reverie: Using infant observation in interventions with traumatised mothers and their premature babies. *Infant Obs*. 2005;8(3):195-208. doi:10.1080/13698030500375693.
15. Lavelli M, Fogel A. Interdyad differences in early mother-infant face-to-face communication: real-time dynamics and developmental pathways. *Dev Psychol*. 2013;49(12):2257-2271. doi:10.1037/a0032268.
16. Lupien SJ, McEwen BS, Gunnar MR, Heim C. Effects of stress throughout the lifespan on the brain, behaviour and cognition. 2009;10(6):434-445. doi:10.1038/nrn2639.
17. Brusweiler-Stern N. Pregnancy: preparation for your new identity. In: Stern D, Brusweiler-Stern N, eds. *The Birth of a Mother: How the Motherhood Experience Changes You Forever*. Vol New York: Basic Books; 1998.
18. Pancer SM, Pratt M, Hunsberger B, Gallant M. Thinking ahead: complexity of expectations and the transition to parenthood. *J Pers*. 2000;68(2):253-280. <http://www.scopus.com/inward/record.url?eid=2-s2.0-0034167201&partnerID=tZOtx3y1>.
19. Stern M, Karraker KH, Sopko AM, Norman S. The prematurity stereotype revisited: Impact on mothers' interactions with premature and full-term infants. *Infant Ment Health J*. 2000;21(6):495-509. doi:10.1002/1097-0355(200011/12)21:6<495::AID-IMHJ7>3.0.CO;2-F.
20. Jotzo M, Poets CF. Helping parents cope with the trauma of premature birth: an evaluation of a trauma-preventive psychological intervention. *Pediatrics*. 2005;115(4):915-919. doi:10.1542/peds.2004-0370.
21. Goldberg S, DiVitto B. Parenting children born preterm. *Handb Parent*. 1:209-231. <http://www.scopus.com/inward/record.url?eid=2-s2.0-0000474955&partnerID=tZOtx3y1>.

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22. Siegel LS. Reproductive, perinatal, and environmental factors as predictors of the cognitive and language development of preterm and full-term infants. *Child Dev.* 1982;53(4):963-973. <http://www.ncbi.nlm.nih.gov/pubmed/6181941>. Accessed December 29, 2015.
 23. Lindberg B, Axelsson K, Öhrling K. The birth of premature infants: Experiences from the fathers' perspective. *J Neonatal Nurs.* 2007;13(4):142-149. doi:10.1016/j.jnn.2007.05.004.
 24. Pohlman S. Fathering premature infants and the technological imperative of the neonatal intensive care unit: An interpretive inquiry. 2009;32(3). doi:10.1097/ANS.0b013e3181b0d68c.
 25. Fegran L, Helseth S, Fagermoen MS. A comparison of mothers' and fathers' experiences of the attachment process in a neonatal intensive care unit. 2008;17(6):810-816. doi:10.1111/j.1365-2702.2007.02125.x.
 26. Lundqvist P, Westas L, Hallström I. From distance toward proximity: fathers lived experience of caring for their preterm infants. *J Pediatr Nurs.* 2007;22:490-497.
 27. Carter JD, Mulder RT, Frampton CMA, Darlow BA. Infants admitted to a neonatal intensive care unit: parental psychological status at 9 months. *Acta Paediatr.* 2007;96(9):1286-1289. doi:10.1111/j.1651-2227.2007.00425.x.
 28. Zelkowitz P, Bardin C, Papageorgiou A. Anxiety affects the relationship between parents and their very low birth weight infants. *Infant Ment Health J.* 2007;28(3):296-313. doi:10.1002/imhj.20137.
 29. Robertson E, Grace S, Wallington T, Stewart DE. Antenatal risk factors for postpartum depression: a synthesis of recent literature. *Gen Hosp Psychiatry.* 2004;26(4):289-295. doi:10.1016/j.genhosppsy.2004.02.006.
 30. Gutierrez-Galve L, Stein A, Hanington L, Heron J, Ramchandani P. Paternal Depression in the Postnatal Period and Child Development: Mediators and Moderators. *Pediatrics.* 2015;135(2):e339-e347. doi:10.1542/peds.2014-2411.
 31. Als H, Duffy FH, McAnulty GB, et al. Early Experience Alters Brain Function and Structure. *Pediatrics.* 2004;113(4):846-857. doi:10.1542/peds.113.4.846.
 32. Feldman R, Weller A, Sirota L, Eidelman AI. Skin-to-Skin contact (Kangaroo care) promotes self-regulation in premature infants: sleep-wake cyclicality, arousal modulation, and sustained exploration. *Dev Psychol.* 2002;38(2):194-207. <http://www.ncbi.nlm.nih.gov/pubmed/11881756>.
 33. Flacking R, Lehtonen L, Thomson G, et al. Closeness and separation in neonatal intensive care. *Acta Paediatr.* 2012;101(10):1032-1037. doi:10.1111/j.1651-2227.2012.02787.x.
 34. Filippa M, Devouche E, Arioni C, Imberty M, Gratier M. Live maternal speech and singing have beneficial effects on hospitalized preterm infants. *Acta Paediatr.* 2013;102(10):1017-1020. doi:10.1111/apa.12356.
 35. Krueger C, Parker L, Chiu S-H, Theriaque D. Maternal voice and short-term outcomes in preterm infants. *Dev Psychobiol.* 2010;52(2):205-212. doi:10.1002/dev.20426.
 36. Lee H, White-Traut R. Physiologic responses of preterm infants to the male and female voice in the NICU. *J Pediatr Nurs.* 2014;29(1):e3-e5. doi:10.1016/j.pedn.2013.04.007.
 37. Caskey M, Stephens B, Tucker R, Vohr B. Importance of parent talk on the development of preterm infant vocalizations. 2011;128(5):910-916. doi:10.1542/peds.2011-0609.
 38. Coppola G, Cassibba R. Mothers' social behaviours in the NICU during newborns' hospitalisation: An observational approach. 2010;28(2):200-211.

- doi:10.1080/02646830903298731.
39. Feldman R, Eidelman AI. Maternal postpartum behavior and the emergence of infant-mother and infant-father synchrony in preterm and full-term infants: the role of neonatal vagal tone. *Dev Psychobiol.* 2007;49(3):290-302. doi:10.1002/dev.20220.
40. Keren M, Feldman R, Eidelman AI, Sirota L, Lester B. Clinical Interview for high-risk Parents of premature infants (CLIP) as a predictor of early disruptions in the mother-infant relationship at the nursery. *Infant Ment Health J.* 2003;24(2):93-110. doi:10.1002/imhj.10049.
41. Lefkowitz DS, Baxt C, Evans JR. Prevalence and correlates of posttraumatic stress and postpartum depression in parents of infants in the Neonatal Intensive Care Unit (NICU). *J Clin Psychol Med Settings.* 2010;17(3):230-237. doi:10.1007/s10880-010-9202-7.
42. Davis L, Edwards H, Mohay H, Wollin J. The impact of very premature birth on the psychological health of mothers. *Early Hum Dev.* 2003;73(1-2):61-70. doi:10.1016/S0378-3782(03)00073-2.
43. Muller-Nix C, Forcada-Guex M, Pierrehumbert B, Jaunin L, Borghini A, Ansermet F. Prematurity, maternal stress and mother-child interactions. *Early Hum Dev.* 2004;79:145-158. doi:10.1016/j.earlhumdev.2004.05.002.
44. Treyvaud K, Anderson VA, Howard K, et al. Parenting behavior is associated with the early neurobehavioral development of very preterm children. *Pediatrics.* 2009;123(2):555-561. doi:10.1542/peds.2008-0477.
45. Treyvaud K, Anderson VA, Lee KJ, et al. Parental mental health and early social-emotional development of children born very preterm. *J Pediatr Psychol.* 2010;35(7):768-777. doi:10.1093/jpepsy/jsp109.
46. Reynolds LC, Duncan MM, Smith GC, et al. Parental presence and holding in the neonatal intensive care unit and associations with early neurobehavior. 2013;33(8):636-641. doi:10.1038/jp.2013.4.
47. Goulet C, Bell L, St-Cyr D, Paul D, Lang A. A concept analysis of parent-infant attachment. *J Adv Nurs.* 1998;28(5):1071-1081. <http://www.ncbi.nlm.nih.gov/pubmed/9840879>.
48. McCormick MC, Workman-Daniels K, Brooks-Gunn J. The behavioral and emotional well-being of school-age children with different birth weights. *Pediatrics.* 1996;97(1):18-25. <http://www.ncbi.nlm.nih.gov/pubmed/8545219>.
49. Beebe B, Steele M, Jaffe J, et al. Maternal anxiety symptoms and mother-infant self- and interactive contingency. *Infant Ment Health J.* 2011;32(2):174-206. doi:10.1002/imhj.20274.
50. Radloff LS. The CES-D Scale: A Self-Report Depression Scale for Research in the General Population. *Appl Psychol Meas.* 1977;1(3):385-401. doi:10.1177/014662167700100306.
51. Spanier GB. Measuring Dyadic Adjustment: New Scales for Assessing the Quality of Marriage and Similar Dyads. *J Marriage Fam.* 1976;38(1):15. doi:10.2307/350547.
52. Scheiner AP, Sexton ME. Prediction of developmental outcome using a perinatal risk inventory. *Pediatrics.* 1991;88(6):1135-1143. <http://www.scopus.com/inward/record.url?eid=2-s2.0-0025718949&partnerID=tZOtx3y1>.
53. Tronick E, Weinberg M. *Infant Regulatory Scoring System (IRSS)*. Boston: The Child Development Unit, Children's Hospital,; 1990.
54. Cohn JF, Tronick EZ. Mother-Infant Face-to-Face Interaction: The Sequence of Dyadic States at

- 3, 6, and 9 Months. *Dev Psychol.* 1987;23(1):68-77.
55. Cohn JF, Tronick EZ. Mother-Infant Face-to-Face Interaction: Influence is Bidirectional and Unrelated to Periodic Cycles in Either Partner's Behavior. *Dev Psychol.* 1988;24(3):386-392.
56. Cohn JF, Tronick EZ. Specificity of infants' response to mothers' affective behavior. *J Am Acad Child Adolesc Psychiatry.* 1989;28(2):242-248.
57. Lavelli M, Fogel A. Developmental changes in the relationship between infant attention and emotion during early face-to-face communication: The 2-month transition. *Dev Psychol.* 2005;41:265-280.
58. Beebe B, Jaffe J, Markese S, et al. The origins of 12-month attachment: a microanalysis of 4-month mother-infant interaction. *Attach Hum Dev.* 2010;12(1-2):3-141. doi:10.1080/14616730903338985.
59. Bakeman R, Quera V. *Analyzing Interaction: Sequential Analysis with SDIS & GSEQ.* New York: Cambridge University Press; 1995.
60. Singer JD, Willett JB. *Applied Longitudinal Data Analysis.* Oxford: Oxford University Press; 2003. doi:10.1093/acprof:oso/9780195152968.001.0001.
61. Beebe B, Messinger D, Bahrack LE, Margolis A, Buck KA, Chen H. A systems view of mother-infant face-to-face communication. *Dev Psychol.* 2016;52(4):556-571. doi:10.1037/a0040085.
62. Moscardino U, Axia G, Scrimin S, Capello F. Narratives from caregivers of children surviving the terrorist attack in Beslan: issues of health, culture, and resilience. *Soc Sci Med.* 2007;64(8):1776-1787. doi:10.1016/j.socscimed.2006.11.024.
63. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol.* 2006;3(2):77-101. doi:10.1191/1478088706qp063oa.
64. Boyatzis R. *Transforming Qualitative Information: Thematic Analysis and Code Development.* Thousand Oaks: Sage; 1998.

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Parental engagement and early interactions with preterm infants during the stay in the Neonatal Intensive Care Unit: protocol of a mixed-method and longitudinal study

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Parental engagement and early interactions with preterm infants during the stay in the Neonatal Intensive Care Unit: protocol of a mixed-method and longitudinal study

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ABSTRACT

Introduction: The preterm infants' developmental outcomes depend on both biological and environmental risk factors. The environmental factors include prolonged parental separation, less exposure to early mother/father-infant interactions and the parents' ability to respond to the trauma of premature birth. In the case of premature birth, the father's ability to take an active part in the care of the infant from the start is essential. The parents' emotional closeness to the preterm infant hospitalized in the NICU may be crucial to the well-being of the newborn, the development of mutual regulation, the establishment of a functioning parent-infant affective relationship, and the parents' confidence in their ability to provide care for their baby.

Methods and analysis: This is a mixed-method, observational and longitudinal study. The methodological strategy will include: (1) ethnographic observation in a level III NICU located in Italy for a duration of 18 months; (2) 3-min video recordings of mother-infant and father-infant interaction in the NICU; (3) a semi-structured interview with fathers during the infants' hospital stay; (4) 3-min video recordings of mother-infant and father-infant face-to-face interaction in the laboratory at 4 months of corrected age; (5) self-report questionnaires for parents on depression and quality of the couple relationship at the approximate times of the video recording sessions.

Ethics and dissemination: The study protocol was approved by the Ethical Committee for Clinical Trials of the Verona and Rovigo Provinces. Results aim to be published in international peer-reviewed journals, and presented at relevant national and international conferences. This research project will develop research relevant to (A) the quality and modalities of maternal and paternal communication with the preterm infant in the NICU; (B) the influence of maternal/paternal social stimulation on the infant behavioral states; (C) the quality and modalities of paternal support to the partner, and possible influences on mother-infant relationship.

KEYWORDS

Preterm infant, Parents, Neonatal Intensive Care Unit, Early interaction, Emotional impact.

Strengths and limitations of this study:

- This is one of a small number of studies focused on maternal/paternal communicative behaviors addressed spontaneously to the preterm infant hospitalized in the NICU, and their effects on the infant's behavioral states.
- Results from this project will increase the very scant knowledge about the presence of early interactive contingencies between mother/father and the preterm infant in the NICU, and their possible predictive role of positive outcomes in mother-infant and father-infant relationship.
- Findings will be limited to the experiences of Italian parents.

INTRODUCTION

The preterm birth is a physiologically traumatic event in which infants' healthy neurological and emotional development is threatened.¹⁻⁵ The preterm infants' developmental outcomes depend on both biological and environmental risk factors.⁶⁻¹⁰ During the period of hospitalization in the Neonatal Intensive Care Unit (NICU), environmental factors include physical (e.g. excessive noise and light levels, painful procedures) and psychosocial (e.g. prolonged parental separation) stressors.^{11,12} Furthermore, preterm infants in incubators cannot experience the earliest mother-infant interactions which play a crucial role in early regulation of the stress response^{13,14} and provide the foundations for the development of mutual regulation.¹⁵ These skills are known to have a long term impact on the functioning of affective relationships and healthy developmental outcomes.⁶ The immature brain of a preterm infant is particularly vulnerable to the quality of these experiences.¹⁶

When a baby is born prior to the physiological term of 39 weeks, the process of preparation for parenthood is also interrupted ahead of time.^{17,18} In this way, parents are also premature.¹⁹ In this situation, parents are required to adjust their emotional structures in order to respond to the trauma of premature birth.^{20,21} This process is exceptionally important as the inability to respond to the trauma may have negative consequences on infant development.^{22,23} Often, mothers require a recovery period after the premature birth. As a result, the father's ability to take an active part in the care of the infant from birth may be crucial.²⁴ However, fathers can face many obstacles that can impact on their roles as partners and fathers,²⁵⁻²⁷ with possible negative consequences for their partners' affective states (e.g., depression, anxiety),²⁸⁻³¹ and for the development of parental relationships with the infants.^{29,32} Furthermore, the birth of a preterm infant might have a negative impact on self-representations of fathers during the child's stay in the NICU. Therefore, in order to adequately sustain fathers in their involvement in the infants' care, and in their transition to parenthood, specific supports are required from the NICU staff.³³ To date, however, only a few studies have focused their investigations on the father's role in preterm birth^{34,35}.

Past and recent studies exploring the quality of care given to preterm infants in the NICUs have shown that parent-preterm infant closeness during hospitalization, particularly skin-to-skin contact with the mother, and interventions aimed at supporting parental involvement in infant care may be crucial to the well-being of the newborn (enhancing neurobehavioral outcomes)³⁶⁻⁴¹, the establishment of parent-infant relationship,⁴² and the parents' sense of confidence in providing care for their baby.³⁸ Other recent studies have shown that exposure to recorded or live maternal/parental voice has beneficial effects on physiological and behavioral states of preterm infants,⁴³⁻⁴⁵ and predicts infants' vocalizations more than the voices of other adults.⁴⁶ However, very few studies have focused on mothers,⁴⁷⁻⁴⁹ or both parents,²⁹ spontaneous behaviors with their infants in the NICU: They have observed caregiving routines before discharge, when the baby was allowed to spend some time out of the incubator. To our

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knowledge, only one study⁵⁰ has been conducted on maternal behaviors addressed to the preterm infant hospitalized in the NICU, particularly when the infant was distressed, and on how the maternally-mediated sensory experience of the infant may impact the infant's behavioral states and mother-infant interaction. The present study expands the focus to maternal and paternal communicative behaviors addressed spontaneously to the preterm infant in a heated cot in the NICU.

It is important to acknowledge that parents of preterm infants are at great risk of psychological distress and depressive symptoms^{28,51,52} that can interfere with their sensitivity to infant cues.^{29,53} For instance, it has been found that mothers who experience traumatic stress in the perinatal period tend to be less sensitive and more controlling at 6 months of infant's corrected age⁵⁰, and that parental depression – as an inhibitory factor of good parent-infant interactions – has a negative impact on the early neurobehavioral⁵⁴ and socio-emotional⁵⁵ development of the infant. Some studies focused on mother-preterm infant interaction have shown that mothers of preterm infants tend to look, vocalize, and touch their infants affectionately less often than mothers of full-term infants; in addition, preterm infants tend to spend less time in alert state, to be more passive as social partners, and to send more unclear communicative signs, so that parent-infant interactions are less co-regulated than with full-term infants^{48,56,57} and a scant dyadic synchrony persists at 12 month of corrected age.⁵⁸ However, studies^{40,56-62} focused on mother-preterm infant interaction have also shown inconsistent findings⁶¹, though part of this discrepancy could be explained by the use of different observational methods and techniques (e.g., rating scales vs. micro-analytic coding systems). Moreover, almost all these studies have looked at interactive and socio-emotional behaviors after discharge from the NICU, over the infant's first two years (usually at 3 or 6, 12, 18, and/or 24 months of corrected age). And yet, to our knowledge, no study has microanalytically coded mother-infant and father-infant interactions during a stay in a level III NICU.

Objectives

In light of the above, the first objective of this study is to examine maternal and paternal communication with their preterm infant in a heated cot in the NICU, analyzing the presence of interactive contingency between parental communicative behaviors and infant gaze direction and expression indexing the infant's engagement in the interaction. 'Interactive contingency' is defined as the predictability of each partner's behavior from that of the other, over time.^{63,64}

A second objective consequent on the first is to assess whether early interactive contingency between mother/father and preterm infant in the NICU predicts positive outcomes in the mother-infant/father-infant relationship and infant development at 4 months corrected age.

A third objective, parallel to the first, is to investigate the emotional impact of the premature birth on parents, particularly on fathers. This objective will be accomplished by examining a number of different factors, namely, the ways through which the fathers' perception of their

parental role (or absence of role) influences their engagement in caring the baby, their support to the partner, and the mother-infant relationship.

Finally, the last and overarching objective is to examine the relationship between (a) maternal and paternal emotional conditions after the premature birth, (b) the infant perinatal risk factors, and (c) the quality of mother-infant and father-infant interactions during the stay in the NICU, and later, at 4 months corrected age.

METHOD AND ANALYSIS

This is a mixed-method, observational and longitudinal study. The methodological strategy will include: (1) ethnographic observation in a level III NICU located in Northern Italy for the duration of data collection over a 18-months period; (2) one 3-minute video recording of mother-infant and father-infant face-to-face interaction in the NICU (with the preterm infant in a heated cot) between 34 and 35+6 weeks post-menstrual age (PMA); (3) a semi-structured interview with the fathers during the infants' stay in the NICU; (4) one 3-minute video recording of mother-infant and father-infant face-to-face interaction in the Social and Language Development Lab-University of Verona, at 4 months corrected age (CA); (5) a self-report questionnaire on depression and a questionnaire on the quality of the couple relationship submitted to the parents at the approximate times of the video recording sessions.

Selection criteria

Inclusion criteria

Infants are eligible to be included in the study if they meet the criterion of: (1) birth before 34 weeks PMA. The reason for choosing a cut-off of 34 weeks (instead, for instance, 32 weeks that is the cut-off for very preterm birth) is to increase the number of participant families, given the difficulties of recruitment in the NICU. Furthermore, this criterion is in line with other studies on maternal caregiving behavior during the stay in the NICU⁵⁰, and on mother-preterm infant interaction after discharge^{57,65}.

Mothers and fathers are eligible to be included in the study if they meet the following criteria: (1) both were born and grew up in Italy; (2) both have given their consent to participate in the study.

Exclusion criteria

Infants will be excluded from the study if: (1) they have perinatal asphyxia; (2) they have neurologic pathologies (periventricular leukomalacia up to stage I and/or intraventricular hemorrhage up to stage II); (3) they experience malformation syndromes and/or major malformations; (4) they have sensory deficits (detected by regular medical checks performed during hospitalization); (5) they present metabolic or genetic disease.

1 Mothers and fathers will be excluded from the study if: (1) they are not of Italian origin; (2)
2 they have a psychiatric illness; (3) they have issues with drug or substance abuse; (4) they are
3 not living together; (5) they are adopting parents; (6) they are a same-sex couple.
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7 To participate in the study it is necessary that both parents and infants meet the inclusion and
8 exclusion criteria.
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11 **Procedure**

12 The timeline of the whole procedure, beginning with ethnographic observation even before the
13 participants' recruitment, is depicted in Figure 1.
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17 *Ethnographic observation in NICU*

18 Ethnography is a methodological approach which involves the researcher participating overtly
19 in the lives of people, in this case in the NICU^{66,67}. Ethnographers work by “watching what
20 happens, listening to what is said, and/or asking questions through informal and formal
21 interviews and collecting documents”⁶⁸. Ethnographic observation was selected over other
22 methods to inform this study and to prepare the best conditions for accomplishing this study, as
23 it aims (A) to minimize the risks potentially associated with having an observing researcher
24 within the observed social context (e.g., perception of intrusiveness, minor spontaneity during
25 videotaped interactions and/or interviews), and (B) to obtain rich qualitative data from
26 participant observation in social interactions which take place in that context. This is even more
27 important in a stressful context such as the NICU, where social interactions are particularly
28 vulnerable.
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30 Initially, the researcher (the psychologist-psychotherapist and PhD student who is the first
31 author) goes through a familiarization period with the parents in the NICU. During this period
32 and later on too, the researcher observes the interactions between (1) parents and their preterm
33 infants, (2) mothers and fathers, (3) parents and staff (nurses, neonatologist and psychologist)
34 and (4) infant and nurses; he attends meetings between neonatologists, observes conversations
35 between staff and parents, and he also holds informal talks with mothers and fathers. Then the
36 researcher presents the research project to the parents who meet the inclusion criteria and
37 “follows” the recruited families until the infant's discharge from the NICU. We think that
38 qualitative data obtained from ethnographic observation can offer a main contribution to the
39 understanding of the NICU-related stress and the impact of preterm birth and ensuing
40 hospitalization on mothers' and fathers' emotional experiences, their couple's relationship and
41 how they cope with the stay in the NICU: all factors that might affect parent-infant relationship
42 and the quality of mother-infant and father-infant interactions. Finally, ethnographic observation
43 is used to identify the best conditions—infant's behavioral states, time, position, etc.—for video
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1 recording parent-infant face-to-face interaction (with the preterm infant in a heated cot) in the
2 NICU.
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5 6 *Recruitment*

7 All parents (mothers and fathers) of preterm infants born between 17 September 2015 and 31
8 March 2017 and hospitalized at level III NICU of the Borgo Roma Hospital - Azienda
9 Ospedaliera Universitaria Integrata Verona (northern Italy) are invited to participate in the
10 study. The researcher invites the parents to participate during the stay in the NICU, when the
11 infant's medical condition has been stabilized: this usually happens around or after 32-33 weeks
12 PMA; therefore, the recruitment of the study participants takes place from 32 to 34+6 weeks
13 PMA. A minimum of 20 families, that is, 20 mother-infant and 20 father-infant dyads will be
14 recruited. This sample size is adequate to perform parametric statistical tests, and is in line with
15 the sample size of previous Italian studies^{47,58,69,70} in the field.
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23 *Parent-infant interaction in NICU*

24 Between 34 and 35+6 weeks PMA, the mother's spontaneous social stimulation addressed to
25 the infant in a cot with a radiant heater (an open cot with an overhead heating source) and the
26 infant's responses are videotaped during a 3-minute interaction. Then the infant rests for at least
27 5 minutes. Afterwards, the father's social stimulation addressed to the infant and the latter's
28 responses are videotaped over a 3-minute interaction. The date and timing for video-recording
29 parent-infant interaction depends on: (1) the infant's medical conditions, (2) the mother's and
30 father's restrictions on the time available to stay in the NICU, (3) the infant's behavioral states
31 (for instance, if the infant is sleeping or crying the video recording is postponed).
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38 *Qualitative interviews in NICU*

39 Previous studies that have conducted interviews with fathers of premature infants provide a
40 coherent picture. The preterm birth of an infant is a traumatic event for the fathers⁷¹, who have
41 been found to show low/moderate levels of adjustment to preterm birth and a limited
42 assumption of paternal role⁷². Research also suggests that fathers experience a sense of lack of
43 control⁷³. Often fathers hide these emotional difficulties from healthcare providers^{74,75}, but
44 reported a need to share⁷⁰ with someone who can understand²⁴. The first moments with the
45 preterm infants evoke a 'rollercoaster of emotions'⁷⁶ which can lead fathers to become
46 emotionally, and sometimes physically, distanced from the situation. After the initial shock and
47 trauma, research has shown that fathers can experience emotional closeness²⁷ with their infants
48 during hospitalization in the NICU.
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50 Before the infant's discharge from the NICU, fathers are contacted to participate in a semi-
51 structured interview. The interviews allow for a deeper understanding of the emotional impact
52 that the premature birth has on fathers. The topic guide includes the following areas: the first
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time that the father saw and/or touched his baby; the bond with the baby; caregiving activities; feelings associated with seeing the partner/mother care for, feed, or cuddle their baby; space for one's own emotions when supporting and assisting the partner; work and management of their responsibilities in the outside world during the period of hospitalization in NICU; the quality of the couple relationship during pregnancy and the period of hospitalization in NICU; and how their feelings towards the baby change from his/her preterm birth to the time of discharge from the NICU.

In addition to the fathers who will participate in the parent-infant interaction, we will recruit an additional number of fathers who meet the inclusion criteria for parents and infants. These additional participants will not need to meet the infants' exclusion criteria. This will allow the study to have a more representative sample of daily clinical reality.

Interviews are carried out in a private room in the NICU, and are digitally recorded.

Questionnaires in NICU

In approximate times with videotaping, parents are asked to complete the Center for Epidemiologic Studies Depression Scale (CES-D)⁷⁷ to assess symptoms of depression, and the Dyadic Adjustment Scale (DAS)⁷⁸ to assess the quality of the couple's relationship.

Parent-infant interaction after discharge

At 4 months CA, 3 minutes of mother-infant and 3 minutes of father-infant spontaneous face-to-face interaction are videotaped in the Social and Language Development Laboratory at the University of Verona. The infant is seated in an infant seat on a table; the mother/father, seated opposite the infant, is asked to play with the baby as she/he would at home but without using toys. Two video cameras are used to generate a split-screen view of the interaction.

Questionnaires after discharge

Parents are asked to complete the CES-D Scale and the DAS Scale again at 4 months CA, in order to assess symptoms of depression and the quality of the couple's relationship around 5 months after discharge from the NICU.

Further data on parents and infants

Data are collected on the parents' demographic and socioeconomic characteristics (age, marital status, years of formal education, occupation, family composition, and social network), on the mothers' gynecological and obstetric history, on their infant's neonatal characteristics (gestational age, weight, height and head circumference) and on the severity of the perinatal problems (evaluated using the Perinatal Risk Inventory; PERI)⁷⁹ will be collected. Information are also collected regarding the infant's hospitalization and developmental outcomes (assessed

1 after discharge in a follow-up based on a pediatric examination including a somatic and
2 neurological status assessment).

3 4 5 6 **Data Analysis**

7 *Video coding*

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9 Mother/father's and infant's behaviors from videotaped interactions are coded micro-
10 analytically, using units of 1 second.⁸⁰⁻⁸² Parent and infant behaviors are coded independently in
11 ordinalized scales required for performing time series analysis (see below).

12
13 With regard to parent-infant interactions in the NICU, both parent and infant behaviors are
14 coded in composite categories of Engagement Scales, recently devised by Lavelli and Beebe⁸³:
15 the *Mother/Father Engagement Scale*, ordinalized from a high of *Maternal Affiliative*
16 *Behavior*⁴⁵ (composed of "Gaze at infant face + Affectionate or Static Touch + Affectionate
17 Talk and/or Positive Facial Affect") to a low of "Gaze off"; and the *Infant Engagement Scale*,
18 ordinalized from high levels of "Gaze at parent face + Smile" and "Gaze at parent face + Active
19 movements" to a low of "Negative Expression". Communicative modalities included in
20 *Maternal Affiliative Behavior* have been described as the main components of the maternal post-
21 partum repertoire in humans and as predictor of positive outcomes.⁴⁸ Among these modalities,
22 in the NICU context maternal/paternal Static Touch as Firm and Sustained Touch⁴⁷ is an
23 effective and salient way to be in contact with the preterm infant, given the loss of physical
24 contact with the mother and the prolonged separation that results from the NICU experience;
25 therefore, otherwise that with full-term infants, Static Touch is not considered less optimal than
26 Affectionate Touch.

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28 With regard to parent-infant face-to-face interaction at 4 months CA, parents' behaviors are
29 coded according to their *Gaze direction* (on-off the infant's face); *Mother/Father Touch*,
30 ordinalized from a high of "Affectionate" to a low of "Intrusive" using the Maternal Touch
31 Scale⁸⁵ adapted to the Italian caregiving culture; *Mother/Father Facial Affect*, based on Beebe et
32 al.⁸² and ordinalized from a high of "Mock surprise" to a low of "Negative". Infants' behaviors
33 are coded according to their *Gaze direction* (on-off the infant's face); *Infant Vocal Affect*,
34 adapted from Beebe et al.⁸² and ordinalized from "High Positive" to "Angry Protest/Cry"; *Infant*
35 *Facial Affect*, adapted from Beebe et al.⁸² and Lavelli and Fogel⁸⁴, and ordinalized from "High
36 Positive" to "Negative".

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38 The inter-rater reliability (Cohen's Kappa) for maternal/paternal/infant behaviors will be
39 calculated on 20% of the videotapes, which will be coded by a second researcher who is blind to
40 the aims of the study.

41 42 43 44 45 46 47 48 *Quantitative data analysis*

49 To explore the possible presence of early interactive contingency between parental
50 communicative behaviors and infant gaze direction and expression (Objective 1), a sequential
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1 analysis (conditional probabilities, GSEQ software)⁸⁴ will be computed to examine the
2 probabilities that the infant gazes at the parent's face with positive/neutral expression when the
3 mother/father provides Affiliative Behavior, and vice versa, that the mother/father provides
4 Affiliative Behavior when the infant shows to be engaged or ready for social stimulation.
5 Furthermore, since the conditional probabilities analysis highlights specific associations of
6 behaviors but not how any interactive contingency unfolds during the entire segment of
7 videotaped interaction, a time-series modeling⁸⁵ of the moment-to-moment sequence of
8 behaviors will be performed to explore the parents and infants capability to coordinate their
9 behaviors at any level of engagement vs. disengagement across the videotaped session. Self-
10 contingency will be computed as exploratory variable of the time-series analysis.

11 With regard to the second objective, that is, to assess whether higher engagement coordination
12 (interactive contingency) between mother/father and preterm infant in the NICU predicts higher
13 engagement coordination (interactive contingency) during parent-infant face-to-face interaction
14 at 4 months CA, a multilevel time-series analysis⁸⁵ will be performed. This analysis will allow
15 to create indices of self-contingency (autocorrelation) and interactive contingency (cross-
16 correlation) using the different possible pairs of parent-infant communication modality coded in
17 behavioral scale (e.g., infant gaze-mother/father gaze; infant vocal affect-mother/father touch,
18 etc.): these results will shed light on the process of mutual regulation during interaction at 4
19 months CA. Then, to assess the hypothesis that interactive contingency between parent and
20 infant in the NICU is longitudinally related to the quality of their relationship at 4 months CA, it
21 will be necessary to create an *Infant Engagement Scale* at 4 months, through an algorithm, as
22 well as a *Mother/Father Engagement Scale* from their interaction at 4 months, in order to have
23 behavioral scales which are comparable with those used for coding interaction in the NICU.

24 Finally, the hypothesis of early interactive contingency as a predictor of later Mutual
25 Engagement will be also assessed by a linear regression analysis. A set of linear regression
26 analyses will be performed using different study variables as possible predictors of quality in
27 mother-infant and father-infant interactions at 4 months CA, in order to contribute to investigate
28 the relationship between the different variables (Objective 4).

29 *Qualitative data analysis, and following mixed analyses*

30 A thematic content analysis^{86,87} of the fathers' interviews will allow us to investigate the
31 emotional impact of the premature birth on fathers (Objective 3). To this aim, results will be
32 integrated with field notes taken during ethnographic observation and results from the self-
33 report instrument assessing symptoms of depression. All transcripts will be verified by one
34 researcher before data analysis by listening to the audio recording and checking for accuracy of
35 the written transcript. The transcripts will be analyzed using a thematic content analysis for each
36 question in the interview. Thematic analysis is a qualitative method for identifying, analyzing,
37 and reporting themes within data.⁸⁸ Transcripts will be read and re-read so as to become

familiarized with the data. Data will be managed using NVivo 11 (QSR International, USA). The first author will use an initial open coding to allow for the emergence of recurrent themes across fathers. Response patterns that will be relevant across all fathers will be coded and organized in thematic categories (along with verbatim quotes which illustrate each theme).^{88,89} All codes will be compared and contrasted, and then examined and discussed by the first author and two other researchers to identify meaningful categories or emergent themes. Codes with a single occurrence will be removed. Coding reliability and face validity achieved by remaining codes will be checked. A final coding scheme (defining each theme with verbatim quotes) will be collated. All transcripts will be re-coded by the first author using the coding scheme. The inter-rater reliability will be calculated on 20% of the transcriptions, which will be coded by a second researcher.

A bi-variate correlation analysis between theme frequencies emerging from the fathers' interviews, the scores questionnaires indexing symptoms of maternal/paternal depression and the quality of the couple relationship, the scores from the Perinatal Risk Inventory (PERI)⁷⁹, and behavioral measures of quality in parent-infant interaction such as Maternal/Paternal Affiliative Behavior, early interactive contingencies and Mutual Engagement at 4 months, will be performed to assess possible concurrent and predictive associations, and patterns of association, between study variables (Objective 4).

Qualitative data will contribute to explain results from statistical analyses.

ETHICS AND DISSEMINATION

Ethical principles

Ethical approval of the study protocol was obtained from the Ethical Committee for Clinical Trials of the Verona and Rovigo Provinces (reference no. 569CESC).

Description of risks

There will be no risks associated with participation in any aspect of the described study.

Informed consent

Before tacking part in the study all mothers and fathers will receive written and oral information about the content and extent of the study. If they are willing to participate, they will sign the informed consent form. They will be able to withdraw from the study at any time without explanation, without any consequences to the care of the family at the Azienda Ospedaliera Universitaria Integrata Verona.

Data protection

1 All the video files, coding sheets, audio files, audio transcriptions, questionnaires and
2 documents, will be provided with a special alphanumeric code and will not contain any
3 identifying information. The electronic data will be stored on a computer that is password
4 protected. The paper materials will be stored in a locked archive. Only members of the study
5 team will have access to the data.
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10 **Scientific, clinical and social impact**

11 To our knowledge, this is the first research project focused on maternal/paternal communicative
12 behaviors addressed spontaneously to the preterm infant hospitalized in the NICU, and their
13 effects on the infant's behaviors and engagement in social interaction. Therefore, this research
14 project will provide new knowledge in the particular area of: (a) the quality and modalities of
15 maternal and paternal communication with the preterm infant in the NICU when the infant is in
16 a cot with a radiant heater; (b) the influence of maternal/paternal social stimulation on infant's
17 behavioral states, and the associated potential benefits for the preterm infant; (c) the quality and
18 modalities of paternal support to the mother/partner, and the ways in which this influences the
19 mother-infant relationship. In addition, results from this project will increase the very scant
20 knowledge about the presence of early interactive contingencies between mother/father and
21 preterm infant in the NICU, and their possible predictive role of positive outcomes in mother-
22 infant and father-infant relationship.
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30 Knowing more about under what conditions preterm infants hospitalized in the NICU could
31 benefit from parental social stimulation has important clinical implications that could inform
32 nursing practice and psychological support. Firstly, this knowledge highlights possible factors
33 on which early intervention programs in the NICU should focus in order to support the
34 development of healthy mother-infant, father-infant, and mother-father relationships. Secondly,
35 analyzing the quality of maternal/paternal communication with the preterm infant in a heated
36 cot allow for the identification of early indices of risk in the developing mother/father-preterm
37 infant relationship. This may in turn help to improve the identification of mother/father-infant
38 dyads who are at-risk and who might benefit from early preventive intervention. With regard to
39 this, staff members in the NICU might become more aware of individual differences in mothers
40 and fathers that could facilitate or interfere with the parents' ability to provide sensitive care for
41 their preterm infants.
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50 **Dissemination**

51 The results of this study will be submitted for publication in international peer-reviewed
52 journals. Additionally, key results will be presented at relevant national and international
53 conferences. Finally, the results of this study will part of the first author's PhD thesis
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58 **Contributors** AS was involved in the general study design as PhD research project. ML served
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1 primarily as research project supervisor. AS focused on- and developed the qualitative aspects
2 of the study protocol. ML designed the coding system and the plan of statistical analysis of the
3 study protocol. AS and ML shared the writing of the manuscript.
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8 **Competing interests** None
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10 **Figure legend** Study Timeline. wk = weeks; PMA = Post-Menstrual Age; CA = Corrected
11 Age.
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14 REFERENCES

- 15 1. Doyle LW, Anderson PJ. Adult outcome of extremely preterm infants. *Pediatrics*.
16 2010;126(2):342-351. doi:10.1542/peds.2010-0710.
- 17 2. Johnson S, Fawke J, Hennessy E, et al. Neurodevelopmental disability through 11 years of age in
18 children born before 26 weeks of gestation. 2009;124(2). doi:10.1542/peds.2008-3743.
- 19 3. Marlow N, Wolke D, Bracewell MA, Samara M. Neurologic and developmental disability at six
20 years of age after extremely preterm birth. *N Engl J Med*. 2005;352(1):9-19.
21 doi:10.1056/NEJMoa041367.
- 22 4. Mwaniki MK, Atieno M, Lawn JE, Newton CRJC. Long-term neurodevelopmental outcomes
23 after intrauterine and neonatal insults: A systematic review. *Lancet*. 2012;379:445-452.
24 doi:10.1016/S0140-6736(11)61577-8.
- 25 5. Talge NM, Holzman C, Wang J, Lucia V, Gardiner J, Breslau N. Late-preterm birth and its
26 association with cognitive and socioemotional outcomes at 6 years of age. *Pediatrics*.
27 2010;126(6):1124-1131. doi:10.1542/peds.2010-1536.
- 28 6. Feldman R. Parent-infant synchrony and the construction of shared timing; physiological
29 precursors, developmental outcomes, and risk conditions. *J Child Psychol Psychiatry*. 2007;48(3-
30 4):329-354. doi:10.1111/j.1469-7610.2006.01701.x.
- 31 7. Feldman R, Eidelman AI. Neonatal state organization, neuromaturation, mother-infant
32 interaction, and cognitive development in small-for-gestational-age premature infants. *Pediatrics*.
33 2006;118(3):e869-78. doi:10.1542/peds.2005-2040.
- 34 8. Greenberg MT, Crnic KA. Longitudinal predictors of developmental status and social interaction
35 in premature and full-term infants at age two. *Child Dev*. 1988;59(3):554-570.
- 36 9. Minde K. Prematurity and serious medical conditions in infancy: Implications for development,
37 behaviour, and intervention. In: Zeanah CH, ed. *Handbook of Infant Mental Health*. Vol New
38 York: Guilford; 2000:176-194.
- 39 10. Treyvaud K, Inder TE, Lee KJ, Northam EA, Doyle LW, Anderson PJ. Can the home
40 environment promote resilience for children born very preterm in the context of social and
41 medical risk? *J Exp Child Psychol*. 2012;112(3):326-337. doi:10.1016/j.jecp.2012.02.009.
- 42 11. Maroney DI. Recognizing the Potential Effect of Stress and Trauma on Premature Infants in the
43 NICU: How are Outcomes Affected? *J Perinatol*. 2003;23(8):679-683.
44 doi:10.1038/sj.jp.7211010.
- 45 12. Montirosso R, Provenzi L. Implications of epigenetics and stress regulation on research and
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

- developmental care of preterm infants. 2015;44(2):174-182. doi:10.1111/1552-6909.12559.
13. Meaney MJ, Szyf M. Maternal care as a model for experience-dependent chromatin plasticity? 2005;28(9):456-463. doi:10.1016/j.tins.2005.07.006.
 14. Mendelsohn A. Recovering reverie: Using infant observation in interventions with traumatised mothers and their premature babies. *Infant Obs.* 2005;8(3):195-208. doi:10.1080/13698030500375693.
 15. Lavelli M, Fogel A. Interdyad differences in early mother-infant face-to-face communication: real-time dynamics and developmental pathways. *Dev Psychol.* 2013;49(12):2257-2271. doi:10.1037/a0032268.
 16. Lupien SJ, McEwen BS, Gunnar MR, Heim C. Effects of stress throughout the lifespan on the brain, behaviour and cognition. 2009;10(6):434-445. doi:10.1038/nrn2639.
 17. Brusweiler-Stern N. Pregnancy: preparation for your new identity. In: Stern D, Brusweiler-Stern N, eds. *The Birth of a Mother: How the Motherhood Experience Changes You Forever*. Vol New York: Basic Books; 1998.
 18. Pancer SM, Pratt M, Hunsberger B, Gallant M. Thinking ahead: complexity of expectations and the transition to parenthood. *J Pers.* 2000;68(2):253-280.
 19. Stern M, Karraker KH, Sopko AM, Norman S. The prematurity stereotype revisited: Impact on mothers' interactions with premature and full-term infants. *Infant Ment Health J.* 2000;21(6):495-509. doi:10.1002/1097-0355(200011/12)21:6<495::AID-IMHJ7>3.0.CO;2-F.
 20. Jotzo M, Poets CF. Helping parents cope with the trauma of premature birth: an evaluation of a trauma-preventive psychological intervention. *Pediatrics.* 2005;115(4):915-919. doi:10.1542/peds.2004-0370.
 21. Stefana A, Lavelli M. I genitori dei bambini prematuri. Una prospettiva psicodinamica. *Medico e Bambino.* 2016;35(5):327-332.
 22. Goldberg S, DiVitto B. Parenting children born preterm. *Handb Parent.* 1:209-231.
 23. Siegel LS. Reproductive, perinatal, and environmental factors as predictors of the cognitive and language development of preterm and full-term infants. *Child Dev.* 1982;53(4):963-973.
 24. Lindberg B, Axelsson K, Öhrling K. The birth of premature infants: Experiences from the fathers' perspective. *J Neonatal Nurs.* 2007;13(4):142-149. doi:10.1016/j.jnn.2007.05.004.
 25. Pohlman S. Fathering premature infants and the technological imperative of the neonatal intensive care unit: An interpretive inquiry. 2009;32(3). doi:10.1097/ANS.0b013e3181b0d68c.
 26. Fegran L, Helseth S, Fagermoen MS. A comparison of mothers' and fathers' experiences of the attachment process in a neonatal intensive care unit. 2008;17(6):810-816. doi:10.1111/j.1365-2702.2007.02125.x.
 27. Lundqvist P, Westas L, Hallström I. From distance toward proximity: fathers lived experience of caring for their preterm infants. *J Pediatr Nurs.* 2007;22:490-497.
 28. Carter JD, Mulder RT, Frampton CMA, Darlow BA. Infants admitted to a neonatal intensive care unit: parental psychological status at 9 months. *Acta Paediatr.* 2007;96(9):1286-1289. doi:10.1111/j.1651-2227.2007.00425.x.
 29. Zelkowitz P, Bardin C, Papageorgiou A. Anxiety affects the relationship between parents and their very low birth weight infants. *Infant Ment Health J.* 2007;28(3):296-313. doi:10.1002/imhj.20137.

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52
53
54
55
56
57
58
59
60
30. Robertson E, Grace S, Wallington T, Stewart DE. Antenatal risk factors for postpartum depression: a synthesis of recent literature. *Gen Hosp Psychiatry*. 2004;26(4):289-295. doi:10.1016/j.genhosppsy.2004.02.006.
 31. Stefana A. La Terapia Intensiva Neonatale, uno spazio per i padri? *Psicologia Clinica dello Sviluppo*. 2016;20(3):485-491.
 32. Gutierrez-Galve L, Stein A, Hanington L, Heron J, Ramchandani P. Paternal Depression in the Postnatal Period and Child Development: Mediators and Moderators. *Pediatrics*. 2015;135(2):e339-e347. doi:10.1542/peds.2014-2411.
 33. Provenzi L, Santoro E. The lived experience of fathers of preterm infants in the Neonatal Intensive Care Unit: a systematic review of qualitative studies. *J Clin Nurs*. 2015:1784-1794.
 34. Stefana A, Lavelli M. I padri dei bambini nati pretermine: una risorsa su cui investire. *Psicologia Clinica dello Sviluppo*. 2016;20(2):165-188. doi:10.1449/84129.
 35. Stefana A, Lavelli M. What is hindering research on fathers of premature infants? *Minerva Pediatrica*. (In press).
 36. Als H, Duffy FH, McAnulty GB, et al. Early Experience Alters Brain Function and Structure. *Pediatrics*. 2004;113(4):846-857. doi:10.1542/peds.113.4.846.
 37. Feldman R, Weller A, Sirota L, Eidelman AI. Skin-to-Skin contact (Kangaroo care) promotes self-regulation in premature infants: sleep-wake cyclicity, arousal modulation, and sustained exploration. *Dev Psychol*. 2002;38(2):194-207.
 38. Flacking R, Lehtonen L, Thomson G, et al. Closeness and separation in neonatal intensive care. *Acta Paediatr*. 2012;101(10):1032-1037. doi:10.1111/j.1651-2227.2012.02787.x.
 39. Welch MG, Firestein MR, Austin J, et al. Family Nurture Intervention in the Neonatal Intensive Care Unit improves social-relatedness, attention, and neurodevelopment of preterm infants at 18 months in a randomized controlled trial. *J Child Psychol Psychiatry*. 2015;56(11):1202-1211. doi:10.1111/jcpp.12405.
 40. Reynolds LC, Duncan MM, Smith GC, et al. Parental presence and holding in the neonatal intensive care unit and associations with early neurobehavior. 2013;33(8):636-641. doi:10.1038/jp.2013.4.
 41. Welch MG, Myers MM, Grieve PG, et al. Electroencephalographic activity of preterm infants is increased by Family Nurture Intervention: A randomized controlled trial in the NICU. *Clin Neurophysiol*. 2014;125(4):675-684. doi:10.1016/j.clinph.2013.08.021.
 42. Goulet C, Bell L, St-Cyr D, Paul D, Lang A. A concept analysis of parent-infant attachment. *J Adv Nurs*. 1998;28(5):1071-1081.
 43. Filippa M, Devouche E, Arioni C, Imberty M, Gratier M. Live maternal speech and singing have beneficial effects on hospitalized preterm infants. *Acta Paediatr*. 2013;102(10):1017-1020. doi:10.1111/apa.12356.
 44. Krueger C, Parker L, Chiu S-H, Theriaque D. Maternal voice and short-term outcomes in preterm infants. *Dev Psychobiol*. 2010;52(2):205-212. doi:10.1002/dev.20426.
 45. Lee H, White-Traut R. Physiologic responses of preterm infants to the male and female voice in the NICU. *J Pediatr Nurs*. 2014;29(1):e3-e5. doi:10.1016/j.pedn.2013.04.007.
 46. Caskey M, Stephens B, Tucker R, Vohr B. Importance of parent talk on the development of preterm infant vocalizations. 2011;128(5):910-916. doi:10.1542/peds.2011-0609.

- 1
2
3
4
5
6
7
8
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51
52
53
54
55
56
57
58
59
60
47. Coppola G, Cassibba R. Mothers' social behaviours in the NICU during newborns' hospitalisation: An observational approach. 2010;28(2):200-211. doi:10.1080/02646830903298731.
 48. Feldman R, Eidelman AI. Maternal postpartum behavior and the emergence of infant-mother and infant-father synchrony in preterm and full-term infants: the role of neonatal vagal tone. *Dev Psychobiol.* 2007;49(3):290-302. doi:10.1002/dev.20220.
 49. Keren M, Feldman R, Eidelman AI, Sirota L, Lester B. Clinical Interview for high-risk Parents of premature infants (CLIP) as a predictor of early disruptions in the mother-infant relationship at the nursery. *Infant Ment Health J.* 2003;24(2):93-110. doi:10.1002/imhj.10049.
 50. Welch MG, Hofer MA, Brunelli SA, et al. Family nurture intervention (FNI): methods and treatment protocol of a randomized controlled trial in the NICU. *BMC Pediatr.* 2012;12(1):14. doi:10.1186/1471-2431-12-14.
 51. Lefkowitz DS, Baxt C, Evans JR. Prevalence and correlates of posttraumatic stress and postpartum depression in parents of infants in the Neonatal Intensive Care Unit (NICU). *J Clin Psychol Med Settings.* 2010;17(3):230-237. doi:10.1007/s10880-010-9202-7.
 52. Davis L, Edwards H, Mohay H, Wollin J. The impact of very premature birth on the psychological health of mothers. *Early Hum Dev.* 2003;73(1-2):61-70. doi:10.1016/S0378-3782(03)00073-2.
 53. Muller-Nix C, Forcada-Guex M, Pierrehumbert B, Jaunin L, Borghini A, Ansermet F. Prematurity, maternal stress and mother-child interactions. *Early Hum Dev.* 2004;79:145-158. doi:10.1016/j.earlhumdev.2004.05.002.
 54. Treyvaud K, Anderson VA, Howard K, et al. Parenting behavior is associated with the early neurobehavioral development of very preterm children. *Pediatrics.* 2009;123(2):555-561. doi:10.1542/peds.2008-0477.
 55. Treyvaud K, Anderson VA, Lee KJ, et al. Parental mental health and early social-emotional development of children born very preterm. *J Pediatr Psychol.* 2010;35(7):768-777. doi:10.1093/jpepsy/jsp109.
 56. Montiroso R, Borgatti R, Trojan S, Zanini R, Tronick E. A comparison of dyadic interactions and coping with still-face in healthy pre-term and full-term infants. *Br J Dev Psychol.* 2010;28(Pt 2):347-368. doi:10.1348/02615009x416429.
 57. Forcada-Guex M, Borghini A, Pierrehumbert B, Ansermet F, Muller-Nix C. Prematurity, maternal posttraumatic stress and consequences on the mother-infant relationship. *Early Hum Dev.* 2011;87(1):21-26. doi:10.1016/j.earlhumdev.2010.09.006.
 58. Sansavini A, Zavagli V, Guarini A, Savini S, Alessandrini R, Faldella G. Dyadic co-regulation, affective intensity and infant's development at 12 months: A comparison among extremely preterm and full-term dyads. *Infant Behav Dev.* 2015;40:29-40. doi:10.1016/j.infbeh.2015.03.005.
 59. McCormick MC, Workman-Daniels K, Brooks-Gunn J. The behavioral and emotional well-being of school-age children with different birth weights. *Pediatrics.* 1996;97(1):18-25.
 60. Forcada-Guex M, Pierrehumbert B, Borghini A, Moessinger A, Muller-Nix C. Early dyadic patterns of mother-infant interactions and outcomes of prematurity at 18 months. *Pediatrics.* 2006;118(1):e107-14. doi:10.1542/peds.2005-1145.
 61. Korja R, Latva R, Lehtonen L. The effects of preterm birth on mother-infant interaction and

- 1 attachment during the infant's first two years. *Acta Obstet Gynecol Scand.* 2012;91(2):164-173.
2 doi:10.1111/j.1600-0412.2011.01304.x.
- 3
- 4
- 5 62. Borghini A, Habersaat S, Forcada-Guex M, et al. Effects of an early intervention on maternal
6 post-traumatic stress symptoms and the quality of mother–infant interaction: The case of preterm
7 birth. *Infant Behav Dev.* 2014;37:624-631. doi:10.1016/j.infbeh.2014.08.003.
- 8
- 9 63. Beebe B, Steele M, Jaffe J, et al. Maternal anxiety symptoms and mother-infant self- and
10 interactive contingency. *Infant Ment Health J.* 2011;32(2):174-206. doi:10.1002/imhj.20274.
- 11
- 12 64. Fogel A. Co-regulation, perception and action. *Hum Mov Sci.* 1992;11:505–523.
- 13
- 14 65. Beebe B, Myers MM, Andrews H, et al. NICU Intervention in First Month Improves Repair of
15 Negative Engagement and Helps Sustain Positive Engagement in Mothers & Preterm Infants at 4
16 Months. In: *The New York State Psychiatric Institute, Columbia University Medical Center;*
17 *International Conference Infant Studies.* Vol New Orleans; 2016.
- 18
- 19 66. Flacking R, Dykes F. “Being in a womb” or “playing musical chairs”: the impact of place and
20 space on infant feeding in NICUs. *BMC Pregnancy Childbirth.* 2013;13(1):179.
21 doi:10.1186/1471-2393-13-179.
- 22
- 23 67. Dykes F, Flacking R. *Ethnographic Research in Maternal and Child Health.* London: Routledge;
24 2015. doi:10.4324/9781315762319.
- 25
- 26 68. Hammersley M, Atkinson P. *Ethnography: Principles in Practice. 3rd Edition.* London:
27 Routledge; 2007.
- 28
- 29 69. Zuccarini M, Sansavini A, Iverson JM, et al. Object engagement and manipulation in extremely
30 preterm and full term infants at 6 months of age. *Res Dev Disabil.* 2016;55:173-184.
31 doi:10.1016/j.ridd.2016.04.001.
- 32
- 33 70. Coppola G, Cassibba R, Bosco A, Papagna S. In search of social support in the NICU: features,
34 benefits and antecedents of parents' tendency to share with others the premature birth of their
35 baby. *J Matern Fetal Neonatal Med.* 2013;(September 2015).
36 doi:10.3109/14767058.2013.798281.
- 37
- 38 71. Tracey N. *Parents of Premature Infants. Their Emotional World.* London: Wiley and Sons; 2000.
- 39
- 40 72. Provenzi L, Barellò S, Fumagalli M, et al. A Comparison of Maternal and Paternal Experiences
41 of Becoming Parents of a Very Preterm Infant. *JOGNN - J Obstet Gynecol Neonatal Nurs.*
42 2016;45(4):528-541. doi:10.1016/j.jogn.2016.04.004.
- 43
- 44 73. Arockiasamy V, Holsti L, Albersheim S. Fathers' experiences in the neonatal intensive care unit:
45 a search for control. *Pediatrics.* 2008;121(2):e215-e222. doi:10.1542/peds.2007-1005.
- 46
- 47 74. Pohlman S. The primacy of work and fathering preterm infants. *Adv Neonatal Care.*
48 2005;5(4):204-216. doi:10.1016/j.adnc.2005.03.002.
- 49
- 50 75. Pohlman S. Fathering Premature Infants and the Technological Imperative of the Neonatal
51 Intensive Care Unit. *Adv Nurs Sci.* 2009;32(3):E1-E17. doi:10.1097/ANS.0b013e3181b0d68c.
- 52
- 53 76. Arnold L, Sawyer A, Rabe H, et al. Parents' first moments with their very preterm babies: A
54 qualitative study. *BMJ Open.* 2013;3(4). doi:10.1136/bmjopen-2012-002487.
- 55
- 56 77. Radloff LS. The CES-D Scale: A Self-Report Depression Scale for Research in the General
57 Population. *Appl Psychol Meas.* 1977;1(3):385-401. doi:10.1177/014662167700100306.
- 58
- 59 78. Spanier GB. Measuring Dyadic Adjustment: New Scales for Assessing the Quality of Marriage
60 and Similar Dyads. *J Marriage Fam.* 1976;38(1):15. doi:10.2307/350547.

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59
60
79. Scheiner AP, Sexton ME. Prediction of developmental outcome using a perinatal risk inventory. *Pediatrics*. 1991;88(6):1135-1143.
80. Tronick E, Weinberg M. *Infant Regulatory Scoring System (IRSS)*. Boston: The Child Development Unit, Children's Hospital; 1990.
81. Cohn JF, Tronick EZ. Mother-Infant Face-to-Face Interaction: Influence is Bidirectional and Unrelated to Periodic Cycles in Either Partner's Behavior. *Dev Psychol*. 1988;24(3):386-392.
82. Beebe B, Jaffe J, Markese S, et al. The origins of 12-month attachment: a microanalysis of 4-month mother-infant interaction. *Attach Hum Dev*. 2010;12(1-2):3-141. doi:10.1080/14616730903338985.
83. Lavelli M, Beebe B. Coding parent-infant interaction in the NICU. *Unpubl Manuscr*. 2016.
84. Bakeman R, Quera V. *Analyzing Interaction: Sequential Analysis with SDIS & GSEQ*. New York: Cambridge University Press; 1995.
85. Singer JD, Willett JB. *Applied Longitudinal Data Analysis*. Oxford: Oxford University Press; 2003. doi:10.1093/acprof:oso/9780195152968.001.0001.
86. Moscardino U, Axia G, Scrimin S, Capello F. Narratives from caregivers of children surviving the terrorist attack in Beslan: issues of health, culture, and resilience. *Soc Sci Med*. 2007;64(8):1776-1787. doi:10.1016/j.socscimed.2006.11.024.
87. Lavelli M, Do ge P, Bighin M. Socialization Goals of Immigrant Mothers from Diverse Cultures and of Their Childrens Preschool Teachers in Italy. *J Cross Cult Psychol*. 2016;47(2):197-214. doi:10.1177/0022022115616870.
88. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol*. 2006;3(2):77-101. doi:10.1191/1478088706qp063oa.
89. Boyatzis R. *Transforming Qualitative Information: Thematic Analysis and Code Development*. Thousand Oaks: Sage; 1998.

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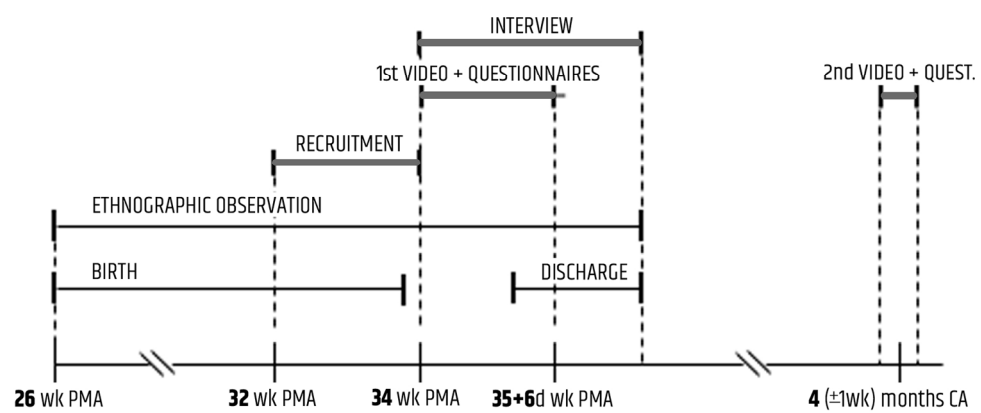


Figure 1. Study Timeline. wk = weeks; PMA = Post-Menstrual Age; CA = Corrected Age.

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