Evaluating the Effects of Kangaroo Care in the NICU

Principal Investigator: Craig Garfield, MD

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Contents

1. Background and Significance

Among 4 million infants born annually in the US, nearly 0.5 million are born prematurely (<37 weeks gestation) and cared for in Neonatal Intensive Care Units (NICUs). These preterm infants are extremely vulnerable in the perinatal period, with increased risks of physiologic instability, apnea, chronic intermittent hypoxemia, impaired temperature and metabolic regulation, and infection (1-7). Such prematurity-related complications are the leading cause of neonatal mortality and morbidity and result in longer average lengths of hospital stay and higher rates of re-hospitalization in preterm infants than in full term infants. Strategies to improve the physiologic stability and maturation of preterm infants during the critical perinatal period are vital to improve preterm infant outcomes, reduce life-long morbidity, and mitigate associated healthcare costs.

Skin-to-skin contact between a preterm infant and a parent, also known as kangaroo care (KC), is an important, inexpensive modality deployed in the NICU to support the infant's development and the formation of the parent-infant bond. During KC, a parent holds an infant against their bare chest, skin-to-skin. NICU implementation of KC typically involves the mother (8), in a practice familiarly termed Kangaroo Mother Care (KMC). Over 1,000 articles supporting the implementation and positive effects of KMC have been published, outlining the positive effects of KMC intervention on physiologic and psychosocial outcomes. KMC is invaluable in promoting strong mother-infant bonds, reducing morbidity and mortality, improving infant physiologic stability, and benefiting overall development trajectories. Additionally, KMC has also been shown to greatly benefit mothers, with improved initiation and duration of breastfeeding, reduced anxiety, and improved sense of confidence in parenting (10).

In contrast to KMC, conspicuously little research has been published about the implementation and benefits of Kangaroo Father Care (KFC). The limited preliminary data that are available support an association between KFC and improved preterm infant physiologic stability (e.g. heart rate variability, respiratory status, blood glucose, oxygen saturation (13)), infant contentment (e.g. crying episodes (12), time to relaxed state (13) and father-infant bonding (12). While both mothers and fathers have been noted to experience doubt, stress, anxiety, depression and loss of control (16) in the NICU, fathers are faced with different challenges than mothers (17,18). Specifically, fathers have been shown to feel less important and less needed than mothers (19), un-empowered in terms of active participation at the bedside, and relegated to return to work and handle external affairs (20). Fathers also report a lack of confidence in how to interact with and care for their premature infant, including a fear of caring for the infant based on the infant's size and perceived fragility (17). Research suggests that these feelings can interrupt the father-infant bond (21). Additionally, fathers have been shown to hide their feelings and return to work while their infant is still in the NICU (19, 22-24) and to experience "pervasive uncertainty" when transitioning home (18). These feelings and experiences may further translate into individual and interpersonal stress, anxiety, and diminished parenting confidence. KFC may be an effective mechanism to support fathers through these experiences, so they can, in turn, better support infants and mothers.

Even though the short and long-term benefits, including cost-effectiveness, of KMC are clear and the World Health Organization recommends that KC be utilized as continuously as possible during the neonatal period (9), the benefits of KFC are only emerging and KC remains thoroughly under-utilized (14) in the NICU (15). We propose to revolutionize KC in the NICU by objectively measuring the effects of the KFC intervention on infants, fathers, and families. Utilizing wireless biosensor technology designed

by members of this team, our study will be the first of its kind to objectively evaluate KFC as an intervention for improving both acute and long-term outcomes of infants, mothers, and fathers in the NICU.

2. Study Hypothesis and Outcomes

2.1. Study Hypothesis

The main hypothesis of this study is that Kangaroo Father Care (KFC) will positively impact acute physiologic and long-term behavioral outcomes in infants, fathers, and families.

2.2. Outcome Measures

2.2.1. *Primary Outcome*

Primary outcome measures include heart rate (HR) and oxygen saturation (SpO2) as indicators of cardiorespiratory stability in infants before, during, and after KC and HR and HR variability (HRV) as indicators of physiologic stress in NICU parents during and after periods of KC. All of these outcomes will be measured using wearable, wireless biosensors.

2.2.2. *Secondary Outcomes*

Secondary outcome measures include 1) Accelerometry data captured using the wearable biosensors and compared to observations of infant position made by a study team member during KC sessions to validate the accuracy of these biosensors in detecting body position and movement during KC; 2) Infant salivary cortisol reactivity, maternal salivary cortisol reactivity, and paternal salivary cortisol, testosterone, and oxytocin reactivity, compared before, during, and after KC; 3) Parenting confidence, relationship quality, and involvement scores as quantitated by the Parenting Sense of Competence Scale (PSOC), the Revised Dyadic Adjustment Scale (RDAS), the Postpartum Bonding Questionnaire, and a Father Involvement Scale at baseline, before discharge, two weeks after discharge, and four weeks after discharge. Two-sample t tests and mixed-effect linear regression models will be used to assess the mean between-group differences. Covariates such as age, education, socio-economic status (SES), stress and depression will be adjusted in the multivariable regression model.

3. Study Design

3.1. Eligibility Criteria

3.1.1. ***Inclusion Criteria***

Infants: Infants who are born at Prentice Women's Hospital between 30 0/7 and 36 6/7 weeks gestation, are ≤20 days old at the time of enrollment, and do not meet any of the study's exclusion criteria will be eligible for participation in this study. Additionally, infants will only be included in this study if both of their biological parents are eligible and agree to participate.

Parents: Parents who are ≥18 years of age, English speaking, expect mother and father to raise the infant together in the same household regardless of their marital status, and do not meet any of the study's exclusion criteria will be eligible for participation in this study. Additionally, family units will only be included in this study if both biological parents of the infant are eligible and agree to participate.

Only English speaking parents will be included in this trial because the study questionnaires are only available in English.

3.1.2. ***Exclusion Criteria***

Infants: Infants who are intubated or sedated, are receiving vasopressors or analgesics, have any congenital anomalies or skin abnormalities deemed likely to impact KC by clinical team, have received or are planned to receive surgical intervention that will impact the utilization of KC, wearable sensors, and/or oral swabs, or are experiencing other symptoms or receiving other intervention that will impact the utilization of KC, wearable sensors, and/or oral swabs will be excluded from this study.

Parents: Parents who are showing any signs of illness or taking corticosteroids or testosterone supplementation will be excluded from this study. Non-English speaking parents will also be excluded from this study because the questionnaires associated with this study are only available in English.

3.2. Screening and Consent

Families who qualify for participation in this study will be identified through review of electronic medical records. Once a potential subject is identified, a study team member will consult the NICU care team in order to assess the condition of the infant and determine the family's approachability for discussion of the study. If the clinical care team feels a family is approachable, a member of the study team will identify the best time to meet with the family. All participation will be discussed at the infant's bedside in a private room.

During this discussion, the study team member will outline the following study details for the family: the rationale of the study, the specifics of data and specimen collection, the study team's legal and ethical obligations and practices to ensure confidentiality, the physiologic monitoring by wearable, wireless biosensor, the KC interventions, the salivary sample collection, the saliva questionnaires and the psychosocial questionnaires and follow-up. The study team member will also discuss the risks of participation, which include the risks of adverse reaction to the adhesive used on the wearable, wireless biosensors. The family will be informed that their commitment or refusal to participate will not affect the care their child receives in the NICU and will be completely optional and anonymous. A copy of the Informed Consent document will be provided to each family. The family will then be left with the consent form to review discuss privately. After this period of private review, the study team member will return and give parents the opportunity to ask questions. Once all questions are answered, the parents will be asked to describe the study process as they understand it in their own words. To minimize the amount of time the study team spends in the infant's bed space an infant's parent(s) may provide consent over the phone or a secure telecommunication platform such as Skype for Business. The consent process as described above will not change. The family will be provided written materials describing the nature of the optional elements and given an opportunity for questions and private discussion.

Consent obtained over the phone or secure telecommunication platform will be obtained according to institutional policy. A member of the study team will explain in detail and review the informed consent document(s) with the parent(s). If the parent(s) agree to participation, they will sign a copy of the informed consent document(s) and the study team member obtaining consent will sign a copy at the

same time. The parent(s) will be required to send their signed document(s) to the study team by mail, fax, or email, and the two signature pages will be combined. The parent(s) will be provided a copy of the fully executed, signed informed consent document(s) by mail, fax, or email prior to any study procedures.

3.3. Study Procedures

Screening:
Participants will be recruited from the NICU at Prentice Women's Hospital. A member of the study team will screen all NICU patients for inclusion and exclusion criteria by reviewing electronic medical records. A screening and enrollment log will be kept to track families who have been approached and agreed or declined to participate in the study. The screening and enrollment log will be kept on a secure REDCap server housed by Northwestern University. Only the study team will have access to this log.

Kangaroo Care (KC) Intervention:
After enrollment, families will be scheduled to participate in two sessions of KC. The goal will be to schedule the KC sessions over two sequential days and at approximately the same time of day (i.e. morning, afternoon, or evening). However, if this is not possible given the parents' schedules, the sessions will be scheduled for the days and time of day that participating parents are able to visit their infant in the NICU. Each session will include two hours of continuous KC, with one day focused on Kangaroo Mother Care (KMC) and the other on Kangaroo Father Care (KFC), in a randomized order. These sessions will include continuous skin-to-skin holding of the infant by the parent, per standard of care protocol.

Physiologic Recording:
Infant: Prior to the first scheduled KC session, two wearable, wireless biosensors will be placed on the infant to continuously capture physiology measures including electrocardiogram (ECG), heart rate (HR), oxygen saturation (SpO2), body temperature, respiratory rate, movement, systolic blood pressure (BP-S), and others for the duration of the study. One device will be placed on the infant's chest or back. A second device will be placed peripherally, on the infant's leg, foot, arm, or hand. The devices are encapsulated in a medical-grade silicone and will be adhered to the infant's skin using a medical-grade adhesive, similar to the adhesives standardly used in the NICU. The biosensors will be left in place for up to 48 hours, but will be checked by study staff at least once every 24 hours to ensure skin integrity and signal quality. The adhesives will be changed between uses.

***Parent*:** The same type of wearable, wireless biosensor will also be used to record 4 hours of continuous physiology including ECG, HR, temperature, movement, SpO2, and others in the infant's parents. The biosensor will be placed on the parent's chest 1 hour before the start of a scheduled KC session and worn for 1 hour preceding the scheduled KC session, during the 2-hour KC session, and for 1 hour after the completion of the KC session. The biosensor will be worn by the parents for approximately 4 hours in total.

Skin Monitoring:
Before and after the wearable biosensors are placed on the infant, the infant's skin integrity will be evaluated using a neonatal skin scoring measure for monitoring skin integrity. Study staff will take

photographs of the skin at the site of biosensor placement before the biosensors are placed and after the biosensors are removed. Skin changes occurring while the biosensor is adhered to the infant's skin will be documented photographically. No faces will be photographed. The study team will consult the bedside care team within 1 hour for any changes in skin integrity (based on the neonatal skin integrity score).

Saliva Sample Collection:
Saliva will be collected from enrolled infants and parents non-invasively to evaluate the effects of KFC on established biomarkers of stress (cortisol and testosterone) and father-infant bonding (oxytocin). Before, during, and after each KC session, saliva will be collected from the participating parent, and their infant. A trained member of the study team will collect saliva from the infant using suction, a method that follows the standard of care for the infant, or oral swabs (27) made from an inert polymer and appropriately sized for an infant mouth (approximately 5 mm). Saliva samples will be taken from the infant immediately prior to beginning a KC session (T1), 30 minutes into the KC session (T2), and 30 minutes post-session (T3). Parents will self-collect saliva samples at the time points outlined above, using an adult-sized oral swab. At T2, the trained study team member will be able to help the parent collect the saliva sample, if necessary, while the parent continues to hold their infant. This approach to salivary sample collection and biomarker analysis is similar to that established by previous studies of kangaroo care (26,27) and takes into consideration the 30-minute delay before cortisol reactivity in saliva.

Saliva Questionnaires:
When saliva is collected from parents at time points T1, T2, and T3, parents will also be asked to complete a brief saliva questionnaire. These questionnaires will take approximately five minutes each to complete and will be completed on paper or directly in REDCap, depending upon the participant's preferences. At T2, a study team member will be able to help the parent complete the survey, if necessary, while the parent continues to hold their infant. Data provided on surveys completed on paper will be transferred to secure REDCap forms by study staff and destroyed within 24 hours. All questionnaire data will be stored long term on the secure REDCap server housed by Northwestern University.

Psychosocial Questionnaires:
This study will employ psychosocial measures to capture the short- and long-term impacts of KFC. Specifically, validated measures of parenting confidence, relationship quality, infant bonding, and father involvement will be assessed via a set of paper or REDCap surveys administered in the NICU (short term) at baseline and the day before discharge (T-1) , and at home (long term) at 2 weeks (T+14) and 4 weeks (T+30) after discharge. Each of these sets of surveys will take approximately 30 minutes to complete. At baseline, each parent will complete the Revised Dyadic Adjustment Scale (RDAS) and the Postpartum Bonding Questionnaire (PBQ). At T-1, each parent will complete the RDAS , the PBQ, and the Parenting Sense of Competence Scale (PSOC). These questionnaires will be completed on paper or directly in REDCap, depending upon the participant's preferences. Data provided on surveys completed on paper will be transferred to secure REDCap forms by study staff and destroyed within 24 hours. At T+14 and T+30, each parent will complete the RDAS, the PBQ, the PSOC, and a Father Involvement Questionnaire. These questionnaires will be completed directly in REDCap only. Each parent will

receive an email containing a link to their set of questionnaires at both post-discharge time points. All questionnaire data will be stored long term on the secure REDCap server housed by Northwestern University.

Wearable Sensor Data Collection:
The wearable sensor that will be used in this study can stream data continuously using near field communication (NFC) or Bluetooth technology. An encrypted laptop, iPad, or similar device will be left in the patient room and used to capture the continuous data stream from the wearable sensor. Additionally, wearable biosensors can include onboard memory, and physiologic streams may be recorded to this onboard memory until transfer to an encrypted laptop for analysis.

We have recently upgraded a new firmware version activating the ability for the sensor to continuously measure bioimpedance for respiratory rate. This function does not require any modification to the physical device itself or the adhesive. However, the bioimpedance functionality does require delivery of low amplitude sinusoidal current through the electrodes of the chest unit. The frequency of the current is 4 kHz – a frequency range used typically for human bioimpedance measurements by FDA cleared systems. The maximum current delivered is 8 µA. The sensors with these parameters are safe to be worn by the infants for the duration of the study, which is up to 48 hours. These parameters are below commonly used body fat percentage impedance analyzers that are widely commercially available. Furthermore, bioimpedance is standard measurements in existing NICUs / PICUs leveraging the ECG electrodes that are then displayed on standard of care monitors. Commercially bioimpedance devices that are FDA approved inject currents that are 10x greater than our system (e.g. the CoVa Monitoring System 2 for continuous wearable sensing of thoracic impedance). Finally, the parameters in our sensor follow IEC 60601-1-2 guidelines for electromagnetic safety.

Standard of Care Data Collection:
In all patients in rooms where data from standard of care monitoring is recorded on the BedMaster system, this data will be used for comparison to data captured using the wearable sensors. In participants in rooms where this system is not available, the MediCollector system will be used to capture background data during the approximately 48-hour study.

3.4. Study Timeline

Activity	**Duration**
Study Set-up	12/2018-3/2019
Recruitment	2/2019-5/2021
Data Collection	2/2019-5/2021
Final Data Analyses + Report	12/2019-12/2021

4. Study Safety

4.1. Privacy Protections

The study team will take measures to protect the privacy and confidentiality of participants. The plan to protect patient privacy includes approaching and consenting participants in a private room. Study procedures will be done in the privacy of the patient rooms in the ICU. Study participation discussions will be limited to members of the study staff and the involved participants.

Participant data will be coded with study identifier only. All data obtained from the bedside monitors will be stored on the Azure Cloud (maintained by Data Analytics Reporting (DAR) at Lurie Children's). All data obtained using wearable sensors will be stored on an encrypted laptop and secure network for later analysis. All questionnaire responses will be collected via Research Electronic Data Capture (REDCap) hosted by Northwestern University. When preferred, parents can fill in questionnaires on paper, and these will be transferred to REDCap by study staff after collection.

To minimize the risks, only the minimum data necessary to complete the study will be collected on each study participant.

Photographs will be labeled only by study code, and will not include subject's face. Video may include the subject's face, but all videos will be scored for position and movement within 1 month of recording, and will be deleted after scoring. All photos and videos will be stored on a password protected server accessed by a password protected computer.

Only authorized personnel listed in the IRB application will have access to study data. The screening and enrollment log used contain the code link, and this file will be stored on the REDCap server and will have access limited to the study team. The link between the participants and their study identifier will be destroyed at the conclusion of this study, so all remaining data will be fully de-identified.

Data transferred to the study team by the NU electronic data warehouse for patients meeting screening criteria in the Prentice NICU will be downloaded onto the Lurie Children's Hospital server. This data file will be used for up to one week to allow the screening process to take place, then will be deleted.

Confidentiality will be maintained with all of the medical records of this study. Subject records will be kept in a locked cabinet, under the control of the Principal Investigator. The subject will also be assigned a code in the data sheets so that the records on the computer will be kept confidential.

Potential Risks

Sensor Risks: There is a risk of discomfort or irritation from the adhesives used with wearable, wireless biosensors. It is possible that the additional handling required to place the biosensors may be temporarily disruptive for the participants. Study staff will check on the participant at least once every 24 hours to monitor for signs of discomfort, irritation, or allergic reaction. Skin integrity will be scored according to the protocol, and the bedside team will be consulted within 1 hour for any concerns. Any adverse events or evidence of discomfort during monitoring will be recorded and the bedside team will be immediately consulted. Photographs will be taken at baseline and after study; skin changes during the period of wearable biosensor use or at subsequent time points will be documented photographically.

Parent Questionnaire Risks: Some questions may make parents uncomfortable or upset. It will be made clear to the parents that they do not have to answer any questions that make them feel uncomfortable or upset. The parents will be informed that they can end their participation in the study at any time

4.2. Discontinuation Criteria

A participant may be discontinued if the participant is unwilling or unable to tolerate the wearable sensors, saliva collection, or skin-to-skin session. Examples may include adverse reactions to the adhesive on the wearable sensors or a patient removing the wearable sensors. The bedside clinical team or family can also request discontinuation at any time. Families participating in the video monitoring can request discontinuation of the video monitoring aspect of this study at any time during the study.

4.3. Patient Withdrawal

Any participants withdrawn from the study will have the wearable sensors removed immediately. Any data collected prior to the withdrawal will remain a part of the study, and this data will be coded.

5. Statistical Analysis

5.1. Statistical Plan

Measurements made through clinical standard of care will be compared to the measurements recorded by the wearable sensors. Distribution checks for normality and data accuracy will be completed for each individual and for the entire study prior to all analyses. For continuous measures of physiology, 30 second epochs will be defined for each method for comparison.

Agreement and correlation of wearable biosensor measures to standard of care measures will be assessed in two ways. First, Bland–Altman plots will be created to assess agreement between each measurement system via bias and precision, which reflect the mean or average difference between two methods and the variation in these differences, respectively. Our second method consists of individual correlations between methods assessed for each person. This correlational method will supplement additional methods, and can be directly transformed to variance shared between wearable biosensor and standard of care measures, a common metric of reliability of any measure.

Formal tests of bias, precision, and correlations: While the above methods will yield useful statistics, they need to be extended to deal with the structured nature of our data. Specifically, our data are clustered, meaning that we have multiple observations within each person and multiple people in our sample, which violates standard independence assumptions inherent to many models. We propose to estimate bias and correlation/reliability using multi-level models, which yield the same statistics discussed above but account for the fact that observations taken from the same patient are more related than comparisons involving different patients.

Data will be cleaned and analyzed using IBM SPSS Statistics 20.0, unless a newer version of SPSS is available. Using repeated-measures analysis of variance (RM-ANOVA), with the study phase (pre-, during-, and post-kangaroo care) as the repeated factor, we will test differences across study phase for maternal cortisol, paternal cortisol, infant cortisol, paternal oxytocin, and paternal testosterone. We will use a two-tailed test with a 5% level of significance analysis. In addition to tracking changes over the period of kangaroo care, we will also examine within-triad correlations in cortisol for mother-father-

infants in the same family, as well as correlations between infant cortisol and father testosterone/oxytocin, and maternal cortisol and father testosterone-oxytocin.

Statistical Power: The large amount of within-person data provides incredibly high statistical power for all planned and many secondary data analyses, allowing this data set to answer all proposed questions. Previous work on power in multilevel models found greater than 99% power to detect associations with the planned observations suggested here within comparable nested designs.

6. References

1.Escobar GJ, Clark RH, Greene JD. Short-term outcomes of infants born at 35 and 36 weeks gestation: we need to ask more questions. Semin
Perinatol. 2006;30(1):28-33.

2.Wang ML, Dorer DJ, Fleming MP, Catlin EA. Clinical outcomes of near-term infants. Pediatrics. 2004;114(2):372-376.

3.Kramer MS, Demissie K, Yang H, Platt RW, Sauvé R, Liston R. The contribution of mild and moderate preterm birth to infant mortality. Fetal and Infant Health Study Group of the Canadian Perinatal Surveillance System. JAMA. 2000;284(7):843-849.

4.Santos IS, Matijasevich A, Silveira MF, Sclowitz IK, Barros AJ, Victora CG, Barros FC. Associated factors and consequences of late preterm births: results from the 2004 Pelotas birth cohort. Paediatr Perinat Epidemiol. 2008;22(4):350-359.

5.Tomashek KM, Shapiro-Mendoza CK, Davidoff MJ, Petrini JR. Differences in mortality between late-preterm and term singleton infants in the United States, 1995-2002. J Pediatr. 2007;151(5):450-456.

6.Pulver LS Guest-Warnick G, Stoddard GJ, Byington CL, Young PC. Weight for gestational age affects the mortality of late preterm infants. Pediatrics. 2009;123(6):e1072-1077.

7.Escobar GJ, McCormick MC, Zupancic JA, et al. Unstudied infants: outcomes of moderately premature infants in the neonatal intensive care unit. Arch Dis Child Fetal Neonatal Ed. 2006;91(4):F238-244.

8.Xue WL, Shorey S, Wang W, He HG. Fathers' involvement during pregnancy and childbirth: An integrative literature review. Midwifery. 2018;62:135-145.

9.World Health Organization recommendations on interventions to improve preterm birth outcomes. In: Geneva, Switzerland: World Health Organization Press; 2015. [Internet].

10.Moore ER, Anderson GC, Bergman N, Dowswell T. Early skin-to-skin contact for mothers and their healthy newborn infants. Cochrane Database Syst Rev. 2012(5):CD003519.

11.Fischer CB Sontheimer D, Scheffer F, Bauer J, Linderkamp O. Cardiorespiratory stability of premature boys and girls during kangaroo care. Early Human Development. 1998;52(2).

12.Kamphorst K Brouwer AJ, Poslawsky IE, Ketelaar M, Ockhuisen H, van den Hoogen A. Parental Presence and Activities in a Dutch Neonatal Intensive Care Unit: An Observational Study. J Perinat Neonatal Nurs. 2018;32(3):E3-E10.

13.Velandia M, Unväs-Moberg K, Nissen E. Sex differences in newborn interaction with mother or father during skin-to-skin contact after Caesarean section. Acta Paediatrica. 2012;101(4).

14.Campbell-Yeo ML, Disher TC, Benoit BL, Johnston CC. Understanding kangaroo care and its benefits to preterm infants. Pediatric Health Med Ther. 2015;6:15-32.

15.Pallas-Alonso CR, Losacco V, Maraschini A, et al. Parental involvement and kangaroo care in European neonatal intensive care units: a policy survey in eight countries. Pediatr
Crit Care Med. 2012;13(5):568-577.

16.Ionio C, Columbo C, Brazzoduro V, Mascheroni E, Confalonieri E, Castoldi F, Lista G. Mothers and Fathers in NICU: The Impact of Preterm Birth on Parental Distress. Eur J Psychol. 2016;12(4):604-621.

17.Logan RM, Dormire S. Finding My Way: A Phenomenology of Fathering in the NICU. Adv Neonatal Care. 2018;18(2):154-162.

18.Garfield CF, Lee Y, Kim HN. Paternal and maternal concerns for their very low-birth-weight infants transitioning from the NICU to home. J Perinat Neonatal Nurs. 2014;28(4):305-312.

19.Helth T, Jarden M. Fathers' experiences with the skin-to-skin method in NICU: Competent parenthood and redefined gender roles. Journal of Neonatal Nursing. 2013;19(3):114-121.

20.Mackley AB, Locke RG, Spear ML, Joseph R. Forgotten parent: NICU paternal emotional response. Adv Neonatal Care. 2010;10(4):200-203.

21.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.

22.Pohlman S. The primacy of work and fathering preterm infants: findings from an interpretive phenomenological study. Adv Neonatal Care. 2005;5(4):204-216.

23.Hugill K, Letherby G, Reid T, Lavender T. Experiences of fathers shortly after the birth of their preterm infants. J Obstet
Gynecol Neonatal Nurs. 2013;42(6):655-663.

24.Arockiasamy V, Holsti L, Albersheim S. Fathers' experiences in the neonatal intensive care unit: a search for control. Pediatrics. 2008;121(2):e215-222.

25. Clearfield MW, Carter-Rodriguez A, Merali AR, Shober R. The effects of SES on infant and maternal diurnal salivary cortisol output. Infant Behav Dev. 2014;37(3):298-304.

26. Early Origins of Health Disparities: Material Deprivation Predicts Maternal Evening Cortisol in Pregnancy and Offspring Cortisol Reactivity in the First Few Weeks of Life. American Journal of Human Biology.
2014; 26(6):723-730.

27. Kahraman A, Başbakkal Z, Yalaz M, Sözmen
EY.The effect of nesting positions on pain, stress and comfort during heel lance in premature infants.Pediatr
Neonatol. 2018 Aug;59(4):352-359.

28. Srinath BK, Shah J, Kumar P, Shah PS. Kangaroo care by fathers and mothers: comparison of physiological and stress responses in preterm infants. J Perinatol. 2016 May;36(5):401-404.