

Effect of Developmental Care on Preterm Neonates' Neurodevelopmental Outcomes at 12 Months of Age

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ABSTRACT

Background: Premature birth and subsequent admission to the neonatal intensive care unit (NICU) may impair the neurodevelopment of neonates. The present study aimed to determine the effect of developmental care on neurodevelopmental outcomes of newborns.

Methods: This quasi-experimental study was conducted on 105 premature neonates (in three groups of 35 newborns). The control group received conventional care, and the intervention group 1 received developmental care beginning since admission to NICU stay. In addition, the intervention group 2 received developmental care since entering the delivery or operating room. The developmental outcomes were evaluated based on the Ages and Stages Questionnaire (ASQ) and Bayley-III Scales of Infant and Toddler Development. Moreover, magnetic resonance imaging was performed to evaluate the brain myelination at the adjusted age of 12 months.

Results: The obtained findings showed that the frequency rates of communication and language impairment were significantly lower in the intervention group 2, compared to those reported for the control group and intervention group 1, based on the ASQ. The comparison of the scores of the Bayley subscales (i.e., cognition, language, and motor) showed that the frequency of language impairment was significantly higher in the control group, compared to those reported for the intervention group 1 ($P=0.012$) and intervention group 2 ($P=0.024$). No significant difference was observed in terms of the neonates' brain myelination ($P>0.05$).

Conclusion: The obtained results showed that developmental care, especially when initiated since birth, may improve some aspects of developmental outcomes in preterm newborns.

Keywords: Development, Infant care, Outcome, Premature infant

Introduction

Technological advancements in newborn care have increased their survival rate; however, the advancements have not been able to reduce the risks of developmental delay, physical disabilities, and behavioral disorders (1). After a preterm birth, the newborn's brain is still premature and develops rapidly during and after infancy (2). The neonatal intensive care unit (NICU) and other hospital wards, characterized by constant lighting and noise and various procedures, are completely different from the intrauterine environment.

Several studies have reported the negative effects of the NICU stressful environment on developmental outcomes, including maturity, visual-hearing organization, sleep patterns, growth, and neural development (3-8).

In recent decades, the focus on caring for preterm neonates has shifted from reducing mortality to minimizing complications and promoting outcomes (9). Many researchers have sought to prevent complications by improving the NICU environment for newborns and their parents

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(6, 10, 11). The development of premature neonates might be enhanced by the continuous provision of developmental and family-oriented care (12, 13).

Developmental care is an approach to adopt nursing and medical interventions to reduce stress levels in premature newborns and their parents (12, 14). The core measures of developmental care are sleep caring, management and assessment of stress and pain, routine and daily care, family-based care, and provision of a healthy environment for the NICU (15). Developmental care is a relationship-based intervention requiring the establishment of trust between parents and health personnel (15, 16). These interventions, such as decreasing known environmental stressors, have been designed for neonates' neurobehavioral development (17).

Several studies have shown that modifying care practices to reduce newborns' stress and pain, support neonates' self-regulation, encourage the presence of parents, and increase bonding and attachment had positive effects on different dimensions of brain development (18-20). However, all studies have not confirmed the beneficial effects of developmental care in this regard.

Wielenga et al. (2007) concluded that the recipients of developmental care were less likely to have severe brain damages (21). Peters et al. (2009) assessed the short- and long-term effects of developmental care and identified significant reductions in hospitalization, need for oxygen, and prevalence of developmental disabilities in very low birth weight newborns receiving developmental care (22). Als et al. (2012) reported the positive effects of developmental care on neuropsychological outcomes, including brain function and structure, in premature newborns with very low birth weight. However, in the aforementioned study, it was recommended to carry out larger studies for the long-term evaluation of such effects (19).

McAnulty et al. (2012) demonstrated that the Newborn Individualized Developmental Care and Assessment Program (NIDCAP) had positive effects on neuropsychological and neuro-electrophysiological functions and brain structure at school age (23). In contrast, in a meta-analysis carried out by Jacobs et al. (2002), the positive effects of developmental care were not fully supported, and it is suggested to perform further studies with more participants and longer duration in this regard (24). Maguire et al. (2009) evaluated the effects of developmental care on

164 premature newborns. They did not find a significant difference in neuromotor (15) development between the study groups at their corrected age (1).

Ohlsson (2009) emphasized the importance of initiating developmental care since birth that is the time the neonate is exposed to severe stressors, such as light and noise and painful stimuli (25). The results of a previous study carried out by the same authors showed that developmental care for preterm newborns, especially when initiated as early as entering the delivery or operating room, could reduce the duration of neonatal hospitalization and frequency of neonatal sepsis (26).

To the best of our knowledge, no study has evaluated the developmental care outcomes at the newborn's corrected age of 12 months, when initiated at birth, in premature neonates in Iran. Nevertheless, similar to other new interventions, developmental care needs precise and scientific evaluation. Therefore, this study aimed to assess the effects of in-hospital developmental care on the developmental outcomes and brain myelination at the age of 1 year in premature neonates born in Alzahra Hospital in Tabriz, Iran. It was hypothesized that developmental outcomes and brain myelination would improve following receiving in-hospital developmental care (compared to traditional care).

Methods

Study Design and Participants

This quasi-experimental study was approved by the Research Council and Ethics Committee of Women's Reproductive Health Research Center in Tabriz University of Medical Sciences, Tabriz (Code: 9345) and registered in the Iranian Registry of Clinical Trials (IRCTID: IRCT201405175563N5). The inclusion criteria were parents' consent for their child's inclusion in the study, gestational age of ≤ 32 weeks, birth weight of ≤ 1500 g, birth in Alzahra Hospital, no reported maternal alcohol or drug use during pregnancy, and initiation of mechanical ventilation or continuous positive airway pressure within 3 h after birth and continuation of the procedure for at least 24 h.

The exclusion criteria were chromosomal and congenital anomalies, severe congenital infections (according to the medical records), need for surgery (according to the medical records), parents' withdrawal from the study, and inappropriate gestational weight (young or old regarding the gestational age based on growth

standards).

The sample size was calculated based on a study carried out by Vameghi et al. (27) and results related to the total score of the Ages and Stages Questionnaire (ASQ) (Mean1=51). By estimating a 20% increase in the mean score of the aforementioned total score (mean2=61.2; standard deviation1=standard deviation 2=12.8; two-sided, $\alpha=0.05$) and statistical power of 90%, the sample size was determined at 32 neonates. Considering a 10% sample attrition, the sample size was determined at 105 newborns in three groups of 35 subjects.

Sampling and Intervention

Convenience sampling was performed in three stages (i.e., before December 2013, late 2014, and early 2015). The participants were matched in terms of gestational age and birth weight.

Control group: The medical records of neonates admitted to Alzahra Hospital before December 2013 (when no developmental care was provided in the NICU of the hospital) were evaluated, and eligible newborns were included in the control group. After selecting the subjects of the control group, developmental care education began in the hospital. Accordingly, the research team held one weekly session for 1 year to train the staff on the dimensions of developmental care. The training sessions were repeated for new personnel. After about 1 year, sampling was started for the intervention groups. Maternal training programs for the control group began immediately after the mother's transfer to the postpartum department. The developmental care was provided to all the neonates born before 33 weeks of gestation.

Intervention Group 1: The neonates received developmental care in the NICU and neonatal ward. The provided care consisted of reduced light, noise, and pain, nesting and positioning,

maternal training program, mother's participation in care, massage, and kangaroo mother care (KMC).

Intervention Group 2: One researcher provided the newborns with developmental care since entering the delivery or operating room. Since the researcher could not support all births, the sampling was performed only during the day. The provided care consisted of cord milking (the cord was clamped and cut at approximately 20 cm distal to the umbilicus and milked from distal toward neonate three times and then clamped 2 to 3 cm from the umbilical stump) (28), covering newborn's eyes with a hat, allocation of a quiet place to the preterm labor, and use of covered incubators for neonate's transfer. The developmental care continued at the NICU and neonatal ward. The differences and similarities of developmental care in three groups of study are shown in Table 1.

The process of sampling continued until obtaining the desired sample size of 35 per group. The maternal training program was provided by the research team for the intervention groups 1 and 2 and included the information on how to express breast milk, perform KMC and baby massage, touch the baby and talk with him/her, and participate in newborn nutrition and health care. The 1-hour training sessions were held once a week during the neonate's hospitalization. Some facilities were provided for the mothers' participation in taking care of their children to accompany their newborns. The facilities were provided for the intervention groups 1 and 2 after beginning developmental care in Alzahra Hospital.

Data Collection

After obtaining written informed consent from all mothers, a questionnaire containing mothers' demographic and obstetric characteristics and neonate's medical background was administered

Table 1. Differences and similarities of developmental care in study groups

Developmental care	Control	Intervention 1	Intervention 2
At Birth	-	-	Cord milking, covering neonate's eyes with hat, allocation of quiet place to preterm labor, and use of covered incubators for neonatal transfer
At neonatal intensive care unit and neonatal ward	-	Reduced light, noise, and pain, nesting and positioning, maternal education, mother's participation in care, massage, and kangaroo mother care	Reduced light, noise, and pain, nesting and positioning, maternal education, mother's participation in care, massage, and kangaroo mother care

to collect data. The initial newborn risk was evaluated by the Clinical Risk Index for Babies (CRIB) and its components, including birth weight, gestational age, maximum and minimum inspired oxygen concentration, maximum base excess in the first 12 h, and congenital anomalies (29).

Developmental care was provided by a researcher at the moment of birth and by trained staff during the newborns' stay in NICU and neonatal unit. The mothers were provided with a telephone number to contact the researcher in case of necessity. The neonates' development was evaluated at the corrected age of 12 months based on the ASQ and Bayley-III Scales of Infant and Toddler Development. The cognition, language, and motor domains of the Bayley scales were completed by a trained expert blinded to study purpose and group assignments. Furthermore, the scores less than -1SD and -2SD below the mean scores of Iranian neonates in both scales were used to classify developmental delay as suspect or definite, respectively (30).

The newborns with definite developmental disorders were referred to a specialist. Finally, magnetic resonance imaging (MRI) was performed to evaluate the brain structures (in terms of myelination) of 10 neonates randomly selected from each group at the adjusted age of 12 months. The MRIs were taken in a single imaging center using hypnotic syrup (i.e., Chloral Hydrate Syrup) without anesthesia. The outcome evaluator and data analysts were all blinded to the assignments of the groups.

Data Analysis

The data were analyzed using descriptive statistics (i.e., number, percentage, mean, and standard deviation). The Kolmogorov-Smirnov test was applied to assess data normality. One-way analysis of variance was used for the comparison of quantitative normal variables, and non-normal quantitative variables were compared by the Kruskal-Wallis test. The Chi-square and Fisher's exact tests were used for comparing qualitative variables. The pairwise comparisons of three groups were performed using Tukey's post hoc test, Mann-Whitney U test, and Chi-square test. All the analyses were performed using SPSS software (version 21, SPSS Inc., Chicago, IL, USA).

Results

At the beginning of the study, 128 neonates were assessed regarding the eligibility criteria, and 6 neonates were excluded due to the mother's

unwillingness to participate in the study. In addition, 11 neonates died, and 16 neonates were transferred to another hospital. Therefore, a total of 105 neonates (35 neonates in each group) were included in the study. At the end of 12 months, three participants from the control group left the study due to a lack of willingness. Two participants from the intervention group 1 (one for lack of willingness and one due to the neonate's leg fracture) and four subjects from the intervention group 2 (one due to neonatal death, two due to a long distance, and one due to wrong telephone number) were also excluded from the study.

The mean age of the mothers in the three study groups was 28 years, and most (51.4%) of them were housewives with secondary and high school educational levels (45%). Most (54.3%) of the mothers in all the three groups were primiparous and gave birth through a cesarean section (77.1%). The frequency of maternal risk factors, such as lack of prenatal care, hypertension, pre-eclampsia, diabetes, thyroid disorders, and history of infertility, was high in all three groups. No significant differences in demographic, obstetric, or pregnancy-related characteristics were observed among the three groups ($P>0.05$). The neonatal characteristics in all three groups were comparable in terms of weight, gestational age, gender, and CRIB score. In addition, there were no significant differences among the groups in this regard ($P>0.05$).

The assessment of developmental condition using the ASQ also showed a significant difference between the frequencies of communication and language delay among the study groups at the corrected age of 12 months (Table 2; $P<0.05$). The pairwise comparisons of the groups showed that the frequency rates of communication and language impairment were significantly lower in the intervention group 2, compared to those reported for the control group ($P=0.014$) and intervention group 1 ($P=0.045$).

The comparison of the scores of the Bayley subscales (i.e., cognition, language, and motor) showed statistically significant differences in terms of the language domain. There were no significant differences in other developmental domains (Table 3). The pairwise comparisons of the groups showed that the frequency rate of language impairment was significantly higher in the control group, compared to those reported for the intervention group 1 ($P=0.012$) and intervention group 2 ($P=0.024$). The three groups

Table 2. Developmental delay in study groups based on Ages and Stages Questionnaire cut-off points at corrected age of 1 year

Ages and Stages Questionnaire subscales	Control n=32 n (%)	Intervention 1 n=33 n (%)	Intervention 2 n=31 n (%)	P-value*
Communication				
<1SD ¹	6 (17.1)	3 (8.6)	0 (0.0)	0.049
<2SD	2 (5.7)	3 (8.6)	0 (0.0)	
Gross motor				
<1SD	6 (17.1)	5 (14.3)	5 (14.3)	0.633
<2SD	6 (17.1)	4 (11.4)	2 (5.7)	
Fine motor				
<1SD	5 (14.3)	5 (14.3)	6 (17.1)	0.871
<2SD	1 (2.9)	3 (8.6)	2 (5.7)	
Problem-solving				
<1SD	8 (22.9)	3 (8.6)	5 (14.3)	0.383
<2SD	2 (5.7)	4 (11.4)	5 (14.3)	
Personal-social				
<1SD	6(17.1)	6 (17.1)	5 (14.3)	0.710
<2SD	0(0.0)	2 (5.7)	2 (5.7)	

¹SD: Standard deviation

*Chi-square test

Table 3. Developmental delay in study groups based on Bayley scale at corrected age of 1 year

Bayley subscales	Control n=32 n (%)	Intervention 1 n=33 n (%)	Intervention 2 n=31 n (%)	P-value*
Cognitive				
<1SD ¹	6 (17.1)	7 (20.0)	4 (11.4)	0.543
<2SD	2 (5.7)	4 (11.4)	1 (2.9)	
Language				
<1SD	10 (28.6)	2 (5.7)	3 (8.6)	0.008
<2SD	3 (8.6)	1 (2.9)	0 (0.0)	
Motor				
<1SD	11 (31.4)	17 (48.6)	14 (40.0)	0.511
<2SD	7 (20.0)	5 (14.3)	3 (8.6)	

*Chi-square test

¹SD: Standard deviation**Table 4.** Brain myelination status at corrected age of 1 year in study groups

Brain myelination	Control n=10 n (%)	Intervention 1 n=10 n (%)	Intervention 2 n=10 n (%)	P-value
Normal	9 (90.0)	8 (80.0)	9 (90.0)	>0.999*
Abnormal	1 (10.0)	2 (20.0)	1 (10.0)	

*Chi-square test

had no significant differences in terms of neonates' brain myelination (Table 4).

Discussion

The current study aimed to determine the effects of developmental care on neurodevelopmental outcomes and brain myelination at the corrected age of 12 months in premature newborns. The results of the present study to some extent supported the study hypothesis that in-hospital developmental care enhanced neurodevelopmental

outcomes. The beneficial effects of developmental care may be due to the modification of the stressful environment of hospitalized neonates. The mother-newborn interaction in the immediate postpartum period and parental involvement in neonatal care may be effective in the reduction of stress. Stress may have adverse effects on the synaptogenesis and function of the central nervous system in preterm neonates (19).

In the present study, the positive impact of developmental care was observed on the

communication and language subscales, and the scores were higher, especially in the group receiving developmental care immediately following the birth. Kelberg et al. (2000) assessed the effects of the NIDCAP on developmental outcomes in 42 premature newborns who weighed ≤ 1500 g at birth. At the corrected age of 3 years, they observed higher levels of communication and language skills in the intervention group (31), which is in line with the results of the current study.

Numerous studies have examined the effects of developmental care on different aspects of neonatal development and mentioned its positive impacts on some dimensions. Als et al. (1994) examined 38 premature neonates born before 32 weeks of gestation (birth weight: 500-1250 g) at the corrected age of 9 months. They reported significantly higher mental developmental index (MDI) and psychomotor developmental index in the NIDCAP group, compared to those reported for the control group (32). Peters et al. (2009) reported higher MDI with the developmental care of the newborns at the corrected age of 18 months (22).

Some studies have also examined the effects of some developmental care components. In a study, Feldman et al. (2014) assessed the effects of KMC on the developmental status of 73 premature newborns at the corrected ages of 6, 12, and 24 months. They reported higher MDI in the intervention group, compared to that reported for the control group (33). In another study, Almadhoob et al. (2015) sought to determine the effects of noise reduction in the NICU on the developmental status of 23 premature neonates at the corrected age of 18-22 months. They detected higher MDI in the intervention group, compared to that reported for the control group (34).

However, not all studies have confirmed the positive effects of developmental care. For instance, Maguire et al. (2009) evaluated the effects of developmental care on neuromotor development in 164 premature neonates and observed no significant differences in neuromotor development between the study groups at the corrected term age (1). They also reported no effect of developmental care on the developmental condition at the corrected age of 1 and 2 years. Nevertheless, the results of the aforementioned study are inconsistent with the findings of the current study. This inconsistency can be attributed to the differences in applied tools, types of intervention, newborns' age at developmental care evaluation, and neonates'

baseline characteristics.

According to the findings of the present study, the three groups were reported with no significant differences regarding brain myelination. Due to financial constraints, 10 newborns from each group were randomly selected for MRI. Moreover, the brain structure was examined only in terms of myelination. Als et al. (2012) assessed the effects of the NIDCAP on the brain structure of 30 premature neonates born at 27-33 weeks of gestation within intrauterine growth restriction (IUGR) at the corrected age of 42 weeks. They showed that the brain structure was more mature in the intervention group (19). Although Als et al. used MRI to examine the general structure of the brain and its dimensions in neonates with IUGR at the corrected age of 42 weeks, the present study only investigated brain myelination at the corrected age of 1 year in newborns without IUGR.

Since neonates are exposed to severe sensory stimuli in the delivery or operating room, one of the strengths of the current study was the initiation of developmental care at birth. Ohlsson (2009) concluded that developmentally sensitive interventions should start at birth when neonates are exposed to excessive stimuli (25). Before being transferred to the NICU, the newborns remain in the operating or delivery room for some time. Therefore, a lack of attention to developmental care at this stage may cause severe stress in newborns. However, drawing a definite conclusion regarding the consequences of such interventions requires performing further studies. The other strength of the present study was the blinding of the evaluator to group assignments.

The limitation of the present study was the small number of participants and lack of random allocation (due to the study conditions). Developmental care was also provided by the nursing staff in the neonatal ward and NICU. In addition, providing incomplete developmental care was expected in certain working shifts, such as night shifts, when the noise, light, and other dimensions of developmental care could not be fully controlled by the researcher. It is required to carry out further studies to examine the effects of developmental care since birth on neonatal outcomes. In this regard, it is recommended to perform further studies with more participants to examine the long-term outcomes up to school age.

Conclusion

The obtained results of the current study showed that the implementation of developmental care, especially when initiated immediately after

birth, may have a positive effect on developmental conditions (i.e., communication and language) of premature neonates at the corrected age of 12 months. The obtained findings of the present study showed no significant effects of developmental care interventions on the newborn's brain myelination at 1 year of age. Non-random sampling restricted the strength of the conclusion, and the results of the current study cannot be generalized and require performing further studies with randomized controlled trial design and sufficient sample size to achieve reliable results.

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Conflicts of interest

The authors declare that there is no conflict of interest.

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