

Neurodevelopmental Outcome Of Very Preterm And Moderate To Late Preterm Babies At The Corrected Age Of First Year

Authors:

^{*1} Alice Jeba – dralicejeba@yahoo.co.in

² Prathap Suganthirababu – emailprathap@gmail.com

³ Shivaprakash Sosale – shivaprakashsosale@gmail.com

⁴ Jagatheesan Alagesan - jagatheesanphd@gmail.com

⁵ Vignesh Srinivasan – vigneshphysio1989@gmail.com

⁶ Nivya Sebastian – niveasebastian@gmail.com

Authors Affiliation:

^{*1} Head of Department, Department of Paediatric Physiotherapy , NRR Hospital,
Chikkabanavara, Bangalore

^{2,4} Professor, Saveetha College Of Physiotherapy, SIMATS, Chennai, Tamil Nadu, India.

³ Assistant Professor, Bangalore Medical College, Neonatologist, Department of Neonatology
& Paediatrics, NRR Hospital, Chikkabanavara, Bangalore.

⁵ Assistant professor, Saveetha College Of Physiotherapy, SIMATS, Chennai, Tamil Nadu,
India.

⁶ Post Graduate Student, Saveetha College Of Physiotherapy, SIMATS, Chennai, Tamil
Nadu, India.

****Corresponding author: Prathap Suganthirababu,***

Professor, Saveetha college of Physiotherapy, Saveetha Institute of Medical and Technical
Sciences, Thandalam, Chennai, India.

E-mail: emailprathap@gmail.com

ABSTRACT:

Background: Preterm newborns are more prone to exhibit neurodevelopmental delays than neonates born at full term gestational age. The aim of this study was to examine the gross motor, fine motor, personal-social, and language development of severely preterm and moderate-to-late preterm infants at one year of age.

Methods: A randomised controlled study with concealed allocation and blinded outcome assessment was done in a tertiary care neonatal centre in Bangalore, India, from May 2019 to

November 2020. The early intervention group included 50 preterm infants born between 28 and 37 weeks gestational age, while the control group included 50 preterm newborns. Premature children with known congenital disorders that affect neurodevelopment were excluded from the study.

Results: The neurodevelopmental outcome was statistically significant when comparing the early intervention group infants to the control group infants. Gross motor, personal-social, fine motor adaptive and language domains have chi square statistic values of 44.61, 50.19, 49.75, and 50.83, respectively, with a P value of 0.001 for all domains, making them statistically significant.

Interpretation & Conclusion: Early intervention programme for preterm infants at the corrected and completed age of one year of life improved the neurodevelopment of extremely preterm and moderate to late preterm newborns.

Keywords: Developmental care, developmental delay, Early intervention Neurodevelopment, Preterm infants

INTRODUCTION:

Preterm newborns who are at danger for long-term difficulties have seen their survival rates improved thanks to improved perinatal and sophisticated treatment in the NICU.^{1, 2} These infants had a higher prevalence of physical and mental disorders because they lived longer.³ Low birth weight diseases have been associated to neuromotor delays, intellectual problems, and behavioural concerns, and can impact the outcome of subsequent development^{4, 3, 5, 6}

Several longitudinal studies have been related to the outcome of development of preterm born infants.⁹⁻¹¹ many studies have found that these babies have a negative long-term neurodevelopmental result.¹²⁻¹⁴ However, there is a scarcity of data on the neurodevelopmental outcomes of these newborns from impoverished nations. In developing nations like India, a substantial number of extremely low birth weight neonates are small for gestational age (SGA). This population's outcome may differ from reports from developed countries. In our limited resource environment, having exact knowledge of the consequences would be helpful in counselling parents and making decisions.

From the moment of birth through the first year of life, early intervention (EI) is defined as continuous multidisciplinary treatment for newborns those who may experience developmental delays. On a regular basis, it also includes a Gross motor, cognitive, fine motor, and language/adaptive skills assessment as part of the developmental process. It aids in the improvement of a child's health, the reduction of developmental delays, the alleviation of existing disabilities, the prevention of functional degradation, and the stimulation of parent-child interaction.¹⁵ A Cochrane analysis recently confirmed the importance of treating early to improve cognitive and motor results.¹⁶

This study done was to determine how EI affected neurodevelopment in a group of neonatal critical care unit graduates who were born prematurely (28-32 weeks) and moderate to late preterm (32-37 weeks).

MATERIALS AND METHOD:

This was a randomised, double-blind, controlled trial that was performed on high-risk newborns hospitalised to a level III neonatal centre in Bangalore from 2019 May to November 2020. The study done was authorised by the Institutional Ethical Committee, and it is now registered in India's Clinical Trials Registry. All infants admitted to the NICU within the first 48 hours with a birth weight of 1000gms-2500gms, an Apgar score of > 7 at the first and fifth minute with no resuscitation required at birth, and who were medically stable with medical conditions primarily related to immaturity such as elevated bilirubin, mild hypoglycaemia, and hypocalcaemia were considered eligible for the study. Premature children with known congenital disorders that affect neurodevelopment were not involved in the study. Parents gave their informed consent before to enrolment, and eligible newborns were randomly divided to two groups: early intervention and control, which were further divided into two groups depending on gestational age: very prematurely born (28-32 weeks) and intermediate to late preterm (32-37 weeks). The envelopes were wrapped, opaque, and serially numbered, and randomization was done using a computer-generated randomization procedure. The charge nurse separated the newborns into groups by unzipping the envelopes.

The primary investigator gave EI to the new borns in the early intervention group after two days, whereas the newborns in the control group received standardized hospital care. The infants in the EI group received two 10 minute sessions of tactile-kinesthetic stimulation over the course of ten days.¹⁷ The stimulation regimen was adapted from a field investigation conducted in 1986.¹⁸

Premature infants in the EI group received 5 minutes of gloved finger oral motor intervention once a in a day and for ten days. The procedures were carried out in an aseptic manner. C-stretching of the cheeks, lip role, lip curl, massage across the gums, lateral boundary of tongue/ cheek, mid blade of tongue/ palate, inducing a suck, and non-nutritive sucking support are all part of it.¹⁹ Placement and nesting, as well as vestibular^{22,35} and auditory stimulation, were given special consideration. Kangaroo mother care was provided to both groups of infants (KMC). Tactile, kinesthetic, vestibular, and auditory stimulation were taught to the mothers in the study group at the same time, and they were told to do so twice daily until the baby reached his corrected age of 40 weeks.

A senior therapist who was blinded to the group allocation assessed the neuro developmental results of both groups in the outpatient department after they completed the 1st, 3rd, 6th, 9th, and 12th month of their corrected age.

The Denver Developmental Screening Test is a quick and easy way to detect developmental impairments in neonates. The test has 4 domains: gross motor, fine motor/adaptive, language, and personal social. The degrees of achievement were assessed as advanced, ok, caution, and fail based on the corrected chronological age to identify the developmental state.²⁴ The date of the assessment and the newborns' adjusted age were written on each milestone. Babies who failed to fulfil developmental milestones were referred to an early intervention clinic for

additional assessment and treatment. To improve follow-up, telephonic reminders were sent to parents/guardians on a regular basis.

SAMPLE SIZE DETERMINATION:

According to a prior study, the study group's Gross motor achievement level was 68.3 percent Advanced and OK, while the Control group's was 27.5 percent. With the information available, the sample size for the study was estimated using the study's power of 80% (= 20%) and confidence of outcome of 95% (type 1 error = 5%). The sample size was estimated to be 22. This study comprised a total of 25 newborns (25 infants for the 28-31.6 weeks Study group + 25 infants for the 28-31.6 weeks Control group + 25 infants for the 32-36.6 weeks Study group + 25 infants for the 32-36.6 weeks Control group) to allow for a 25% dropout rate.

SPSS version 16.0 software was utilized to analyze the obtained data. For data analysis, the intention to treat principle was used, and a two-tailed significance threshold of 0.05 was used.

RESULTS:

A step-by-step study flow diagram is shown in Figure 1. The baseline characteristics of preterm babies are tabulated in Table I. There was no significant difference between the two groups on the matching variables. The impact of EI therapy on preterm infants' achievement in gross motor, fine motor/adaptive, personal social, and linguistic domains was assessed using the Chi-square test of independence. Table II shows the developmental parameters of preterm neonates. According to the study's findings, the chi square statistic values for the gross motor, fine motor adaptive, personal-social, and linguistic domains are 44.61, 50.19, 49.75, and 50.83, respectively. Because the P value for all domains was 0.001, the null hypothesis was rejected. It means that early interventional therapy affects levels of achievement across the field. In addition, the infants in the early intervention group had advanced levels of achievements in all domains than the control group. (Tables III and IV), which the Z-statistic was used to test. This showed that EI has a positive and significant impact on neurodevelopment.

DISCUSSION:

The goal of this randomised controlled trial was to investigate if administering EI to newborns and moderate to late preterm infants at 12 months corrected age would improve their neurodevelopmental outcomes in many domains. We discovered that EI and control group infants had different neurodevelopmental outcomes, with EI group infants performing better in both groups. This study discovered that EI has a positive impact on neurodevelopment when compared to the results of the control group.

EI can begin shortly after birth, throughout the first year of life, or after a developmental delay is detected. It can also begin in the NICU, post hospitalization, or during the third month of life.²⁵⁻²⁸ It has both advantages and disadvantages. It should be administered to neonates who are at risk of neuromotor delay at the earliest in order to prevent future developmental difficulties.²⁹ In the current research work, however, we began EI

immediately after the baby was born, before the hospital discharge. According to the CDC model, early stimulation therapy was effective after one year. The beneficial effect was remained present at the conclusion of the second year without any extra interventions. In Trivandrum, EI was able to reduce poor performance by 40% in babies born with low birth weight.³⁰

Premature children post hospitalization were still at risk of experiencing developmental delays later in life, according to several studies.^{31, 32} monitoring, follow-up, and early intervention services must be implemented in a systematic manner. By evaluating both groups of infants in our study, we were able to start early intervention in the period of infancy and analyse neurodevelopment during the first twelve months of life.

It was discovered that the two groups of newborns had different gross motor, fine motor, personal social, and language domains, and it was also discovered that EI had altered neurodevelopment and aided in the process of achieving higher levels of performance. Similar studies have reached the same conclusion as ours.^{28,33,34}

This research helped to develop clinical practise guidelines, not only for early assessment and intense follow-up recommendations, but also for appropriate interventions if an underlying weakness is detected in order to improve results. Furthermore, in order to ensure proper health resource allocation, this research provided recommendations for the role of the multidisciplinary team in the follow-up of children.

The standardised technique we used to assess neurodevelopment outcomes is a strength of our study, and our findings indicate to a bright future for high-risk infants' neurodevelopment. More research is needed to discover if EI has a long-term impact on these infants' neurodevelopment. In conclusion, EI therapy aids in the process of reaching higher levels of function in multiple domains when compared to the control group infants.

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Figure-1: Study flow chart

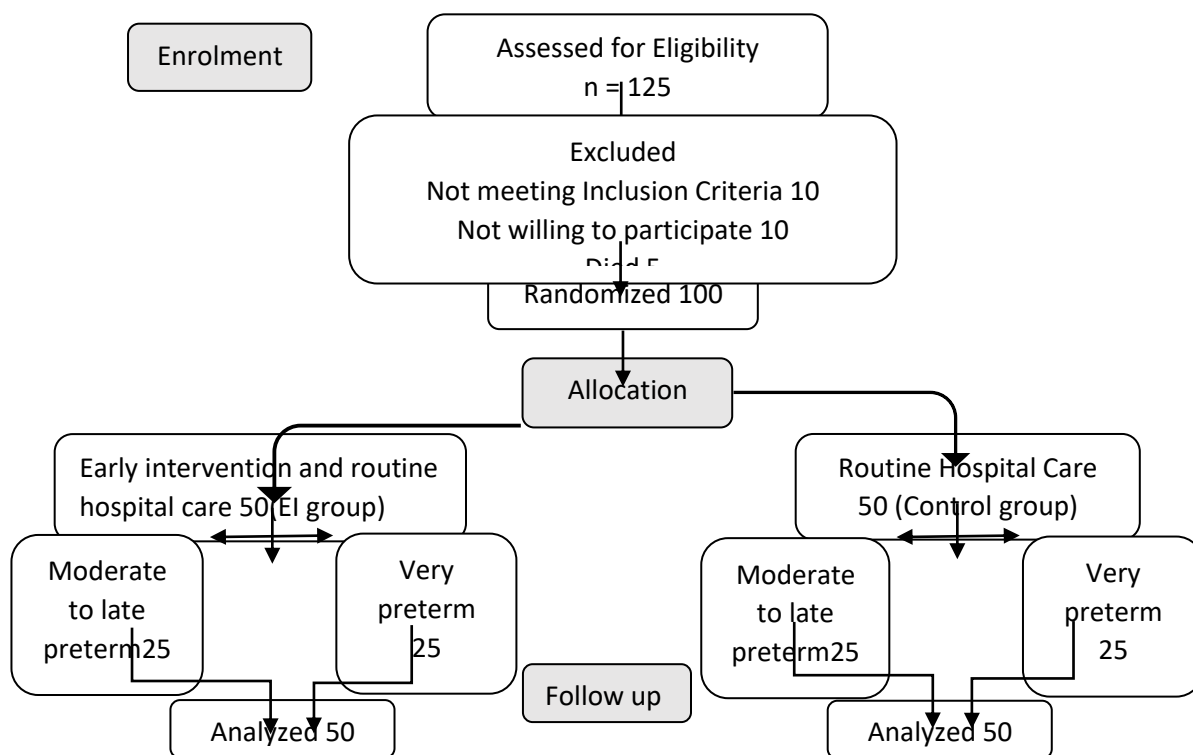


Table I Demographic characteristics of the variables

| Variables | Study Group(Mean/SD) | | Control Group(Mean/SD) | |
|--------------------------|----------------------|---------------------------|------------------------|---------------------------|
| | Very preterms | Moderate to late preterms | Very preterm | Moderate to late preterms |
| Gestational Age(weeks) | 30.5(0.9) | 33.34(0.74) | 30.4(0.85) | 33.4(0.63) |
| Birth Weight(gms) | 1154.8(56.6) | 1499.1(192.8) | 1161.8(45.1) | 1457.5(139.9) |
| Apgar at 1st minute | 7.4(0.5) | 7.76(0.4) | 7.4(0.5) | 7.68(0.48) |
| Apgar at 5th minute | 8.76(0.4) | 9.44(0.5) | 9.44(0.5) | 9.68(0.48) |
| Age at enrolment(days) | 2.6(0.91) | 2(0.3) | 2.3(0.5) | 2.08(0.3) |
| PMA at enrolment(weeks) | 30.84(0.8) | 33.7(0.8) | 30.8(1.0) | 33.7(0.7) |
| Weight at enrolment(gms) | 1074.6(70.9) | 1380.9(180.6) | 1088.6(69.23) | 1336.4(11.1) |

Table II :COMPARISON OF NEURODEVELOPMENT BETWEEN GROUPS

| DOMAINS | Achievement | Very preterm study group (n=25) | Very preterm control group (n=25) | Moderate to late preterms study group (n=25) | Moderate to late preterms control grup (n=25) |
|-----------------|-------------|---------------------------------|-----------------------------------|--|---|
| | | % | % | % | % |
| GROSS MOTOR | Advanced | 48.00% | 8.00% | 60.00% | 12.00% |
| | Ok | 44.00% | 32.00% | 40.00% | 24.00% |
| | Caution | 0.00% | 32.00% | 0.00% | 40.00% |
| | Fail | 8.00% | 28.00% | 0.00% | 24.00% |
| FINE MOTOR | Advanced | 56.00% | 4.00% | 60.00% | 8.00% |
| | Ok | 44.00% | 40.00% | 40.00% | 40.00% |
| | Caution | 0.00% | 20.00% | 0.00% | 28.00% |
| | Fail | 0.00% | 36.00% | 0.00% | 24.00% |
| PERSONAL-SOCIAL | Advanced | 52.00% | 4.00% | 48.00% | 4.00% |
| | Ok | 40.00% | 28.00% | 44.00% | 32.00% |
| | Caution | 8.00% | 48.00% | 8.00% | 60.00% |
| | Fail | 0.00% | 20.00% | 0.00% | 4.00% |
| LANGUAGE | Advanced | 60.00% | 4.00% | 68.00% | 24.00% |
| | Ok | 40.00% | 36.00% | 32.00% | 36.00% |
| | Caution | 0.00% | 44.00% | 0.00% | 40.00% |
| | Fail | 0.00% | 16.00% | 0.00% | 0.00% |

Table III Level of significance in all four domains (Very preterms)

| Achievement level | EXPERIMENTAL | CONTROL | Z-VALUE | P1 | P2 | P-VALUE |
|------------------------|--------------|---------|---------|--------|--------|----------|
| GROSS MOTOR | | | | | | |
| ADVANCED | 12 | 2 | 3.1497 | 48.00% | 8.00% | 0.0016* |
| OK | 11 | 8 | 0.8741 | 44.00% | 32.00% | 0.3843 |
| CAUTION | 0 | 8 | -3.0861 | 0.00% | 32.00% | 0.002* |
| FAIL | 2 | 7 | 0.8741 | 8.00% | 28.00% | 0.3843 |
| FINE MOTOR | | | | | | |
| ADVANCED | 14 | 1 | 4.0119 | 56.00% | 4.00% | <.00001* |
| OK | 11 | 10 | 0.2865 | 44.00% | 40.00% | 0.77182 |
| CAUTION | 0 | 5 | -2.357 | 0.00% | 20.00% | 0.0183* |
| FAIL | 0 | 9 | -3.3129 | 0.00% | 36.00% | 0.0009* |
| PERSONAL SOCIAL | | | | | | |
| ADVANCED | 13 | 1 | 3.7796 | 52.00% | 4.00% | 0.00016* |
| OK | 10 | 7 | 0.8956 | 40.00% | 28.00% | 0.3681 |
| CAUTION | 2 | 12 | -3.1497 | 8.00% | 48.00% | 0.0016* |
| FAIL | 0 | 5 | -2.357 | 0.00% | 20.00% | 0.0183* |
| LANGUAGE | | | | | | |
| ADVANCED | 15 | 1 | 4.2444 | 60.00% | 4.00% | <.00001* |
| OK | 10 | 9 | 0.2914 | 40.00% | 36.00% | 0.7718 |
| CAUTION | 0 | 11 | -3.7553 | 0.00% | 44.00% | 0.0001* |
| FAIL | 0 | 4 | -2.0851 | 0.00% | 16.00% | 0.0366* |

*Significant

Table IV Level of significance in all four domains (Moderate to late preterms)

| Achievement level | EXPERIMENTAL (n=25) | CONTROL (n=25) | Z-VALUE | P1 | P2 | P-VALUE |
|------------------------|---------------------|----------------|---------|--------|--------|---------|
| GROSS MOTOR | | | | | | |
| ADVANCED | 15 | 3 | 3.5355 | 60.00% | 12.00% | 0.0004* |
| OK | 10 | 6 | 1.2127 | 40.00% | 24.00% | 0.2263 |
| CAUTION | 0 | 10 | -3.1497 | 0.00% | 40.00% | 0.0016* |
| FAIL | 0 | 6 | -2.6112 | 0.00% | 24.00% | 0.0090* |
| FINE MOTOR | | | | | | |
| ADVANCED | 15 | 2 | 3.881 | 60.00% | 8.00% | 0.0001* |
| OK | 10 | 10 | 0 | 40.00% | 40.00% | 1 |
| CAUTION | 0 | 7 | -2.853 | 0.00% | 28.00% | 0.0044* |
| FAIL | 0 | 6 | -2.6112 | 0.00% | 24.00% | 0.0091* |
| PERSONAL SOCIAL | | | | | | |
| ADVANCED | 12 | 1 | 3.5465 | 48.00% | 4.00% | .0004* |

| | | | | | | |
|----------|----|----|---------|--------|--------|-----------|
| OK | 11 | 8 | 0.8741 | 44.00% | 32.00% | 0.3843 |
| CAUTION | 2 | 15 | -3.881 | 8.00% | 60.00% | 0.0001* |
| FAIL | 0 | 1 | -1.0102 | 0.00% | 4.00% | 0.3125 |
| LANGUAGE | | | | | | |
| ADVANCED | 17 | 6 | 3.1213 | 68.00% | 24.00% | 0.0018* |
| OK | 8 | 9 | -0.2985 | 32.00% | 36.00% | 0.76418 |
| CAUTION | 0 | 10 | -3.1497 | 0.00% | 40.00% | 0.00164* |
| FAIL | 0 | 0 | | 0.00% | 0.00% | <0.00001* |

*Significant