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Effectiveness of Reach Out and Read Literacy Program on Neurodevelopment in High-Risk Infants: A Randomized Controlled Trial

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ABSTRACT

Background: High-risk infants are vulnerable to adverse neurodevelopmental outcomes despite improved neonatal survival. Early, parent-mediated interventions that enhance caregiver–infant interaction are crucial during the first months of life. Reach Out and Read (ROR) is a literacy-based program that has been shown to promote early development. Yet, evidence of its effect on global neurodevelopment in high-risk infants in early infancy remains limited.

Methods: A randomized controlled trial with a parallel-group design was conducted at a tertiary care hospital in Belagavi. Thirty-two high-risk infants (2 weeks of age) were randomly allocated to an experimental (ROR) or control (standard care) group. Infants in the experimental group received a vernacular ROR book with structured, age-appropriate activities and parental guidance, reinforced through follow-up calls and clinic visits. Neurodevelopment was assessed at 6, 10, and 14 weeks of age using the Caregiver Reported Early Development Instrument (CREDI).

Results: Data were analysed using descriptive statistics and repeated-measures ANOVA, with significance set at $p < 0.05$. Baseline infant and parental characteristics were comparable between groups. Significant improvements over time were observed across all developmental domains in both groups ($p < 0.001$). However, significant time × group interactions favored the ROR group for language ($F = 54.23$, $p < 0.001$), motor ($F = 18.86$, $p < 0.001$), and socio-emotional domains ($F = 4.04$, $p = 0.029$). Effect size analysis demonstrated the largest intervention effects for language (partial $\eta^2 = 0.383$) and overall development (partial $\eta^2 = 0.37$).

Conclusion: The ROR program is an effective early intervention to enhance language, motor, and socio-emotional development in high-risk infants during the early months of life. Integrating culturally adapted, parent-mediated literacy interventions may strengthen developmental outcomes and caregiver engagement alongside standard care.

Keywords: High-risk infants; Reach Out and Read; Early intervention; Neurodevelopment; Parent-mediated intervention; Physiotherapy.

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INTRODUCTION

High-risk infants are newborns with an increased likelihood of mortality and long-term morbidity due to complications occurring during the antenatal, perinatal, or postnatal periods [1, 2]. Although advances in neonatal care have improved survival, a growing proportion of these infants experience developmental delays affecting cognition, language, motor skills, and behaviour [3].

Early developmental interventions focusing on parent–child interaction have demonstrated promising outcomes in this population [3]. Reach Out and Read (ROR) is a research-based literacy and parent-engagement program designed to enhance early language development and strengthen caregiver–infant interaction[4]. Evidence from neonatal and pediatric settings suggests that ROR positively influences early developmental trajectories [5,6].

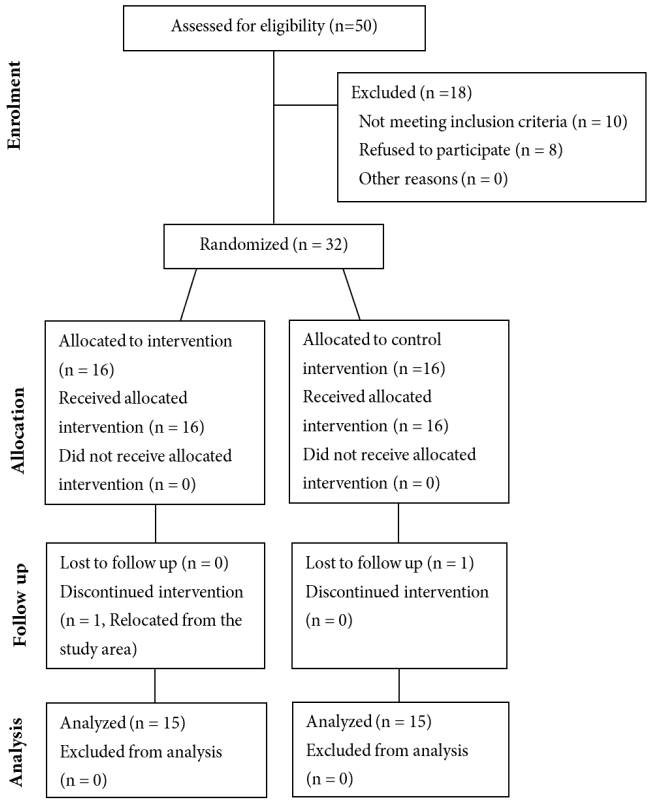
Studies conducted in NICU and preschool settings have demonstrated the feasibility and effectiveness of ROR in promoting language and school readiness [4,7]. However, evidence regarding its impact on global neurodevelopment among high-risk infants in the early months of life remains limited.

Physiotherapists play a vital role in early developmental surveillance and parent education. Integrating literacy-based, movement-oriented interventions such as ROR may augment traditional physiotherapy approaches. Therefore, this study aimed to evaluate the effectiveness of the Reach Out and Read program on neurodevelopment in high-risk infants using a caregiver-reported developmental measure.

METHODS

A randomised controlled clinical trial with a parallel-group design and a 1:1 allocation ratio was conducted after obtaining approval from the Institutional Ethical Committee of the KAHER Institute of Physiotherapy, Belagavi, and registration with the Clinical Trials Registry–India (CTRI/2024/01/061640). Written informed consent was obtained from the legal guardians of all participants. Thirty-two male and female high-risk infants attending their first visit at two weeks of age were recruited from the High-Risk Baby Clinic of a tertiary care hospital in Belagavi between November 2024 and May 2025. Infants were included if their parents could read and comprehend the vernacular language, had access to a mobile phone, and were willing to participate. Infants who were critically ill, had hearing or visual impairments, had undergone surgery in the previous six weeks, or were scheduled for surgery within the next six months, as well as twins and triplets, were excluded. Participants were randomly assigned to experimental or control groups using a concealed opaque-envelope method, with parents blinded to group allocation. Pre-assessment was conducted when the infant was 6 weeks old (35-42 days), followed by a follow-up assessment at 10 weeks (63-70 days). The post-assessment was conducted when the infant was 14 weeks old (91-98 days). Infants in the experimental group received a take-home Reach Out and Read (ROR) literacy program book in their vernacular language, along with structured instructions and demonstrations of age-appropriate activities to be performed at home; adherence was monitored through activity logs and periodic telephonic follow-up, with reinforcement provided during subsequent clinic visits. The control group received routine standard care. Neurodevelopmental outcomes were assessed at all three visits using the Caregiver-Reported Early Development Instrument (CREDI), which evaluates cognitive, language, motor, and socio-emotional domains. The reliability and validity of the CREDI, as well as its application and performance in rural India, have been documented [8, 9]. Data were analysed using SPSS version 21, employing descriptive statistics, independent and paired t-tests, and repeated measures ANOVA to examine time and group interaction effects, with statistical significance set at $p < 0.05$.

Figure 1: The flow of participants at each stage of the study



RESULTS

The flow of participants at each stage of the study is presented in Figure 1. Table 1 shows that baseline demographic characteristics of high-risk infants were comparable between groups. The intervention group had a slightly higher mean age (3.93 ± 2.04 weeks) than the control group (3.00 ± 1.15 weeks), with similar gestational age (33.93 ± 3.62 vs. 32.62 ± 4.27 weeks) and corrected age (37.87 ± 3.86 vs. 35.62 ± 3.77 weeks). Birth weight was marginally higher in the intervention group (1.98 ± 0.61 kg) compared to controls (1.77 ± 0.63 kg). Gender distribution was identical in both groups (10 males, 6 females each), and low birth weight was the most common risk factor in both groups.

Table 1 shows the baseline demographic characteristics of

high-risk infants in both groups. The intervention group had a slightly higher mean age (3.93 ± 2.04 weeks) and birth weight (1.98 ± 0.61 kg) than the control group (3.00 ± 1.15 weeks) and (1.77 ± 0.63 kg), respectively. Gender distribution was identical in both groups (10 males, 6 females each), and low birth weight was the most common risk factor in both groups.

Table 1: Baseline demographic characteristics of high-risk infants in both groups.

Variables	Categories	Groups	
		Intervention	Control
		(Mean ±SD)	(Mean ±SD)
Age	Age (Weeks)	3.93 ± 2.04	3 ± 1.15
	Gestational Age (Weeks)	33.93 ± 3.62	32.62 ± 4.27
	Corrected Age (Weeks)	37.87 ± 3.86	35.62 ± 3.77
Birth Weight (Kgs)	-	1.98 ± 0.61	1.77 ± 0.63
		N(%)	N(%)
Gender	Male	10	10
	Female	6	6
Birth Order	1	11	9
	2	5	7
Risk Factors	Perinatal Asphyxia	4	3
	Low Birth Weight	12	11
	Perinatal Asphyxia And Low Birth Weight	0	1
	Others	0	1
SD: Standard Deviation, N: Sample, %: Percentage			

As presented in Table 2, parental demographics were largely comparable across groups. Most mothers were unemployed, and Kannada was the predominant vernacular language. Pregnancy-induced hypertension was the most frequently reported antenatal complication. The majority of families belonged to the upper-middle socioeconomic class.

Table 2: Demographic Characteristics of the parents of participating infants in the study.

Variables	Categories	Groups			
		Mother		Father	
		INTERVENTION	CONTROL	INTERVENTION	CONTROL
		(Mean ±SD)		(Mean ±SD)	
Age (Years)		27.31 ± 5.89	29.43 ± 6.59	34 ± 4.75	34.31 ± 6.75
		N(%)		N(%)	
Education	Professional	1	1	2	3
	Graduate	5	4	7	6
	Intermediate/diploma	6	4	4	4
	High School	2	5	3	3
	Middle school	1	1	0	0
	Primary school	1	1	0	0
	Illiterate	0	0	0	0
Occupation	Professional	0	0	2	1
	Semi professional	1	2	4	2
	Clerical, shop-owner, Farmer	0	0	5	3
	Semi-skilled worker	0	0	4	7
	Unskilled worker	0	0	1	2
	Unemployed	15	14	0	0
Vernacular Language	Hindi	2	3	0	1
	Kanada	10	11	2	3
	Marathi	4	2	10	11
	English	0	0	4	2
Complications During Pregnancy	Hypothyroidism	0	0	0	0
	Pregnancy-induced Hypertension	4	3		
	Gestational diabetes mellitus	0	3		
	No complications	12	10		
Type of delivery	LSCS	7	11		
	Normal Delivery	9	5		
Family socio economic status (Kuppuswamy Scale)	less than 100	0	0		
	Upper middle class	8	5		
	upper lower class	5	9		
	lower middle class	4	2		
SD: Standard Deviation, N: Sample, %: Percentage					

Table 3 demonstrates time-wise changes in developmental outcomes of high-risk infants in the study. Across visits, the intervention group consistently showed higher mean scores than the control group in language (third visit: 45.68 ± 0.45 vs. 45.36 ± 0.32), motor (42.97 ± 0.44 vs. 42.98 ± 0.21), socio-emotional (44.12 ± 0.38 vs. 43.76 ± 0.40), and overall domains (40.28 ± 0.77 vs. 39.35 ± 0.77), while cognitive scores showed similar improvement trends in both groups (44.57 ± 0.46 vs. 44.28 ± 0.48).

Table 3: Demonstrates time-wise changes in developmental outcome (CREDI) of high-risk infants in the study.

CREDI Domain	Assessment Intervals	Groups	
		Experimental (Mean ± SD)	Control (Mean ± SD)
Cognitive Raw Score	T0	43.62 ± 0.20	43.36 ± 0.04
	T1	43.70 ± 0.32	43.60 ±0.08
	T2	44.57 ±0.46	44.28± 0.48
Language Raw Score	T0	45.37 ± 0.06	45.08 ± 0.01
	T1	45.10 ± 0.12	45.12 ± 0.02
	T2	45.68 ± 0.45	45.36 ± 0.32

Motor Raw Score	T0	42.55 ± 0.08	42.24 ± 0.03
	T1	42.55 ± 0.16	42.52 ± 0.08
	T2	42.97 ± 0.44	42.98 ± 0.21
Socio-Emotional Raw Score	T0	43.06 ± 0.18	42.83 ± 0.04
	T1	43.16 ± 0.26	43.11 ± 0.09
	T2	44.12 ± 0.38	43.76 ± 0.40
Overall	T0	37.82 ± 0.42	37.48 ± 0.07
	T1	38.29 ± 0.58	38.06 ± 0.18
	T2	40.28 ± 0.77	39.35 ± 0.77
SD: Standard Deviation, T0: 6 Weeks of Infant's age, T1: 10 Weeks of Infant's age, T2: 14 Weeks of Infant's age			

Repeated-measures MANOVA results (Table 4) revealed a significant main effect of time for all domains, including cognitive ($F = 58.04$, $p < 0.001$), language ($F = 34.29$, $p < 0.001$), motor ($F = 54.91$, $p < 0.001$), socio-emotional ($F = 94.42$, $p < 0.001$), and overall development ($F = 114.94$, $p < 0.001$). Significant time × group interactions were observed for language ($F = 54.23$, $p < 0.001$), motor ($F = 18.86$, $p < 0.001$), and socio-emotional domains ($F = 4.04$, $p = 0.029$), indicating greater improvement in the intervention group. In contrast, interactions were not significant for cognitive ($F = 2.08$, $p = 0.144$) and overall scores ($F = 2.39$, $p = 0.111$).

Table 4: Efficacy of ROR Intervention on the Outcome Variable Using Repeated Measure MANOVA.

CREDI Domains	Assessment Intervals	Wilk's Lambda	F	P
Cognitive Raw Score	Time	0.189	58.037	<0.001*
	Time*Group	0.866	2.082	0.144
Language Raw Score	Time	0.283	34.287	<0.001*
	Time*Group	0.199	54.234	<0.001*
Motor Raw Score	Time	0.197	54.905	<0.001*
	Time*Group	0.417	18.86	<0.001*
Socio-Emotional Raw Score	Time	0.125	94.418	<0.001*
	Time*Group	0.77	4.043	0.029*
Overall	Time	0.105	114.939	<0.001*
	Time*Group	0.849	2.392	0.111
*: Statistical Significance at $p < 0.05$				

Between-group effect size analysis (Table 5) showed statistically significant effects of the intervention across all domains, with the largest effects observed for language (partial $\eta^2 = 0.383$, $p < 0.001$) and overall development (partial $\eta^2 = 0.37$, $p < 0.001$), followed by socio-emotional (partial $\eta^2 = 0.282$, $p = 0.003$), cognitive (partial $\eta^2 = 0.225$, $p = 0.008$), and motor domains (partial $\eta^2 = 0.17$, $p = 0.024$).

Table 5. Efficacy of ROR intervention on the between-group effect size

CREDI Domains	Significance	Partial ETA Square
Cognitive Raw Score	0.008	0.225
Language Raw Score	<0.001*	0.383
Motor Raw Score	0.024	0.17
Socio-Emotional Raw Score	0.003	0.282
Overall	<0.001*	0.37
*: Statistical Significance at $p < 0.001$		

DISCUSSION

Facts Found in the Study

The present study evaluated the effectiveness of the Reach Out and Read (ROR) intervention on developmental outcomes in high-risk infants. The results demonstrated that infants who received the ROR intervention showed significant improvements in language, motor, and socio-emotional development compared with the control group, with the strongest effects observed in language development and overall developmental scores. In contrast, cognitive scores and overall developmental scores improved in both groups, suggesting that maturation and standard follow-up care may also contribute to developmental gains, but without a distinct intervention-specific effect in these domains.

Baseline characteristics indicated that infants in the intervention group were slightly older in chronological, gestational, and corrected age and had marginally higher birth weights than those in the control group. These factors may have provided a modest maturational advantage, particularly in domains such as language and motor development, which are sensitive to neurobiological readiness in early infancy. Despite a higher prevalence of perinatal asphyxia in the intervention group, the developmental outcomes remained superior in the intervention group.

Caregiver characteristics also revealed that most parents were relatively young, had comparable levels of education, and belonged predominantly to upper-middle socioeconomic backgrounds. Additionally, a large proportion of infants in the study were firstborn children, which may have allowed caregivers to provide more focused attention to developmental activities. The ROR book was provided in the parents' vernacular language and reinforced through demonstrations and follow-up, allowing caregivers to integrate structured developmental stimulation into their daily routines.

Comments on the Facts

The observed improvements in language, motor, and socio-emotional domains may be explained by interrelated infant-, caregiver-, and contextual mechanisms. The slightly higher gestational age, corrected age, and birth weight among infants in the intervention group may have contributed to better developmental readiness. However, the superior developmental outcomes observed despite a higher prevalence of perinatal asphyxia suggest that structured parent-mediated stimulation may help mitigate early biological risks.

From a caregiver perspective, the parents' socio-demographic profile likely facilitated active participation in the intervention. Relatively young parents with adequate education and favourable socioeconomic status may have been better able to engage with the intervention materials and apply them consistently during daily interactions with their infants. The delivery of the ROR book in the vernacular language likely enhanced comprehension, accessibility, and cultural relevance, thereby strengthening

parental responsiveness and confidence in engaging with their infants.

The high proportion of firstborn infants may also have contributed to increased caregiver attention and involvement in developmental activities. Previous research suggests that enriched caregiver–infant interactions play a crucial role in shaping early developmental trajectories. Such interactions promote synaptic connectivity and neural plasticity, particularly in domains related to language acquisition and socio-emotional development [10].

Furthermore, the home-based nature of the intervention allowed caregivers to provide frequent and developmentally appropriate stimulation integrated into routine activities. This approach has been identified as a key factor in the successful implementation of early developmental interventions in neonatal follow-up and low-resource settings [5, 7]. By incorporating storytelling, object naming, and guided play activities, the intervention provided structured visual, verbal, and motor experiences, which may have enhanced language development, motor exploration, and social engagement.

The findings of the present study are consistent with the broader literature on the ROR program, which has demonstrated that shared reading and interactive activities support neural development through repeated verbal, visual, and tactile stimulation during sensitive developmental periods [6]. Although traditional ROR programs primarily target language and emergent literacy outcomes, studies conducted in clinic-based and community-based Indian settings have shown that culturally adapted ROR interventions can influence multiple developmental domains when implemented early in life [7].

In contrast to some studies where the benefits of ROR were largely confined to language development, the multidomain improvements observed in this study may be attributed to the integration of motor-based activities and visual stimuli within the ROR materials, which resemble play-based intervention models used in early developmental therapy. Previous randomised trials involving high-risk infants have demonstrated that structured play activities and developmentally appropriate stimulation enhance motor and cognitive outcomes by promoting active exploration and caregiver–infant interaction [3].

Similarly, studies conducted in neonatal intensive care units and high-risk infant follow-up clinics have reported that ROR-based interventions improve caregiver engagement, responsiveness, and confidence, even among infants with significant medical vulnerabilities [4, 5]. These findings support the notion that parent-mediated stimulation can buffer the negative effects of early biological risk factors, such as prematurity and low birth weight.

Theoretical Implications of the Findings

The findings of this study contribute to the growing body of evidence that early developmental interventions grounded in caregiver–infant interaction and environmental enrichment can significantly influence developmental trajectories in high-risk infants. The improvements observed in the language, motor, and socio-emotional domains suggest that the ROR intervention may act through mechanisms of experience-dependent neuroplasticity, whereby repeated sensory and motor experiences strengthen neural circuits during critical periods of brain development.

The integration of verbal stimulation (storytelling and naming), visual engagement (picture exploration), and motor interaction (play-based activities) may provide a multidimensional sensory environment that promotes early learning and functional skill acquisition. Such mechanisms align with developmental theories emphasizing the importance of active exploration, caregiver scaffolding, and enriched environments in shaping early brain development.

Importantly, the results also highlight ROR's potential as more than a literacy promotion strategy. When culturally adapted and delivered through caregiver education, ROR can function as a scalable, low-cost, parent-centred early intervention approach that can improve multiple developmental domains in high-risk infant populations [4-7]. This is particularly relevant in resource-constrained settings, where access to intensive early intervention services may be limited.

CONCLUSION

This randomised controlled trial demonstrates that the Reach Out and Read literacy program is an effective early intervention for improving language, motor, and socio-emotional development in high-risk infants during the first three months of life. These findings support the role of structured, culturally adapted, parent-mediated literacy interventions as a valuable complement to standard care. Early integration of such programs may enhance neurodevelopmental outcomes in high-risk infants and strengthen caregiver engagement during a critical window of early brain development.

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