# Effect of Child Development Centre Model Early Stimulation Among At-risk Babies – *A Randomized Controlled Trial*

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**Objective:** To study the effectiveness of Child Development Centre (CDC) model early stimulation therapy done in the first year of postnatal life, in improving the developmental outcome of at-risk neonates at one and two years of age.

**Design**: Randomized controlled trial.

**Setting and subjects:** The study participants included a consecutive sample of 800 babies discharged alive from the level II nursery of Medical College, Thiruvananthapuram.

**Intervention**: The control group received routine postnatal check-up as per hospital practice. Intervention group in addition received CDC model early stimulation therapy (home-based).

**Results:** The intervention group of babies had a statistically significant higher score for mental developmental index (MDI) and psychomotor developmental index (PDI) at one and two years of age. After adjusting all significant risk factors for development, the babies who had intervention had significantly higher Bayley scores, 5.8 units at one year and 2.8 units at two year, as compared to control babies.

**Conclusion**: Early stimulation therapy was effective at one year. The beneficial effect also persisted at two years, without any additional interventions in the second year.

**Key words:** *At-risk neonates, Child development, Early stimulation, Intervention, MDI, PDI.*

There is an increasing awareness among pediatricians on the role of the environment in mental and cognitive development. Early stimulation programs were developed that targeted preservation of the mother-infant relationship, improved stimulation for preterm infants and reduced stress in the neonatal nursery(1). By early "infant stimulation" we mean early interventional therapy for babies at-risk for developmental delay. Developmental deficits occur among babies with genetic and metabolic disorders, environmental risk factors and biological risk factors like low birth weight(2). Infants born low birthweight (<1800g) to disadvantaged mothers are at developmental risk for both biological and social reasons(3).

Meta-analysis of early intervention efficacy studies has shown that early intervention is effective in improving the developmental status, although there is no uniform agreement as to whether the effects last long(4). A recent Cochrane review of sixteen studies has shown that early intervention programs for preterm infants have a positive influence on cognitive outcomes in the short to medium-term(5). Long-term developmental follow-up of at-risk babies in the community, supported by early intervention therapy needs to be established, as shown by the experience in the developed countries(6). Large community early stimulation programs have shown that efficacy was greatest with programs involving both the parents and the baby; long-term stimulation improved cognitive outcomes

and child-parent interactions, cognition showed greater improvements than motor skills and, larger benefits were obtained in families that combined several risk factors(7).

In India, it has been shown that early intervention program can be successfully conducted through the high risk clinic approach(8). But, before a national policy is evolved in this regard, a randomized controlled trial showing efficacy of early intervention is mandatory. Hence this randomized controlled trial was conducted to study the effectiveness of Child Development Centre (CDC) model early stimulation therapy, done in the first year of postnatal life, in improving the developmental outcome among at-risk babies.

## METHODS

The study was conducted at the level II neonatal nursery of Sree Avitam Thirunal (SAT) hospital and follow-up was done at CDC, Medical College, Thiruvananthapuram (***Fig.* 1**). The entry criteria included; born in SAT hospital, admitted to level II neonatal nursery, discharged alive and, informed consent for follow-up and early stimulation. No exclusion criteria were used, so as to give generalisability to the results obtained. A pilot study on a sample of 100 babies was done to make sure that the randomization procedure, early stimulation, outcome measurements and blinding proceeded as planned.

***Sample Size***: As this was designed as a pragmatic clinical trial, the study participants included a consecutive sample of 800 babies discharged alive, with no exclusion criteria. A sample size of 336 in each group was obtained, which was adequate to detect between groups, 4 clinically significant mental developmental index (MDI), using Bayley

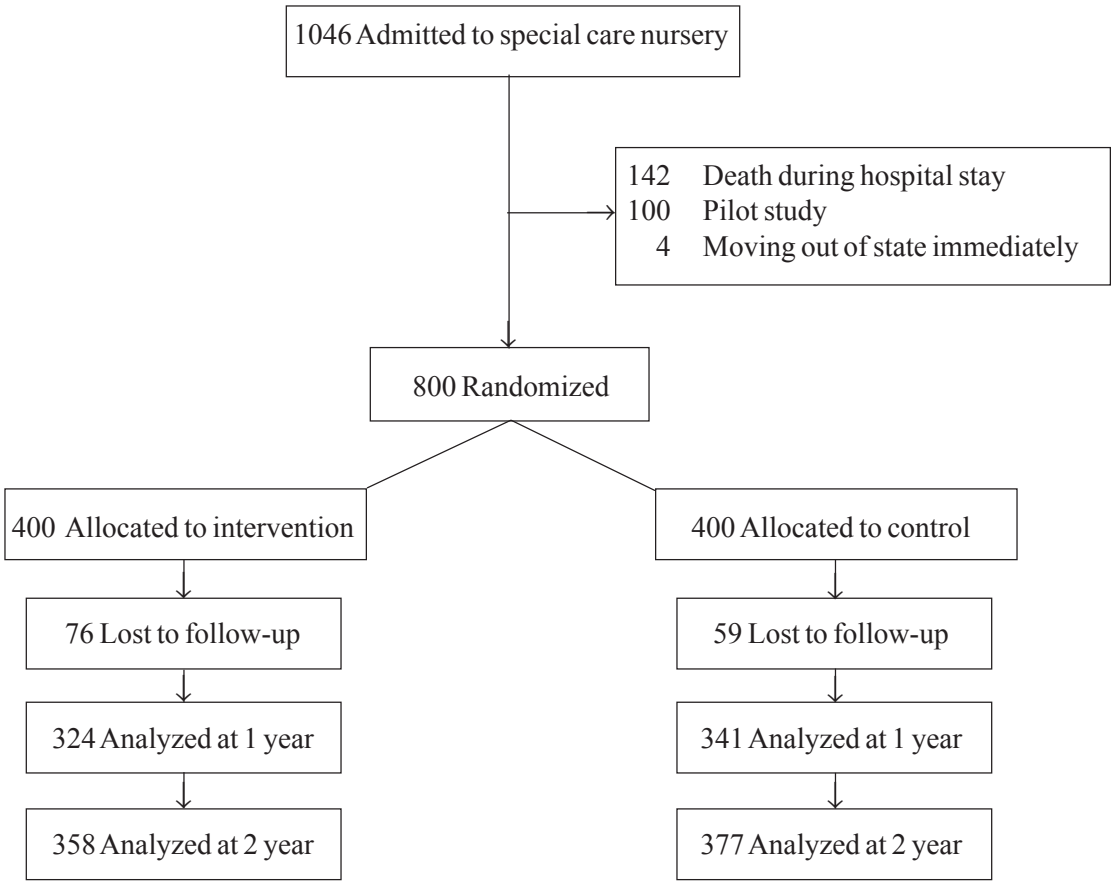


**FIG. 1** *Participant flow in the study.*

scales of infant development (BSID) with alpha error of 5% and beta error of 20%. A difference of 4 in the MDI scores was taken as clinically significant difference because it is same as ¼ standard deviation on Bayley scales, after normalisation of the raw scores to scores with a mean of 100 and standard deviation of 16 as explained in the Bayley manual(9,10). Allowing for 20% loss to follow-up, a total of 800 eligible subjects, who met all the inclusion and exclusion criteria were randomised to intervention and control group on the day of discharge.

***Randomization and allocation:*** Simple randomisation was done using RALLOC software. Serially numbered opaque envelops containing the allocation details of a subject were developed at the Department of Biostatistics, Christian Medical College, Vellore. The control group received the routine postnatal check-up as per hospital practice and the intervention group, in addition, received CDC model early stimulation therapy(11). CDC model early stimulation aims at stimulating the child through the normal developmental channel, prevention of developmental delay, prevention of asymmetries and abnormalities, detection of transient tone abnormalities and minimization of persistent tone abnormalities. The four major sensory modalities used are; visual stimulation, auditory stimulation, tactile stimulation and vestibular-kinaesthetic stimulation. An occupational therapist at CDC, trained the mothers individually and in groups, to give CDC model early stimulation and the mothers continued to do the same at home. The compliance was assessed during monthly follow-up visits by observing the ease with which the mother did the early stimulation. Compliance score was derived from a structured questionnaire designed for this purpose, with a total score of 35, any score below 31 was taken as poor compliance and above 31 as good compliance.

Outcome measurements were made at one and two years of age by an observer blind to the treatment status of the babies. These included MDI, PDI and Bayley score derived as per the Bayley manual. The Bayley scores represent the motor and mental raw scores together and, MDI and PDI represent the deviation quotients for mental and motor scores, respectively. Anthropometric measurements of weight, length and head circumference were measured as per standard procedure. Those who did not report for one-year assessment were contacted individually at home before the second-year assessment.

Quality check of the data collected was done by perusal of individual data sheets and random checking of about 10% of the admission record sheets by the principal investigator. Data were entered and analysed using Foxplus, and SPSS PC+ softwares. For continuous outcome, Student's *t*-test was used to compare the means in the two groups. Student's *t*-test and two-way analysis of variance were used to compare the means of the study variables between intervention and control group. A 95% confidence interval for the true difference in means was also calculated. For multivariate analysis, the study variables, which were significant at 10% level of significance in bivariate analyses, were considered. Stepwise multiple regression analysis was done separately for MDI, PDI and Bayley scores at the end of first and second year. Significance of the regression model was obtained by F test. $R^2$ was also computed. Wald test was used to identify the significance of the variables included in the model. The ethical committee of Medical College, Trivandrum provided the ethical clearance for the study.

## RESULTS

A total of 1046 babies, born in SAT hospital were admitted to the level II neonatal nursery during the study period. Out of these 142 babies died in the nursery, 100 babies were used for the pilot study and 4 babies planned to move outside the state and hence could not participate in the study. Outcome measurements were available at the end of one year for 665 babies excluding 135 lost to follow-up, and at the end of second year for 735 babies excluding 65 lost to follow-up. ***Table* I** shows that the baseline variables are equally distributed in both arms. Nearly one third of the mothers studied up to middle school. Of the children studied, nearly 27% were preterm and 50-55% of the babies were born with low birth weight. Nearly one fourth of them were SGA. ***Table* II** shows one year and two-year outcomes by

**TABLE I** STUDY VARIABLES AT BASELINE

| Study variable | Intervention *n* (%) | Control *n* (%) |
|---|---|---|
| Residence: Rural | 298 (74.5) | 324 (81.0) |
| Religion | | |
| Hindu | 304 (76.0) | 278 (69.5) |
| Muslim | 56 (14.0) | 55 (13.8) |
| Christian | 40 (10.0) | 67 (16.8) |
| Male sex | 217 (54.3) | 221 (55.3) |
| Caste | | |
| SC/ST | 33 (8.4) | 42 (10.6) |
| Others | 360 (91.6) | 356 (89.4) |
| Education of father | | |
| Middle school | 130 (32.8) | 130 (33.0) |
| High school | 266 (67.2) | 264 (67.0) |
| Education of mother | | |
| Middle school | 125 (31.6) | 134 (33.9) |
| High school | 271 (68.4) | 261 (66.1) |
| Occupation of father | | |
| Irregular job | 181 (46.3) | 198 (50.5) |
| Employed | 210 (53.7) | 194 (49.5) |
| Occupation of mother | | |
| Not employed | 352 (90.7) | 354 (90.8) |
| Employed | 36 (9.3) | 36 (9.2) |
| Families with 1 child | 111 (29.0) | 108 (28.4) |
| Monthly income | | |
| Low | 266 (68.4) | 272 (69.9) |
| High | 123 (31.6) | 117 (30.1) |
| Nuclear family | 98 (25.6) | 115 (29.8) |
| Joint family | 285 (74.4) | 271 (70.2) |
| Birth order >1 | 174 (44.6) | 161 (41.4) |
| Consanguinity | 39 (9.8) | 37 (9.4) |
| High risk pregnancy | 133 (33.6) | 134 (33.6) |
| Assisted delivery | 169 (42.5) | 178 (44.5) |
| Fetal distress | 70 (17.7) | 70 (17.7) |
| Intrauterine infection | 4 (1.0) | 8 (2.0) |
| Pre-term | 108 (27.1) | 111 (27.8) |
| Birthweight <2500g | 202 (50.8) | 217 (54.3) |
| SGA baby | 94 (23.7) | 97 (24.3) |
| Asphyxia | | |
| Mild | 86 (28.8) | 106 (26.5) |
| Moderate | 10 (3.3) | 16 (4.0) |
| Normal | 203 (67.9) | 278 (69.5) |
| Neonatal seizures | 17 (4.3) | 20 (5.0) |
| Respiratory problems | 65 (16.3) | 62 (15.5) |
| Meningitis | 3 (0.8) | 2 (0.5) |
| CNS Malformation | 2 (0.5) | 2 (0.5) |
| Chromosomal anomaly | 2 (0.5) | 2 (0.5) |

intervention and control groups. There was a statistically significant difference observed with the intervention group having a higher score for MDI, PDI, Bayley score and length both at one year and two year.

After converting the raw mental, motor and Bayley scores at 1 year and 2 years to percentile rankings, using tables in the Bayley manual, the same was compared between intervention and control group. Percentile ranking position 1 denotes lowest raw scores group (<3rd percentile) and rank 5 denotes highest raw score group (>50th percentile). The proportion of babies with rank 1 was higher in the control groups and less in the intervention groups for one year and 2 year motor and mental scores. On the other hand, the proportion of babies with rank 5 was higher in the intervention groups and less in the control groups for one year and 2 year motor and mental scores. These differences observed were statistically significant. In the intervention group, the mean SD of 1 year and 2 year MDI, PDI and Bayley scores were compared by the compliance score derived from a structured questionnaire, below 31 denoting poor compliance for home intervention program and above 31 denoting good compliance. It was observed that as the compliance score increased, there was a statistically significant increase in the MDI, PDI and Bayley scores, both at 1 and 2 years.

Multiple regression analysis of the study variables for the outcome measure of Bayley scores at 1 and 2 year was done separately. Normal birthweight babies had a significantly higher Bayley score, 5.6 units at one year and 6.2 units at two year, as compared to low birthweight babies. Babies who did not have neonatal seizures had a significantly higher Bayley score, 7.9 at one year and 9.9 at two year. Babies who did not have intrauterine infection had significantly higher Bayley score, 10.8 units at one year and 11.7 units at two, as compared to others. After adjusting all these significant risk factors for development, the babies who had intervention had significantly higher Bayley scores, 5.8 units at one year and 2.8 units at two year as compared to control babies. The regression models were statistically significant both at 1year ($R^2$ = 15.0%, $P$<0.0001) and at 2 years ($R^2$ = 18.7%, $P$<0.0001). ***Table* III**

**TABLE II** MEAN AND SD OF OUTCOME AT ONE YEAR AND TWO YEAR

| | Mean | SD | Mean | SD | *P* value | 95% CI |
|---|---|---|---|---|---|---|
| | Intervention (*n*=324) | | Control (*n*=341) | | | |
| One Year | | | | | | |
| MDI | 83.6 | 13.7 | 78.5 | 13.3 | <0.001 | 3.05, 7.15 |
| PDI | 90.9 | 18.1 | 83.7 | 18.2 | <0.001 | 4.44, 9.96 |
| Bayley Score | 87.3 | 14.1 | 81.1 | 14.2 | <0.001 | 4.05, 8.35 |
| Weight (kg) | 8.1 | 1.0 | 7.9 | 1.0 | <0.001 | 0.17, 0.32 |
| Length (cm) | 72.5 | 2.9 | 72.1 | 3.0 | 0.035 | 2.40, 4.39 |
| Head circumference | 44.4 | 2.3 | 44.3 | 1.7 | 0.580 | –0.206, 0.406 |
| Two Year | Intervention (*n*=358) | | Control (*n*=377) | | | |
| MDI | 83.1 | 13.9 | 80.3 | 13.4 | <0.005 | 0.83, 4.77 |
| PDI | 99.9 | 15.6 | 95.8 | 16.6 | <0.005 | 1.77, 6.43 |
| Bayley Score | 91.5 | 13.0 | 88.0 | 13.7 | <0.005 | 1.57, 5.43 |
| Weight (kg) | 10.3 | 1.4 | 10.1 | 1.3 | 0.089 | 0.005, 0.39 |
| Length (cm) | 83.5 | 3.6 | 82.4 | 5.2 | 0.002 | 0.45, 1.75 |
| Head circumference | 46.1 | 1.8 | 46.3 | 1.7 | 0.173 | -0.45, 0.05 |

shows that for an increase of every 500 grams, there is a significant and consistent increase in mean values of Bayley scores, both at one year and two year. Similarly, in every birth weight group, the mean values were higher for the intervention group and these differences were statistically significant. Similar findings were observed for MDI (*P*=0.005), PDI (P=0.001), and length (*P*=0.002), but not for head circumference (*P*=0.171) and weight (*P*=0.090).

**TABLE III** BAYLEY SCORES AT THE AGE OF ONE YEAR AND TWO YEAR

| | Intervention | | | Control | | |
|---|---|---|---|---|---|---|
| | Mean | SD | N | Mean | SD | N |
| Bayley score (1 year)* | | | | | | |
| Below 1500g | 83.8 | 12.0 | 38 | 75.3 | 13.2 | 36 |
| 1501 – 2000g | 83.0 | 16.6 | 65 | 80.5 | 15.0 | 67 |
| 2001 – 2500g | 84.4 | 13.4 | 66 | 76.7 | 13.8 | 71 |
| 2501 – 3000g | 91.2 | 12.9 | 100 | 84.2 | 13.1 | 109 |
| 3001 and above | 91.0 | 12.4 | 54 | 85.0 | 14.0 | 58 |
| Bayley score (2 year) | | | | | | |
| Below 1500g | 89.1 | 13.7 | 43 | 81.9 | 13.6 | 43 |
| 1501 – 2000g | 88.0 | 13.5 | 75 | 86.5 | 14.5 | 82 |
| 2001 – 2500g | 87.9 | 14.1 | 71 | 85.1 | 13.3 | 80 |
| 2501 – 3000g | 94.5 | 10.6 | 109 | 91.9 | 11.9 | 110 |
| 3001 and above | 96.4 | 11.9 | 59 | 91.2 | 14.9 | 61 |

** P value <0.001*

**WHAT THIS STUDY ADDS?**

- CDC model early stimulation therapy done by the mother at home is effective in improving the developmental status of neonatal nursery graduates at 1 year and the effect persists at 2 years without additional intervention.

## DISCUSSION

In spite of a long history of mandatory provision of early intervention programs for at-risk infants in USA, there are still a few, who genuinely doubt the usefulness of massive state funding for early intervention programs(12). The term family-centred early intervention refers to both a philosophy of care and a set of practices, as both have been used to guide research, training and service delivery(13). Although, there is no uniform agreement as to the ideal group of babies who would benefit maximally from early intervention, the neonatal nursery graduates would probably form the best captive population for providing early stimulation.

The sample size estimated was a total of 672 and we have outcome measurements for 665 babies at one year and 735 babies at two year. In spite of our best efforts, we were not able to evaluate many babies who missed their one-year assessment appointment date. Home visits helped to reduce the dropout rate from 17% at one year to only 8% at two year. Availability of good objective outcome measurements is crucial for successful completion of any good trial. Hence the objective neurodevelopmental outcome measurement of MDI and PDI using internationally accepted Bayley Scales of Infant Development (BSID), which has been standardized for the Indian population was appropriately used at one and two years in this study(10).

The intervention group of babies having a statistically significant higher score for MDI and PDI at one and two year of age, suggests that not only early stimulation therapy is effective at one year but also that effect is present even at two years, without additional intervention in the second year. The observation that, for increase of every 500 grams, there is a significant and consistent increase in mean values of the outcomes at 1 and 2 year and that in every birthweight group, the mean values are higher for the intervention group, again suggest that early stimulation is effective across the birth weight groups. Early intervention programs that go into homes have a greater chance of reaching high-risk infants, compared with those provided at a distant centre. Better-educated mothers are more likely to be convinced about the benefits of such inputs(14). In the Indian context, there is a potential for introducing home-based early stimulation program through the Integrated Child Development Services. The data provided shows conclusively that early intervention is effective and hence the results of this study may have policy implications.

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