

Effect of an early intervention programme on low birthweight infants with cerebral injuries

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Objective: To determine the effect of an early intervention programme (EIP) on low birthweight infants with cerebral injuries.

Methods: Subjects were 23 high-risk low birthweight infants (periventricular leukomalacia 15, intraventricular haemorrhage 5, both 3) receiving care in the neonatal intensive care unit (NICU) at Nagasaki University Hospital. Subjects were randomly assigned to the EIP group ($n = 12$) or the control group ($n = 11$). Participants in the EIP group received a Neonatal Behavioral Assessment scale (NBAS)-based intervention combined with developmental support designed to enhance the infants' development and the quality of the parent–infant relationship. The control group received routine medical nursing care without the EIP. The EIP began prior to discharge from the NICU and lasted until 6 months of corrected age. All children were examined on the NBAS preintervention and again at 44 weeks postconceptional age. Maternal anxiety status (STAI) and maternal feelings of confidence in dealing with her baby (LCC) were measured pre and postintervention. Mental and motor development was assessed postintervention using the Bayley Scale of Infant Development.

Results: Orientation and State Regulation of infant behavioural profiles, the STAI and LCC scores significantly improved in the EIP group (mean difference (95% CI): Orientation 0.7 (0.4, 1.1), State Regulation 0.9 (0.3, 1.5), STAI -5.5 ($-9.1, -1.9$, LCC 5.3 (4.2, 6.5)), but not in the control group. Bayley mental developmental index (MDI) score in the EIP group was higher than in the control group, but there was no significant difference between the two groups (mean difference (95% CI): MDI 8.5 ($-0.8, 17.8$), PDI 6.7 ($-1.9, 15.4$)).

Conclusion: The EIP has beneficial effects on neonatal neurobehavioural development and maternal mental health of low birthweight infants with cerebral injuries. This evidence suggests that short-term changes in maternal mental health and infant neurobehaviour promoted by an EIP may serve to initiate a positive interaction between parents and infants.

Key words: cerebral injuries; early intervention; low birthweight infants; maternal mental health; Neonatal Behavioural Assessment scale (NBAS).

Developments in medical technology have markedly improved the survival rate of premature and low birthweight infants. Nevertheless, such infants remain at an increased risk for later developmental difficulties. A number of studies have demonstrated that early intervention with non-brain-injured low birthweight infants can facilitate early infant–mother interaction, and result in beneficial developmental outcomes.^{1–5} However, studies on the efficacy of early intervention or physiotherapy on low birthweight and/or premature infants with cerebral injuries have not shown the same beneficial effect on developmental outcomes and maternal mental health.^{6–9}

It has been reported that children with physical disabilities are at increased risk for problems of relationship between parents and child, and that parents of such children experience elevated levels of depression, stress and anxiety.^{10–13} Parents who have high-risk infants also reported significantly more difficulty in interacting with and handling their babies. Parents need help to modify their caregiving or parenting practices to enhance their infant's development or to adapt to the infant's abilities. Previous studies of early 'family centered intervention' based on the Neonatal Behavioural Assessment (NBAS) scale for healthy newborn and premature infants have shown positive effects on infant–mother interaction and their developmental outcome.^{14–19} The NBAS-based intervention was designed to facilitate the development of the infants by

enhancing parenting skills and improving parental recognition of their infants' abilities.

The 'family centered intervention' based on the NBAS might take precedence over the 'disabilities-focused approach' in the first stage of planning the early intervention. However, no studies have yet been carried out to determine whether an early intervention programme based on the principles of the NBAS for infants with cerebral injuries effectively promote maternal mental health and their developmental progress. The aim of this study was to examine the efficacy of an early intervention programme for low birthweight infants with cerebral injuries, based on the NBAS and combined with developmental support, on the maternal mental health and their infants' developmental outcome.

METHODS

Subjects

The sample size was obtained as follows: the primary variable was Bayley mental and psychomotor developmental indices and the sample size was based on a two-tailed *t*-test with a significance level of 0.05, a power level of 0.80, and with an anticipated effect size $d =$ differences of means/standard

deviation = 0.75. The effect size was estimated from the finding of the previous studies.²⁰ The required sample size was 29 in each group for a total of 58.

This study was conducted at the Neonatal Intensive Care Unit of the Nagasaki University Hospital, Japan. Recruitment began in April 1997. It proceeded much slower than expected, because of a decrease in the birth rate of low birthweight infants with cerebral injuries. Thus, after having studied only 26 infants, we decided to terminate this study in December 2002.

Inclusion criteria were: (i) birthweight was below 2500 g (ii) singleton birth (iii) cranial abnormality: cystic periventricular leukomalacia (PVL) and intraventricular haemorrhage (IVH) as shown by ultrasound (iv) residence in Nagasaki city or its vicinity and (v) consent of parents to participate in the research. PVL was defined as increased echogenicity in the periventricular region with cyst formation by serial cranial ultrasound examinations. Infants who developed cysts of 3 mm or more in diameter in the periventricular white matter were diagnosed as having 'cystic PVL'. The maximum size of the cysts in the records of each infant was described as small (5 mm or less in diameter), moderate (6–14 mm) and large (15 mm or more). IVH was defined according to the grading system described by Papile *et al.* as follows: grade I, subependymal haemorrhage with no IVH; grade II, IVH with no ventricular dilatation; grade III, IVH with ventricular dilatation; grade IV, IVH with parenchymal hemorrhage.²¹ Serial ultrasound scans were performed by paediatric clinicians at discharge from the NICU.

A total of 252 infants were hospitalized in the NICU during the study period. Of these, 26 infants (10.3%) met the aforementioned sampling requirements over this study period. Two of these infants had to be excluded because they were born in the mothers' hometown and were later taken to the places where their mothers currently lived. Of the remaining 24 infants, half were randomly assigned to the EIP and the other half were randomly allocated to the control group. With the reduced sample size, the power of this study fell to 40% to find the hypothetical difference in means of 0.75 standard deviation.

Procedure

Subjects (infants and their mothers) were enrolled in the study when the cranial abnormality was elucidated by the serial ultrasound scans prior to discharge from the NICU. At enrolment, subjects were randomized to receive either an early intervention programme (EIP group) or traditional care without EIP (control group). Randomization was performed according to the method of minimization.^{22,23} Minimization aims to ensure treatment arms are balanced with respect to predefined patient factors as well as for the number of patients in each group. Assignment of a new patient to a treatment group is determined so as to minimize the differences between the groups in terms of these factors.

In both groups, the results of the scans were shown to the parents and possible neurodevelopmental consequences were explained by the paediatrician. The parents in the EIP group were told that the study examined the effects of an EIP on maternal mental health and child development outcome. The subjects in the control group, as usual, received standard medical and nursing care during the NICU, and attending regular hospital follow up clinics (Paediatric unit, Nagasaki University Hospital) after discharge. When signs of neurological dysfunction were noted, subjects in the control group were referred to the Rehabilitation Unit by a paediatrician. The

paediatrician was not blinded to the group allocation. All participating families gave informed consent.

Early intervention programme (EIP)

The intervention strategy had two major components. The first component was designed to facilitate the mother–infants' interaction using the NBAS-based intervention method.^{18,19,24} The NBAS-based intervention was performed by the infant specialist (NBAS certified examiner; author SO), who asked the parent to observe baby during the demonstration of the NBAS examination. Then, the infant specialist commented on, and discussed the baby's behaviour (e.g. strengths and weaknesses, attempts at self-regulation, how to read and support infants' coping strategies, etc.), and demonstrated to parents the method of intervention that the infant would benefit from. It was designed to optimize caregiving interactions by enhancing the mothers' adjustment to their infants' behaviour. This programme had the following aims: (i) to enable the mother to appreciate her baby's specific behavioural characteristics; (ii) to sensitize her to the baby's cues, especially those that signal stimulus overload, distress, and readiness for interaction; (iii) to teach her to respond appropriately to those cues in order to facilitate mutually satisfying interactions; (iv) to share with parents concerns about the baby's future development; and (v) to promote a positive collaborative relationship between the clinician which will continue the care of the infant and family. This NBAS-based intervention session was performed three to four times, about 30 minutes per session prior to discharge from the NICU, usually at 36–40 weeks of postconceptional age.

The second component was focused on advice to the mothers on how to handle their infants according to the infants' abilities and developmental needs. This programme had the following aims: (i) to adapt the immediate physical and sensory environment to the infant's thresholds for stimulation (e.g. handling, positioning, swaddling, protection from light, noise, overstimulation, etc.) (ii) to modulate the sleep–awake states (iii) to promote feeding ability (iv) to allow the infants to experience normal sensory–motor development (e.g. tactile/kinesthetic stimulation through massage therapy, vestibular stimulation, orientation towards visual–auditory stimulation, etc.), and (v) to promote the development of normal posture and muscle tone while inhibiting abnormal postural reactions based on the neurodevelopmental therapy (NDT).^{25,26} For example, activities to promote symmetry of head, shoulders and trunk for feeding; to promote range of motion and mobility in the upper extremities, trunk and lower extremities; to improve trunk stability and rotation in prone and sitting, to improve trunk extension with upper extremities free for reach in prone, sidelying, sitting, etc. This second session began from rooming-in (about 1 week). These programmes were taught to the parents during the visits at the hospital. After discharge from hospital, the EIP infants received intervention and treatment at the Rehabilitation Unit, Nagasaki University Hospital once every week or every other week. These sessions lasted approximately 40–60 minutes.

Infants in the control group received traditional care during their hospitalization and after discharge. The nursing staff provided general caregiving instructions during parental visitation to the hospital. After discharge, all the infants regularly attended follow-up clinics (Paediatrics Unit, Nagasaki University Hospital), and referrals to developmental services (Rehabilitation Unit) were made available to all infants and parents as needed. The referral criterion for additional therapy

was the presence of signs of neurological dysfunction and developmental delay, in which case the paediatrician responsible for the follow-up referred the infants to the Rehabilitation Unit for assessment and treatment by a physical or occupational therapist.

Outcome measures

Neurobehavioural examination: Infants' neurobehavioural functioning was assessed with the Neonatal Behavioral Assessment Scale (NBAS)¹⁸ before starting the intervention at 36–40 weeks of postconceptional age (preintervention) and re-assessed after one month of the trial (postintervention). The NBAS was performed by the same blinded NBAS-certified examiner (TA). The NBAS scores were reduced to seven clusters: (i) Habituation (ii) Orientation (iii) Motor performance (iv) Range of state (v) State regulation (vi) Autonomic stability and (vii) Reflexes, in accordance with the data reduction scheme described by Lester *et al.* Individual item scores were re-coded and the cluster scores were calculated. The supplemental NBAS items were included in the corresponding cluster (for example, the supplemental item 'Quality of alert responsiveness' was included in the Orientation cluster). Higher NBAS cluster scores indicated a better behavioural response, except for the Reflexes cluster where higher scores indicated more abnormal responses.

Infants' developmental outcome: Infants' neurological outcomes and mental and motor developmental were examined at the corrected age of 6 months. Neurological examinations and observations of neurological signs were performed according to the methods reported by Touwen and Prechtl.²⁷ The Bayley Scale was administered to determine mental and psychomotor developmental indices (MDI and PDI).²⁸ Bayley Scale items measure memory, language, cognitive skills, personal-social development, hand-eye coordination and gross motor abilities. This scale is a standardized developmental assessment with the MDI and PDI scores having a mean of 100 and a SD of 16.

Maternal mental health: To evaluate maternal mental health, the mothers were asked questions regarding anxiety levels and feelings of confidence in caregiving for infants at enrolment (preintervention) and at the corrected age of 6 months (postintervention). Maternal anxiety status was measured using the State anxiety scale (Form X-1) of the Spielberger's State-Trait Anxiety Inventory (STAI).²⁹ The STAI measures a transitory emotional response to a stressful situation and consists of 20 phrases with responses on a four-point Likert scale. It has also been commonly used with parents to assess their anxiety during paediatric procedures. The instrument defined the cut-off for 'state anxiety' total score as 42.³⁰ Accordingly, mothers in the present study with a total score of 42 points or higher were categorized as having maternal state anxiety.

Maternal feelings of self-efficacy in dealing with their baby were assessed. This assessment was taken from the 'Lack of Confidence in Caregiving; LCC' items of the Mother and Baby Scale.³¹ The 13 items, LCC scale provides a quick check as to whether or not a mother feels confident in dealing with her baby (Appendix I). As shown in the appendix, each item was rated on a six-point Likert scale ranging from 0 (not at all) to 5 (Very often/Very much). This scale is scored by totalling the individual items scores (some items need inversion), lower scores indicated lower confidence.

The assessor (TA) performing these evaluations was blind to the group to which the mothers and infants had been assigned.

Data analysis

Parents' and infants' characteristics were compared using the Mann-Whitney *U*-test and Student's *t*-test for continuous data and Fisher's exact test or χ^2 test for discrete data. The paired *t*-test was used to analyse the difference between pre and postintervention in the cluster scores of the NBAS, STAI and LCC scores. The mean differences (post minus pre-intervention) were calculated and compared between the two groups using Student's *t*-test. ANCOVA was conducted for the Bayley Scale comparison of the two groups. Gender, birth-weight, diagnosis type (PVL vs IVH vs both) and with versus without abnormal neurological examination results were chosen as covariates. *P*-values less than 0.05 (two-tailed tests) were regarded as statistically significant. The statistical software SPSS (version 10.0J) was used for statistical analysis.

RESULTS

1. Background comparison

The characteristics of the study infants and those of their mothers are presented in Table 1. No differences between the groups were observed in infant and maternal factors. The diagnoses of those infants in the EIP group were: eight infants with PVL, two infants with IVH and two infants with both. In the control group, infants were diagnosed as follows: eight infants with PVL, two infants with IVH and one infant with both. There was thus no statistically significant difference in distribution of the diagnoses between the two groups. Also, the distribution of these severities between two groups were not statistically significant. With regards to social factors, there were no single mothers and no fathers who were out of work in either group. The existence of siblings, living with grandparent(s) and maternal education (graduated from high school) were not statistically significantly different between the two groups.

In the control group, two infants at 4 months corrected age and two infants at 5 months corrected age were referred to the Rehabilitation Unit by paediatricians for assessment and treatment. They received physical therapy, and these infants and their mothers were re-evaluated at this point.

2. The Neonatal Behavioral Assessment scale cluster scores

The NBAS cluster scores for both groups, pre and postintervention (1 month corrected age), are shown in Table 2. Postintervention Orientation and State Regulation cluster scores were significantly improved in the EIP group, but not in the control group. Comparisons of individual items on the NBAS yielded significant differences between the two groups on the Animate Visual Orientation item, the Auditory and Visual-Auditory Orientation items and on the Alertness, Cuddliness, Self-quieting, Cost of attention, General irritability items.

3. Infants' developmental outcome

Ten infants in the EIP group and eight infants in the control group had abnormal neurological examination results. There was no significant difference between the two groups in terms

Table 1 Characteristics of study subjects

	EIP	Control	P-value
No. of subjects	12	11	
Gender (M/F)	9/3	8/3	1.00 ^{††}
Birthweight [†]	1272.6 (310.1)	1359.6 (381.41)	0.55 ^{††}
Gestational age (weeks) [†]	30.3 (3.3)	30.3 (2.7)	0.96 ^{††}
Apgar Score			
1 min [†]	5.8 (1.9)	5.4 (1.8)	0.54 ^{††}
5 min [†]	7.3 (1.5)	7.2 (1.7)	0.92 ^{††}
Diagnosis (PVL/IVH/both)	8/2/2	8/2/1	0.87 ^{§§}
PVL classification (small/moderate/large) [‡]	3/5/2	4/3/2	0.90 ^{§§}
IVH grade (I/II/III/IV) [§]	0/2/2/0	0/2/1/0	0.87 ^{§§}
Abnormal neurological examination results	10	8	0.64 ^{††}
Maternal age [¶]	30 (18–36)	30 (22–33)	0.65 ^{¶¶}
Single mother	0	0	
Siblings	4	3	1.00 ^{††}
Maternal education (graduated high school)	12	11	
Living with grandparents	4	3	1.00 ^{††}
Unemployed of household	0	0	

EIP, early intervention programme; IVH, intraventricular haemorrhage; PVL, periventricular leukomalacia.

[†]The maximum size of the cysts; small (5 mm or less in diameter), moderate (6–14 mm) and large (15 mm or more); [§]IVH was defined according to the grading system described by Papile *et al.*; [†]mean (standard deviation); [¶]median (range); ^{††}Fisher's exact test; ^{†††}t-test; ^{§§}Chi-square test; ^{¶¶}Mann-Whitney U-test.

of the proportion of infants with abnormal neurological examination results. (Table 1) The Bayley Scale's MDI and PDI scores for both groups are shown in Table 3. The MDI and PDI scores for the EIP group were higher than the control group, but there were no significant differences between the two groups for either score.

(4) Maternal mental health

The STAI scores pre and postintervention for both groups are shown in Table 4. The STAI scores decreased significantly in the EIP group but did not change in the control group. At baseline, 10 mothers in the intervention group and nine mothers

Table 2 The Neonatal Behavioral Assessment scale (NBAS) cluster scores

	Pre Mean (SD)	Post Mean (SD)	Mean difference (95%CI)
Habituation			
EIP	6.5 (0.6)	6.9 (0.3)	0.4 (–0.1, 0.8)
Control	6.6 (0.6)	6.8 (0.4)	0.3 (–0.2, 0.6)
Orientation			
EIP	4.5 (0.9)	5.3 (1.1)	0.7 (0.4, 1.1) ^{††}
Control	4.6 (0.8)	4.7 (0.6)	0.1 (–0.5, 0.6)
Motor			
EIP	3.9 (0.5)	4.1 (0.6)	0.2 (–0.04, 0.5)
Control	3.9 (0.6)	4.1 (0.5)	0.1 (–0.2, 0.5)
State range			
EIP	3.8 (0.8)	4.1 (0.5)	0.2 (–0.03, 0.5)
Control	3.6 (0.6)	3.9 (0.8)	0.3 (–0.1, 0.6)
State regulation			
EIP	4.1 (0.6)	5.0 (1.2)	0.9 (0.3, 1.5) ^{††}
Control	3.9 (0.7)	4.2 (1.0)	0.2 (–0.2, 0.7)
Autonomic stability			
EIP	6.3 (0.7)	6.7 (0.7)	0.4 (0.02, 0.7) [†]
Control	6.2 (0.5)	6.7 (0.4)	0.5 (–0.1, –0.8) [†]
Reflexes			
EIP	3.8 (1.2)	4.2 (1.4)	0.4 (–0.6, 1.5)
Control	3.5 (1.4)	4.3 (1.5)	0.8 (–0.4, 2.0)

95% CI, 95% confidence interval; EIP, early intervention programme; SD, standard deviation. [†]Significantly different between pre and postintervention. Orientation ($P < 0.01$), State regulation ($P < 0.01$) and Autonomic stability ($P = 0.04$) cluster scores improved significantly in the EIP group. Autonomic stability ($P = 0.02$) cluster scores improved significantly in the control group. ^{††}Significantly different between the two groups. The mean difference of the Orientation ($P = 0.03$) and State regulation ($P = 0.05$) cluster scores were significantly higher in the EIP group than in the control group.

Table 3 The Bayley Scales of Infant Development

	EIP Mean (SD)	Control Mean (SD)	Adjusted mean difference (95% CI)	P-value
MDI	76.4 (15.4)	67.9 (15.1)	8.5 (-0.8, 17.8)	0.07
PDI	69.8 (19.2)	63.1 (13.6)	6.7 (-1.9, 15.4)	0.29

95% CI, 95% confidence interval; EIP, early intervention programme; MDI, mental developmental index; PDI, psychomotor developmental index; SD, standard deviation. †ANCOVA (adjusted gender, birthweight, diagnosis categories, and with or without abnormal neurological examination results).

in the control group had state anxiety (higher total score ≥ 42). Postintervention, eight intervention and 9 nine control mothers were classified as having state anxiety. The LCC score increased significantly in the EIP group. Mothers in the EIP group had a more positive perception of their parenting and childcare and judged their infants to be easier to care for.

DISCUSSION

Although this study was a small randomized trial, the findings suggest that an early intervention programme, based on the NBAS combined with developmental support (EIP), for low birthweight infants with cerebral injuries, has beneficial effects on neonatal neurobehavioural development and maternal mental health.

The results on the NBAS showed that the Orientation and State Regulation clusters were significantly improved in the EIP group. The infants who received EIP improved their abilities to: (i) be less irritable and fussy, (ii) have a higher capacity for maintaining stable state organization in the face of increasing levels of stimulation, (iii) have a higher capability for state-regulation in their ability to move when crying, and (iv) have less stress behaviour. It is therefore likely that the improved behavioural characteristics in the EIP group would have a positive modifying influence on the interactions between the infants and their parents.

Developmental outcome as shown by the results on the Bayley Scale at 6 months corrected age showed that neither the mental nor the psychomotor developmental indices were significantly different between the two groups. However, the PDI was higher for the experimental group, almost reaching statistical significance ($P = 0.07$). A number of studies on intervention for high-risk premature infants have shown that early intervention has positive, significant effects on cognitive developmental outcome measures.¹⁻⁵ In the present study, statistical significance may not be achieved due to our small

sample size. Failure to detect differences may be due to the variability in cognitive responses in this small sample.

Maternal mental health determined by the STAI and the LCC showed significant improvement in the EIP group, but not in the control group. This suggests that the EIP had positive, significant effects on reducing maternal anxiety, with improvement in maternal mental health. In addition, the results on the LCC score highlight enhancement of maternal perception of parenting expectations. This result suggests that the EIP also helped mothers modify their caregiving or parenting practices to be better adapted to the infants' abilities. These EIP-induced changes in maternal mental health and attitude at this early phase of life may promote a positive cycle of interaction between parents and infants that may lead, albeit indirectly, to desirable long-term consequences.

Several studies have indicated that early intervention can have substantial benefits on improving parent-infant interaction for infants who are at risk for developmental disabilities.^{13,32-34} Our findings in the present study support these previous findings. Lambrenos suggested, however, that an early physiotherapy intervention had no effect on the prevalence of depression in mothers whose children were at risk for the development of cerebral palsy.⁸ This could be because this type of 'disabilities-focused intervention' may not have a positive effect on maternal mental health. Our EIP was based on the following goals: (i) to facilitate the mother-infant interaction using the NBAS-based intervention method, and (ii) to use the NBAS to sensitize mothers to the individuality of their infant's behaviour (strengths and weaknesses), thereby helping mothers bond with their infants. The NBAS-based intervention helped parents to learn their infants' behavioural cues, so as to promote mother-infant interaction and the infants' behavioural development.¹⁴⁻¹⁹ The developmental intervention also focused on adapting the mothers' handling of their infants to match the infants' developmental abilities and developmental needs. Provision of handling skills promoted positive mother-infant interaction as well as assisted the infants' sensory-motor

Table 4 The STAI and LCC scores

	Pre Mean (SD)	Post Mean (SD)	Mean difference (95% CI)
STAI			
EIP	48.8 (6.8)	43.3 (4.1)	-5.5 (-9.1, -1.9) ^{††}
Control	47.2 (8.1)	49.1 (6.9)	
LCC			
EIP	32.3 (3.3)	37.7 (3.7)	5.3 (4.2, 6.5) ^{††}
Control	31.8 (3.7)	33.1 (4.4)	

95% CI, 95% confidence interval; EIP, early intervention programme; LCC, Lack of Confidence in Caregiving; STAI, State-Trait Anxiety Inventory. Higher STAI scores indicate greater anxiety. †Significantly different between pre and postintervention. The STAI ($P = 0.02$) and LCC ($P < 0.01$) scores improved significantly in the EIP group. ‡Significantly different between the two groups. The mean difference of the STAI ($P = 0.03$) was significantly lower and of the LCC ($P < 0.01$) score was significantly higher in the EIP group than in the control group.

development. We believe our EIP was able to influence the parent-infant relationship by helping the parents learn techniques to help them deal with their infant's individual behavioural characteristics, thereby facilitating their development. Our results suggest that although there may not be direct or immediate results on the infant's development, long-term beneficial effects may be derived indirectly due to the improved parent-infant early relationship. We believe that the interaction between parents and their infants is likely to facilitate the infant's development and the parents' own recovery and stability, by reducing parental anxiety and encouraging 'kizuna' (bonding) between the parents and the infant.

Several limitations are present in this study. First, the sample size was small. There were two major reasons for terminating the trial before the desired number of subjects were obtained; (i) the recruitment took a much longer time than anticipated, and (ii) paediatricians and nurses became convinced of beneficial effects. A larger multi centre randomized trial should be considered in future so that the results can be generalized and applied to all high-risk infants. Second, this study was limited to 6 months, though longer-term intervention studies are needed to ascertain if the tendency to improve outcomes for EIP recipients as found in this study can reach statistical significance. In the control group, four infants were referred to the Rehabilitation Unit by paediatricians for assessment and treatment until 6 months corrected age. Also, four infants received physio-occupational therapy immediately after they were re-evaluated for the outcome measures at 6 months corrected age, because they had developmental delay and/or disabilities. Since developmental disabilities in brain injured infants become more evident around 6 months of corrected age, the use of a randomized controlled trial study becomes very difficult, if not impossible to carry out. Finally, there were some limitations of the outcome measures. We relied exclusively on self-report measures concerning maternal mental health that were completed by mothers. In future studies, direct observation of infant-mother interaction and family dynamics must be made. Also, the developmental course of brain injured infants could be more meaningfully described. Developmental outcome using the Bayley Scale alone may be inappropriate as this test may lack the sensitivity to identify the effects of developmental intervention and variability in motor and cognitive responses in this sample.

CONCLUSIONS

In conclusion, while acknowledging that sample size was small and the length of follow up was only short-term, these data provide evidence for the effectiveness of EIP in improving infant neurobehaviour, maternal mental health and a trend to enhance developmental outcome.

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APPENDIX I

Maternal feelings of confidence in dealing with their baby (Lack of Confidence in Caregiving; CCS)

The following questions have been designed to help us better understand you and your confidence in caretaking. Please answer each question by circling one of the numbers. '0' is circled if the statement does 'not at all' apply. The choices '1, 2, 3, 4' indicate increasing degrees of agreement, and '5' indicates that the feeling occurs 'very often/very much'.

1. It makes me insecure when my baby cries	0	1	2	3	4	5
2. I have felt confident about looking after my baby	0	1	2	3	4	5
3. I have felt clumsy in caring for my baby	0	1	2	3	4	5
4. I would have liked more advice about looking after my baby	0	1	2	3	4	5
5. Looking after my baby has been more difficult than I expected	0	1	2	3	4	5
6. I have been feeling anxious about coping when my baby when I get home	0	1	2	3	4	5
7. I think I have been coping alright with my baby	0	1	2	3	4	5
8. I have been afraid that I might drop my baby	0	1	2	3	4	5
9. I have asked the nurse for help when my baby is unsettled	0	1	2	3	4	5
10. I have felt worried I might hurt my baby when handling him/her	0	1	2	3	4	5
11. I have asked the nurse whether I have been doing the right thing whilst looking after my baby	0	1	2	3	4	5
12. I cope well with my baby when she/he is unsettled	0	1	2	3	4	5
13. I think I have been making a good job of being a mother	0	1	2	3	4	5