Effect of a developmental program on motor performance in infants born preterm

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A randomised controlled trial was conducted to evaluate the effect of a motor developmental program in improving motor performance in Thai infants born preterm. Eighty-four preterm born infants were randomly assigned to either a control or intervention group. Additionally, 27 low-risk preterm infants were included, forming a comparative group for this study. From term equivalent age to four months adjusted age, all infants had their motor performance assessed monthly with the Test of Infant Motor Performance by one of the physiotherapist research assistants blind to group assignment and infants' adjusted age. In addition, the intervention infants received a developmental program at each monthly visit. Motor performance for each group plotted against age revealed linear trends of progression. The intervention group showed the greatest improvement. Two-way repeated measures ANOVA revealed significant differences across age and among groups. Scheffé comparisons indicated that the mean differences between each pair of the three groups were significant and supported the finding of greater improvement of the intervention infants over the control group. Thus the results suggest that the intervention program is likely to have beneficial effects when offered to a similar population of preterm born infants. **[Lekskulchai R and Cole J (2001): Effect of a developmental program on motor performance in infants born preterm. *Australian Journal of Physiotherapy* 47: 169-176]**

Key words: Child Development; Infant, Premature; Randomized Controlled Trials

Introduction

Preterm birth has been considered to be one of the risk factors for developmental disabilities (Morgan et al 1988, Ruiz et al 1981). Infants born preterm may have a lower threshold for sensory input than their fullterm born peers and have difficulty in tolerating handling and interaction (Georgieff et al 1986). These problems could diminish critical experiences in their early lives. Among the preterm born infant population, it has been indicated that the shorter the gestation, the higher the level of risk factors for the infants. Piper et al (1986) found that infants born at earlier gestational ages (< 32 weeks), when compared with later ages (32-36 weeks) scored lower on tests of gross motor development. Thus time spent in the mother's womb may relate to the quality of motor performance at a later age. In addition, poor quality postural stability and mobility in the preterm population might be related to differences in experiences such as longer hospital stays, neurological impairment associated with medical complications, or immobility due to the constraints of medical technology (Case-Smith 1993, Georgieff and Bernbaum 1986). Therefore, developmental programs for this preterm born infant population are thought to be of value to compensate for the disadvantages of their preterm birth.

Infant developmental assessment Various developmental assessments have been published (Bayley 1969, Burns 1992, Folio and Fewell 1983, Piper and Darrah 1994). Selection of an assessment for use in the clinic or in research studies needs to ensure the appropriateness of the instrument and a direct relationship to the aim of the assessment. Since the changing nature of postural control and the accomplishment of active movements among preterm born infants during the period of very early infancy was the major focus for this study, the Test of Infant Motor Performance (TIMP) was selected as the evaluation instrument. This test is appropriate for evaluation of motor development in preterm born infants aged 32 weeks postconceptional age through four months post term (Campbell et al 1995). The TIMP consists of 28 observed and 31 elicited items of posture and active movement. The average time required for this test is 36 minutes.

Developmental intervention for at-risk infants Physiotherapists have several choices in providing developmental intervention for preterm born infants. Neonatal intervention programs implemented during hospitalisation have been widely studied (Downs et al 1991, Korner 1990, Updike et al 1986). Results from such studies have shown that appropriate activities during the early period of life may play an important role in muscle fibre differentiation and subsequent hypertrophy as well as being effective in promoting the infants' further development (Cole 1988, Elder and McComas 1987, Moore and Goldspink 1985).

Most developmental programs need special training and require a multidisciplinary team for their implementation (Als et al 1994, Barrera et al 1986, Bennett and Guralnick 1991, Brooks-Gunn et al 1994). Studies of the effectiveness of such programs have found them to be useful. However, there have been few studies using a randomised controlled trial to evaluate the effects of intervention programs in at risk infants (Als et al 1994,

Table 1. Descriptive data for the infants in each group and summary results of unpaired *t*-test between complete and incomplete follow-up subjects for each variable.

	Control		Intervention		Comparative	
	A (n = 34)	B‡ (n = 7)	A (n = 38)	B‡ (n = 5)	(n = 27)	*p**
Sex						
Number (Male)	18	4	22	3	12	
%	52.9	57.1	57.9	60.0	44.4	
Birth weight (grams)						0.50
Mean	1637.4	1618.8	1628.7	1620.0	1817.8	
SD	365.2	307.9	332.0	356.9	250.8	
Gestational age (weeks)						0.86
Mean	31.9	33.0	32.3	32.2	33.6	
SD	2.4	3.1	2.2	3.4	1.6	
APGAR (at 1 minute)						0.11
Mean	6.4	6.1	6.9	6.0	8.9	
SD	2.7	2.5	2.3	2.8	1.2	
APGAR (at 5 minutes)						0.16
Mean	8.8	8.6	8.8	8.2	9.8	
SD	1.7	2.2	1.5	2.7	0.7	
Length of hospital stay (days)						0.65
Mean	32.2	27.3	29.8	25.0	5.2	
SD	17.0	11.3	14.5	10.0	2.3	

A Complete follow-up group, B ‡ Incomplete follow-up group

*p from unpaired t-tests between data of complete and incomplete follow-up infants

Barrera et al 1986, Cole 1988). In addition, programs specific for physiotherapists have not been widely reported and studied. Cole (1988) evaluated the effect of a developmental program using a randomised controlled trial and demonstrated that the program was more beneficial when continued after hospital discharge. In addition, research investigating the effects of follow-up programs have revealed that the programs appear to be more advantageous developmentally when the therapist works directly with parents rather than exclusively with infants (Barrera et al 1986, Cole 1988).

Based on these findings, home programs and parent education have been integrated into developmental follow-up programs. Manuals for parents have been developed to emphasise the elements of the programs (Baker et al 1991, World Health Organization 1993). However, different clinics and countries seem to demonstrate individual differences and needs. Motor developmental programs appropriate for one setting may need some modification to make them more suitable for another setting.

This study aimed to examine motor performance of Thai infants born preterm who were randomly assigned to intervention and control groups where the intervention group received a program designed to facilitate motor development.

Method

Subjects Infants with a gestational age of less than 37 weeks, who were free of congenital abnormalities and genetic disorders, were eligible for this study. However, infants meeting the inclusion criteria who subsequently underwent surgery for any reason or developed serious illnesses including hydrocephalus, periventricular haemorrhage Grade III and above, ventricular dilatation or retinopathy of prematurity Stage III and above were excluded prior to randomisation. Three infants were excluded because of these criteria.

Subject recruitment Infants included in the study were identified from a cohort consisting of preterm infants nursed in the special care nurseries of Siriraj Hospital, Bangkok, Thailand. During the study period, 111 infants were eligible. Of these 111 infants who were assessed, 27 scored a total of 67 or greater on the TIMP at 40 weeks

Table 2. Physiotherapy motor developmental program.

	Aim	Procedure
40 weeks postconceptional age	To promote symmetrical, flexed body posture	Positioning the infant in hammock during the day
	To encourage head in the midline, to assume and maintain chin-tuck and to promote symmetrical, flexed body posture	Positioning the infant in supine on a mattress with postural support provided by rolled towels
	To promote free movement of the hip joint	Folding of a cloth nappy to promote free movement of the legs
1 month adjusted age	To promote experience in various positions	Instruction in the use of a variety of positions for playing and sleeping
	To strengthen the leg muscles, and to promote reciprocal movements of the legs	Assisted kicking
	To promote eye following and to strengthen the eye and neck muscles	Promotion of eye following and head movement
2 months adjusted age	To promote weight bearing on forearms in prone	Encouragement of weight bearing on forearms in prone
	To exercise neck and upper trunk extensor muscles	Carrying in supported sitting position, over the care-giver's arm
	To promote rolling from supine to prone position	Assisted rolling using upper and lower extremities
3 months adjusted age	To promote hands together and touching mouth and legs	Facilitating hand to midline and hands together activities
	To strengthen neck and upper trunk muscles	Encouraging the development of head righting
	To promote reaching in prone and supine	Structuring the environment and play sessions to promote reaching

postconceptional age and were assigned to the comparative group. The 84 remaining infants were randomly assigned to either a control or intervention group using a container of 45 "C" and 45 "I" same size and shape slips. A slip was drawn blindly from the container for the infants at 40 weeks postconceptional age. Forty-one infants with a "C" slip were included in a control group and 43 infants with an "I" slip were allocated to the intervention group. The TIMP total score of 67 was selected as a cut-off point to divide the infants into either the at-risk (total score of less than 67) or not-at-risk groups for the present study. This cut-off point was selected according to the suggested score ranges on the TIMP for typical and atypical performance for infants aged 38 to 41 weeks postconceptional age. The TIMP total score of 67 is the lowest score recorded from the average range group, while total scores of 66 or less were recorded by the below, to far below average groups (Campbell SK, unpublished data). Thus the infants included in the control and intervention groups were infants who were at risk of developmental delay and those included in the comparative group were infants with minimal risk of developmental delay.

During the longitudinal study, seven control and five intervention infants had incomplete follow-up because of inconvenience caused to their parents in bringing the infants to the follow-up clinic. At the end of the study, complete data were obtained from 34, 38 and 27 infants in the control, intervention and comparative groups, respectively. Table 1 summarises the descriptive data for the subjects in each group. For data analysis, only the data of the subjects with complete follow-up were included. Unpaired *t*-tests were employed to compare the demographic data of the infants with complete and incomplete follow-up data. None of the demographic data of the incomplete follow-up infants were significantly different from those of the complete follow-up infants (Table 1). According to the inclusion and exclusion criteria defined for this study, the infants who participated had no serious complications (apart from their preterm birth) which were likely to affect their further development. This

Table 3. Mean difference, standard error and *p*-values of the Scheffé tests for Rasch-scaled TIMP ability scores assessed at 40 weeks PCA and at four months AA.

TIMP ability scores assessed at	Source	Mean difference	Standard error	*p*
40 weeks post conceptional age	control vs intervention group	-0.003	0.049	0.998
	control vs comparative group	-0.808	0.053	< 0.001
	intervention vs comparative group	-0.805	0.052	< 0.001
4 months adjusted age	control vs intervention group	-3.071	0.175	< 0.001
	control vs comparative group	-2.715	0.191	< 0.001
	intervention vs comparative group	0.356	0.186	0.167

fact was confirmed by the results of the Neuromotor Behavioral Assessment administered at 36 weeks postconceptional age for all infants (Carmichael et al 1997). Based on the scale used for the Neuromotor Behavioral Assessment, no infant included in the sample was found to have a total score falling outside the normal range (Carmichael et al 1997).

Developmental program for intervention infants A follow-up developmental physiotherapy program was specially selected and modified for the group of Thai preterm infants in this study. To maintain the consistency of intervention provided for each infant, the number of activities per month and aims of activities in each month were the same for each intervention infant at each specific age.

The program included a total of 12 activities for infants at 40 weeks postconceptional age and at one, two, and three months adjusted age, with three activities introduced in each month. Some activities included specific modifications appropriate to the age of the infant but maintained the original aim of that activity (Table 2). Either the original activity or its modified form was chosen through a process of discussion between the principal researcher and the primary care-giver. The primary care-giver (in most instances, the mother) was the person responsible for carrying out the intervention program. Since the intervention consisted of a program of home-based activities, demonstration and a practice session were provided to the infants' primary care-givers to ensure the correct performance at home. The first intervention was provided once the infant was assigned to the intervention group at 40 weeks postconceptional age. Subsequent interventions were provided at one, two, and three months adjusted age.

Prior to presenting the new home program to the care-givers, the principal researcher evaluated the previous month's home program as provided by the care-giver. For example, evaluation of the 40 weeks postconceptional age home program was completed before giving the one month home program. The care-givers were not made aware that they were being evaluated. The evaluations were performed through an interview and then demonstration of the activities by the care-giver. The results of the evaluations were recorded. Care-givers who could not demonstrate the previous month's activities or showed incorrect activities for two consecutive months were liable to have their infants excluded from the study. Throughout the study, however, no care-givers demonstrated inappropriate activities for two consecutive months and therefore no infants were excluded from the study for this reason.

Motor performance assessment Permission to use the TIMP was obtained from the test's senior author and discussions with the author were undertaken. Scoring and administrative skills of the principal researcher were evaluated by the original authors of the TIMP and met all criteria for the test.

Since the study involved a randomised controlled trial, the assessors needed to be appropriately blind to the group assignment of the subjects. However, since the principal researcher had to provide the intervention for the intervention infants, group assignment could not be unknown to the principal researcher. To meet the assumptions of the research design, three physiotherapist research assistants were employed. Each of these assessors was blind to the infants' group assignments and information about the infants' gestational age and adjusted age was withheld. They were trained in using the test and practice was undertaken on non-study infants prior to commencement of the study. Scoring performances of the three physiotherapy assistants were monitored. Feedback and comments on the testing performance were given to the physiotherapy assistants regularly. Periods of practice scoring infants using the TIMP and discussions among testers were undertaken to maintain the standard of the testing.

Intra- and inter-tester reliability of the three research assistants as well as the principal researcher were assessed concurrently on 21 non-study infants prior to the main study (Eliasziw et al 1994). The ICC for inter-tester reliability was 0.95 and those for intra-tester reliability for

Table 4. Descriptive data of total TIMP scores for all infant groups (means and standard deviations).

	Control Group		Intervention Group		Comparative Group	
40 weeks postconceptional age	57.0	(3.7)	57.0	(3.7)	71.0	(3.10
1 month adjusted age	68.2	(4.2)	86.3	(5.9)	98.3	(7.8)
2 months adjusted age	83.0	(5.7)	112.0	(7.4)	116.4	(10.6)
3 months adjusted age	96.4	(5.8)	134.5	(8.2)	132.6	(9.6)
4 months adjusted age	114.2	(9.2)	152.3	(6.3)	148.4	(9.9)

each tester ranged from 0.98 to 0.99 (Lekskulchai and Cole, unpublished data).

Procedure Ethical approval for this study was obtained from the Human Research Ethics Committee, Curtin University of Technology, Western Australia, and the Human Rights Committee, Faculty of Medicine Siriraj Hospital, Mahidol University, Thailand. Parents of infants meeting the inclusion criteria for this study were contacted and written permission obtained. All infants were scheduled to have their motor development assessed at 40 weeks postconceptional age. Their scores were used to categorise the infants into "at-risk" or "not-at-risk" for motor delay. Infants with the total developmental assessment score at 40 weeks postconceptional age of 67 or greater were categorised as the "not-at-risk group" and formed the comparative group for this study, whereas the "at-risk group" included those with the score of less than 67 (Campbell SK, unpublished data). The at-risk infants were then randomly allocated to either the control or intervention group. At one, two, three and four months adjusted age, all infants had appointments to return to the clinic for the purpose of this study. Initially, all infants met the principal researcher for an interview and general growth index measurements. This protocol was designed to maintain contact between all infants and the principal researcher. All infants' care-givers took this opportunity to discuss their concerns with the principal researcher. Additionally, the intervention infants' care-givers were evaluated on the previous month's motor program during this period. Following the initial interview, each infant was assessed for motor development by one of the three research assistants. After the assessment, each infant was assigned to see the principal researcher again to receive the next month's appointment card. During this session, the intervention infants received the appointment card as well as the motor developmental activities appropriate for their age. The intervention infants' care-givers had an opportunity to practise the activities on the infant under the supervision of the principal researcher. However, if the infants were too tired for practice, a doll was offered to provide the care-givers with the opportunity for practice. The practice period was completed when the principal researcher was assured that the care-givers could carry out the program appropriately. Table 2 reports the motor development program in outline. Results of the motor performance for each infant were set aside without analysis until the end of the period of data collection.

Data analysis Scores of all TIMP items were transformed to an ability score for each infant, that is a transformation of the categorical scale to a continuous scale. The Rasch Unidimensional Measurement Model (RUMM) Version 2.7 was used for this process (Sheridan et al 1998). A two-way mixed repeated measures ANOVA was used to examine the effects of age and group (with and without intervention as well as not-at-risk preterm born infants) on the infants' motor performance. If a significant difference was found, a Scheffé test was employed to identify the different pairs. The magnitude of the mean difference between each pair was then examined.

The assumptions for the repeated measures ANOVA were tested and revealed that the TIMP ability scores assessed at all ages for all subject groups were distributed normally ($p > 0.001$ on the Shapiro-Wilks statistic), all groups also had homogeneity of variance ($p > 0.001$ on the Levene test). However, the value for the Mauchly test for sphericity was equal to 0.262 and was significant ($p < 0.001$). Therefore, the Huynh-Feldt Epsilon (0.603) was used to recalculate the degrees of freedom for the within-subjects effects (age) and the interaction, to deal with the non-sphericity (Coakes and Steed 1999). This adjustment to the degrees of freedom does not affect the calculated F ratios, but does modify the p-value to ensure that the sphericity assumption is met.

Results

Each infant's ability scores at term equivalent age, one, two, three and four months adjusted age and were plotted against age. Figure 1 compares mean TIMP ability scores among groups. In order to investigate the effectiveness of the motor developmental program, a group (3) × age (5) ANOVA was conducted, with repeated measures on the second variable. The two-way mixed repeated measures ANOVA revealed significant differences for the TIMP ability scores assessed across ages ($F_{(2, 232)} = 1421.03$) and among groups ($F_{(2,96)} = 272.30$). In addition, the interaction effect was significant ($F_{(5, 232)} = 88.94$).

In order to investigate the significant interaction further, two one-way ANOVAs were conducted to compare the groups at 40 weeks postconceptional age and again at four

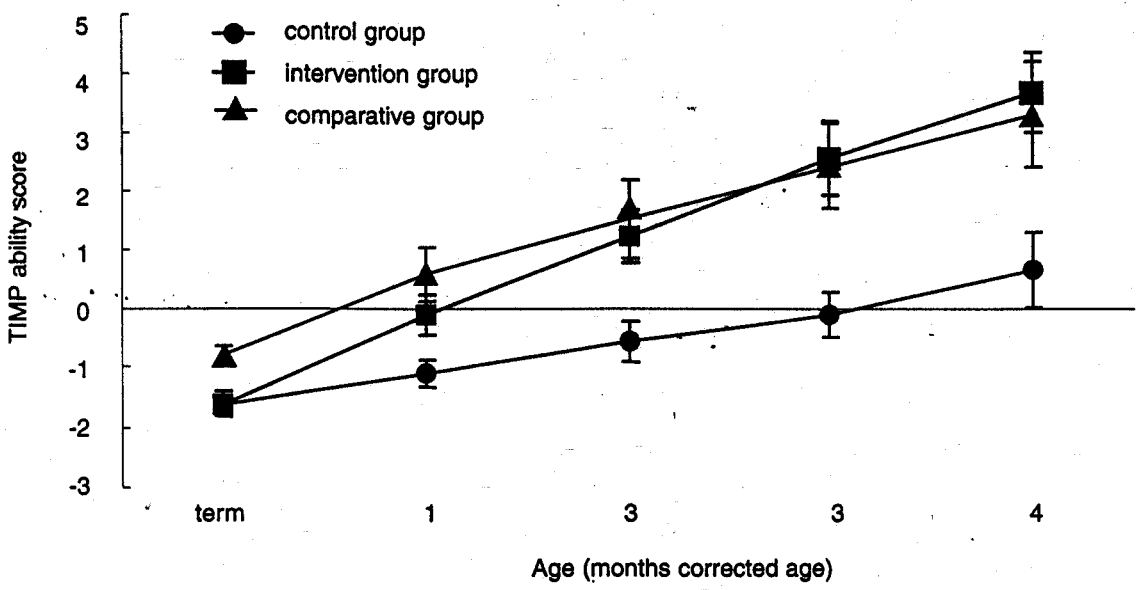

Figure 1. Mean ± 1 standard deviation of Rasch-scaled TIMP ability scores for each group across time.

months adjusted age. These ANOVAs yielded significant results, both at 40 weeks ($F_{(2, 96)} = 150.58, p < 0.001$) and at four months adjusted age ($F_{(2, 96)} = 175.75, p < 0.001$). At 40 weeks postconceptional age, Scheffé tests indicated that the intervention group did not score significantly higher than the control group ($p = 0.998$) but these two groups scored significantly lower than the comparative group ($p < 0.001$). At four months adjusted age, Scheffé tests indicated that the intervention group scored significantly higher than the control group ($p < 0.001$), and no longer differed significantly from the comparative group ($p = 0.167$) (Tables 3 and 4).

These results suggest that the infants who received the motor developmental program showed significantly greater improvement in motor performance during the study period than the infants in the control group. At four months adjusted age, infants who had received the intervention program did not differ significantly in motor performance from the not-at-risk preterm born infants (comparative group).

Discussion

Since a statistically significant interaction between the infants' groups and ages was revealed, the magnitude of progression of the motor performance across time appeared to differ among the three groups. A clear picture of the interaction effect is presented in Figure 1. At 40 weeks postconceptional age, the mean difference between the intervention and the comparative groups (intervention minus comparative) was –0.805 (Table 3; see also Table 4). The value with a negative sign suggested that at 40 weeks postconceptional age, the intervention infants started with lower scores than those of the comparative group. When comparing the control and intervention groups, it was found that the infants with no intervention offered showed slower motor progression at four months adjusted age than those receiving the intervention program, since at four months adjusted age, the mean difference between the control and intervention groups (control minus intervention) was –3.071. This negative value indicated that the intervention infants showed more improvement than the control infants. Additionally, it was found that the mean difference between the intervention and the comparative groups at four months adjusted age was 0.356. This positive value would indicate that the motor performance of the intervention group at four months adjusted age seemed to be greater than that of the comparative group. However, this mean difference was not statistically significant. Thus the motor development intervention offered to the intervention infants appears to have been effective in assisting the preterm infants who were at risk for developmental delays at 40 weeks postconceptional age (intervention group) to catch up with those whose developmental status was normal at 40 weeks postconceptional age (comparative group). The present study, therefore, supports other reports of the effectiveness of intervention during the early life of infants born preterm (Als et al 1994, Barrera et al 1986, Cole 1988).

The motor developmental program used in the present study was designed for preterm born infants, however, care-givers played a major role in carrying out the program for their infants. The care-givers were provided with information regarding the development of posture and active movements of their infants and were informed about the aims for each activity, and how these activities could help their infants. Therefore, the effectiveness of the

program relied on the care-givers' understanding and co-operation. The motor developmental program was modified specially for the population of preterm born infants in Thailand, where child rearing style is quite different from that of Australia and other Western countries.

Encouragement to allow the infants to play on a mattress and instruction on carrying in ways that provided opportunities for exercise of the infant's muscles and which promoted motivation to be active appeared to be of value for this population. It was observed that most parents in this study obtained assistance in caring for their infants from grandparents. With the capacity to benefit from the experience of grandparents, it could be suggested that care-givers may not have needed further information about child rearing or exercise programs provided by physiotherapists. However, the results of this study indicated that even though the care-givers had support from older family members, the exercise program positively influenced the infants' motor development.

The significant effect of the motor developmental program has been demonstrated to be of value over and above the effects of the general consultation that the physiotherapist provided for the infants' care-givers monthly. All infants' care-givers participating in the study had the opportunity to discuss their concerns and were also offered the primary researcher's contact number that they could call at any time. This offer was made to provide general reassurance relating to issues of development apart from the developmental program. Since the results revealed greater improvement in the intervention group over the control group, the additional motor developmental program can be identified as being useful in improving motor performance in this population. In addition, general consultation seemed not to be a sufficient intervention for improving the infants' motor performance.

Conclusion

Effectiveness of the physiotherapy developmental program was examined in a cohort of Thai infants born preterm using a randomised controlled trial with the assessors blind to the group assignment. Greater improvements in motor performance of the at-risk preterm born infants who received the intervention program when compared with those with no intervention were revealed. Additionally, at four months adjusted age, the outcome for the intervention group was comparable with that for the comparative group. Thus the follow-up developmental physiotherapy program was found to be useful in promoting motor performance of Thai preterm born infants who were detected as being at risk for developmental delays during the early stage of life.

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