

# Early Physical Therapy Effects on the High-Risk Infant: A Randomized Controlled Trial

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**ABSTRACT.** A prospective, randomized, controlled trial was conducted to assess the effects of early physical therapy on infants at risk for neurologic sequelae and to evaluate the impact of such early treatment on the prevention or minimization of future handicaps. A cohort of 134 infants who had received care in two Montreal inborn neonatal intensive care units was identified prospectively. Infants were stratified according to prognosis and birth weight and were randomly assigned to either an experimental or control group. Babies assigned to the experimental group received early physical therapy, whereas those allocated to the control group received conventional follow-up care. Outcome measures were administered by independent evaluators at 12 months and included measures of neurologic status, motor and overall development, and physical growth. No statistically significant differences on any of the measured outcomes at 12 months were found between the experimental and control groups. Infants weighing less than 750 g at birth, regardless of group assignment, consistently demonstrated significant delays in their growth and development when compared with their heavier peers. The early physical therapy program investigated in this study was not efficacious in altering the pattern of motor development in those high-risk infants participating in the trial. *Pediatrics* 1986;78:216-224; *physical therapy, high-risk infant, prematurity, neuromuscular development, clinical trial.*

young children with motor handicaps secondary to CNS deficits.<sup>1,2</sup> Yet, careful investigations of the efficacy of these therapeutic approaches as they are applied to involved children are lacking.

Advocates of physical therapy argue that early referral is required to elicit optimal results. Unfortunately, affected children are often not identifiable at birth, thus making early treatment impossible. Accordingly, proponents of very early treatment are suggesting that intervention should be provided for infants who are at risk for neuromotor disorders and should be treated as soon as possible to minimize future handicaps.<sup>3</sup>

Due to inevitable methodologic problems, ethical issues, and practical constraints, the question concerning the efficacy of physical therapy in the treatment of either children at risk for or children with neuromotor delays remains unanswered. In addition, the effect of the timing of intervention, ie, early v late, remains unknown. The few studies conducted to date have produced equivocal results that may be questioned on methodologic issues such as a lack of control groups, sample size, outcome measures, and sample population.<sup>4-8</sup> The dearth of studies is understandable given the fact that physical therapy has become an accepted form of treatment for these children, making the withholding of treatment almost impossible. Similarly, the question regarding the prevention of delays by intervening early is complicated by the lack of definitive characteristics of abnormality in the newborn stage

Physical therapy has long been the treatment of choice for children suffering with neuromotor disorders such as cerebral palsy. Specific treatment approaches and handling techniques have been developed and are now being offered to infants and

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with severity.

The present randomized controlled clinical trial was conceived to overcome some of the methodologic problems that have plagued earlier investiga-

tions. The aim of this study was to assess the role of physical therapy in the treatment of infants at risk for neuromotor delays and to evaluate the impact of such early treatment on the prevention or minimization of future handicaps.

## METHODS

### Design

A cohort of 134 surviving infants who were considered to be at risk for neurologic sequelae was identified during a 24-month period (March 1, 1982, to February 28, 1984). Two at-risk groups of infants were included in the cohort: infants weighing 1,500 g or less at birth and infants, regardless of birth weight, who had experienced birth asphyxia, seizures, or CNS dysfunction with a subsequent abnormal EEG tracing during their newborn period.

All study infants received neonatal care at the inborn neonatal care unit of either the Royal Victoria or the Jewish General Hospitals. An asphyxiated infant was defined as any infant who had an Apgar score of 3 or less at one minute and required bag and mask ventilation for more than three minutes immediately after birth. Infants with overt congenital abnormalities were excluded from the study.

The cohort of 134 children does not include all of the children who met the inclusion criteria, as some parents refused to provide consent for participation in the trial. Although we failed to document either the number or characteristics of the "non-consenters", it is our impression that the two primary reasons for nonparticipation were (1) distance of program from place of residence and (2) the unwillingness of some parents to agree to the possibility of being randomly assigned to the experimental group and having to attend the program.

All infants meeting the inclusion criteria with consenting parents were assessed within 2 weeks of term by one of the two neonatologists associated with the study using the Prechtl Neurological Examination of the Full-Term Newborn Infant.<sup>9</sup> Gestational age was determined from the maternal history of her last menstrual period and confirmed by early ultrasound findings. To avoid any bias associated with prior knowledge of the infant's medical condition, the neonatologist from the first hospital assessed the neonates from the second hospital and vice versa. This examination includes a comprehensive list of age-specific items that assess the important subsystems of the nervous system. The examination also controls for the behavioral state of the infant when the items are administered.

Prechtl<sup>9</sup> has applied the optimality concept to this scale for the purpose of objective scoring. For

an item to be scored "optimal," the best possible response must be obtained. Hence, the definition of an optimal response is more narrow and more precise than the definition of normality which presumes the absence of a pathologic condition. A list

surements for 42 items on the neonatal scale.<sup>10</sup>

criterion, a point is added to the total score, which reaches a maximum of 42 if all of the items are found to be optimal.

Following the assessment, infants were classified according to the Prechtl score as either "optimal" (total score of  $\geq 32$ ) or "nonoptimal" (total score of  $< 32$ ) and also according to birth weight. Three birth weight groups were selected:  $< 750$  g, 750 to 1,500 g, and  $> 1,500$  g. Infants were then stratified according to optimality and birth weight and were randomly assigned to the experimental or control groups using a balanced system of block randomization. The randomization scheme was set up before the study began in a series of sealed envelopes. Until the consent form was signed and the Prechtl assessment completed, the group assignment was unknown.

### Treatment Procedure

Physical therapy programs were initiated at term for all infants assigned to the experimental group. These treatment programs emphasized teaching parents specific handling, positioning, and stimulation techniques based on neurodevelopmental treatment principles and patterns of movement in order that the infant experience normal positions and movements.<sup>1,2,11</sup> For the first 3 months, infants were seen weekly by the same physical therapist, who is a certified instructor in the neurodevelopmental treatment approach, for a one-hour private session. Following this 3-month period, experimental infants were seen once every 2 weeks for the next 9 months. Treatment sessions comprised three components: individualized treatment, demonstration, and parent instruction. Approximately 30 minutes of the session was used for individualized treatment of the infant by the therapist; the remaining 30 minutes was devoted to demonstration and instruction. Handling, positioning, and specific exercise routines were demonstrated, and parents were instructed to incorporate these routines into their daily activities, such as diaper changing, bathing, and feeding. Individualized written treatment programs were provided weekly to the parents in a notebook. Parents were requested to record in the notebook on a daily basis whether or not they had carried out the activities as well as any specific

problems they had encountered or pertinent developmental observations. Transportation to and from the treatment sessions was provided, as was baby-sitting for older siblings.

This treatment protocol was chosen for several reasons. Because neuromotor dysfunction is not always identifiable at birth and because asymptomatic infants may manifest pathologic conditions during the first year, we chose to evaluate the efficacy of physical therapy in preventing or minimizing handicap with all children in an at-risk sample. The specific frequency and intensity of the treatments were based on the belief that initially parents would require more input by the therapist to learn and carry out the exercise routines. Following the first 3 months of intensive treatment, parents would be able to assume a more active role in the treatment of their children and require less contact with the therapist. The neurodevelopmental treatment orientation was selected because in our opinion this approach is currently the treatment most widely advocated and used in North America for the prevention and remediation of neuromotor disorders.<sup>11</sup>

In addition to the physical therapy treatment programs, all infants assigned to either the experimental or the control group continued to attend their respective neonatal follow-up program. Individual referrals of the control children to physical therapy by the neonatologists, pediatricians, or neurologists were accepted at any time during the follow-up period. Control infants referred to physical therapy received treatment as it was offered in the local pediatric hospital.

## Measures

The infants were classified and stratified according to birth weight and their Prechtl scores prior to the randomization to make the experimental and control groups comparable. However, to ensure that the stratification/randomization process did, in fact, result in comparable groups, the following independent variables were collected and recorded for all trial infants: birth weight, gestational age, birth length, head circumference, time to regain birth weight, age at hospital discharge, discharge weight and length, length of infant's hospital stay, maternal and paternal age, Apgar scores, Prechtl score, sex, delivery, appropriate or small for gestational age, living arrangement, level of maternal and paternal education, socioeconomic status, asphyxia, seizures, hypoglycemia, and prolonged ventilation. It was judged that any of these variables might affect the performance of the infants in the trial.

To assess the impact of early physical therapy on the motor status of the developing infant, we evaluated outcomes at 12 months for all of the study children. The children's ages were corrected for prematurity by subtracting the number of weeks born prematurely from the child's chronologic age. Independent evaluators who were unaware of the group assignment of the participating infants performed the outcome evaluations.

We selected a variety of measures to assess the various aspects of development. The Wolanski Gross Motor Evaluation<sup>12</sup> is designed to evaluate motor development from 3 to 13 months of age and provides an overall score as well as a score for four motor subsections: head and trunk movements, sitting, standing, and locomotion.

The Wilson Developmental Reflex Profile<sup>13</sup> assesses the quality of primitive and postural reflexes. A chart listing the reflexes present from birth to 2 years of age indicates graphically the normal development of these reactions. The infants' responses are compared to the expected reactions, and the number of abnormal responses is calculated.

The Milani-Comparetti Motor Development Screening Test<sup>14</sup> evaluates motor development from birth to 2 years of age. Postural control and reflex reactions are evaluated, and the results obtained are compared to the age norms of the profile. The number of abnormal or deviant responses is calculated.

The Griffiths Mental Development Scale<sup>15</sup> provides mental ages and developmental quotients for five subscales, locomotor, personal-social, hearing and speech, eye-hand, and performance, as well as a general development quotient.

The Neurological Examination of the Collaborative Perinatal Project<sup>16</sup> involves a complete pediatric examination of neurologic function and developmental skills as well as the neurologist's final judgement on the overall status of the infant: normal, suspect, or abnormal.

In addition to the developmental and neuromotor assessments, physical measurements, weight, height, and head circumference, were collected.

## RESULTS

Of the 134 infants who entered the trial during the 24-month period, 19 (14%) dropped out of the study prior to the 12-month assessment. Four families moved, eight families became disinterested in the study and refused to return for assessments, two families who had given their initial consent refused to participate, one family with twins was advised by their pediatrician to discontinue, one family discontinued due to the death of the child's

**TABLE 1.** Balanced System of Block Randomization\*

Birth Wt (g) and Prechtl Neurologic Examination Classification	Experimental Group (n = 56)	Control Group (n = 59)
<750		
Optimal	1	0
>1,500		
Optimal	1	3
Nonoptimal	9	8

\* Results are numbers of infants.

mother, and two families refused treatment but returned for assessments. The results of the initial block randomization process for the remaining 115 children is shown in Table 1. The 19 infants who had dropped out were equally distributed between the experimental group (n = 10) and the control group (n = 9). Analyses were conducted to determine whether the experimental and control groups were comparable on the 25 independent variables. No significant differences were found between the two groups on any of the background variables. Summaries of these analyses are provided in Tables 2 and 3.

Analyses comparing the 19 infants who dropped out with the 115 remaining children on the 25 independent variables revealed that the infants no longer in the program were more likely to have single parents and mothers and fathers with lower levels of education than the remaining children.

Three-way analyses of variance were then performed with all of the 12-month dependent variables (weight, height, head circumference, Wilson Reflex Profile, Milani-Comparetti, Wolanski, and Griffiths scores). The three independent factors and levels associated with each factor are given in Table 4. No significant main group effect was noted for any of the dependent variables; ie, experimental children did not significantly differ from control children on any of the measured outcomes at 12 months. Neurologically optimal children differed significantly from nonoptimal children on only one outcome measure: height ( $P = .05$ ). Children who weighed <750 g at birth performed consistently more poorly at 12 months than their heavier counterparts. They were significantly lighter and smaller, had smaller head circumferences, and exhibited slower motor development and lower locomotor and personal-social developmental quotients than the other two birth weight groups. Subsequent multiple comparison analyses (Scheffé) revealed that infants weighing <750 g achieved significantly lower Wilson reflex, Milani-Comparetti and Wo-

**TABLE 2.** Comparison of Experimental and Control Groups on Independent Variables

Variable and Group	Mean	SD	T Value	P Value
Birth wt (g)				
Experimental	1,356.34	596.05	-0.01	.99
Control	29.32	3.11		
Birth length (cm)				
Experimental	38.56	4.80	-0.02	.98
Control	38.57	4.56		
Head circumference (cm)				
Experimental	27.05	3.35	0.77	.44
Control	26.58	3.19		
Time to regain birth wt (d)				
Experimental	14.43	6.42	-0.77	.44
Control	15.32	6.08		
Age at discharge (d since conception)				
Experimental	278.89	34.91	1.22	.22
Control	272.51	19.33		
Discharge wt (g)				
Experimental	2,520.36	540.49	-0.11	.92
Control	2,530.25	463.51		
Discharge length (cm)				
Experimental	46.47	3.86	1.00	.32
Control	45.79	3.41		
Length of infant's hospital stay (d)				
Experimental	69.46	42.06	0.62	.54
Control	65.31	29.30		
Maternal age				
Experimental	28.59	5.60	0.14	.89
Control	28.46	4.70		
Paternal age				
Experimental	30.73	6.09	.31	.75
Control	30.39	5.12		
Apgar score (1 min)				
Experimental	3.80	2.58	-1.74	.08
Control	4.61	2.40		
Apgar score (5 min)				
Experimental	6.54	2.04	-1.19	.24
Control	6.97	1.74		
Prechtl score				
Experimental	23.27	7.47	-0.86	.39
Control	24.36	5.97		

lanski locomotor scores, and lower locomotor and personal-social Griffiths quotients than infants weighing 750 to 1,500 g at birth. The smallest infants also differed significantly from the two larger birth weight groups on measures of height and head circumference and on Wolanski standing scores. The results of these analyses for the three main effects are grouped according to physical measurements, motor development items, and developmental quotients and are reported in Tables 5 to 7. Finally, no significant two-way or three-way interactions were noted.

**TABLE 3.** Comparison of Experimental and Control Groups on Independent Variables

Variable	Experimental Group	Control Group	$\chi^2$	P Value
Sex				
Male	24	26	.00	1.0
Female	32	33		
Pregnancy				
Single	40	45	.14	.70
Multiple	16	14		
Delivery				
Vertex	23	31	1.59	.45
Breech	3	2		
Cesarean section	30	26		
Gestational age				
Small	8	2	3.03	.08
Appropriate	48	57		
Maternal education				
Grade school	9	11	4.83	.30
High school	17	24		
Technical school	8	9		
University	21	12		
Information unavailable	1	3		
Paternal education				
Grade school	8	12	5.18	.27
High school	10	16		
Technical school	12	10		
University	24	16		
Information unavailable	2	5		
Socioeconomic status				
Professional or executive	24	18	2.94	.40
Technical or skilled labor	29	36		
Unskilled labor or unemployed	2	1		
Information unavailable	1	4		
Asphyxia				
Yes	26	20	1.39	.23
No	30	39		
Seizures (abnormal EEG finding)				
Yes	4	6	.06	.81
No	52	53		
Hypoglycemia				
Yes	4	6	.06	.81
No	52	53		
Prolonged ventilation				
Yes	16	13	.35	.55
No	40	46		

**TABLE 4.** Factors and Levels in Analyses of Variance

Factor	Levels
Group	Experimental, control
<i>Precht</i> Neurological Examination	Optimal, nonoptimal
Birth wt category	<750 g, 750-1,500 g, >1,500 g

A stepwise discriminant analysis was then per-

discriminant function had a  $\chi^2$  of 17.24 with an

perimental and control groups. Six variables (Performance Developmental Quotient, Eye-Hand Developmental Quotient, Wilson Reflex Profile, Personal-Social Developmental Quotient, Speech/Hearing Developmental Quotient, and Wolanski Sitting) were entered in the analyses. The derived

Compliance was monitored during the 12-month period for the experimental children to assess whether the treatment programs were being implemented. Compliance was subjectively rated independently by the project coordinator and the physical therapist as being excellent, moderate, or poor.

**TABLE 5.** Analyses of Variance: Physical Measurements at 12 Months

Source of Variation	Wt (g)		Height (cm)		Head Circumference (cm)	
	Mean	P Value	Mean	P Value	Mean	P Value
Group						
Experimental	9,062.7	NS	74.6	NS	45.7	NS
Control	9,171.8		74.5		46.0	
Prechtl Neurological Examination						
Optimal	9,561.5	NS	75.9	.05	46.5	NS
Nonoptimal	9,039.2		74.3		45.7	
Birth wt (g)						
<750	7,741.7	.001	70.9	.001	44.0	.007
750-1,500	9,173.7		74.8		46.0	
>1,500	9,501.8		75.1		46.0	

**TABLE 6.** Analyses of Variance: Motor Development at 12 Months

Source of Variation	Wilson Reflex Profile (No. of Abnormal Responses)		Milani-Comparetti (No. of Abnormal Responses)		Wolanski (Score)							
					Head and Trunk		Sitting		Standing		Locomotor	
	Mean	P Value	Mean	P Value	Mean	P Value	Mean	P Value	Mean	P Value	Mean	P Value
Group												
Experimental	2.39	NS	2.84	NS	45.05	NS	55.20	NS	67.32	NS	74.25	NS
Control	2.68		2.78		45.27		56.07		69.81		75.88	
Prechtl Neurological Examination												
Optimal	2.12	NS	1.76	NS	45.71	NS	58.00	NS	71.65	NS	77.29	NS
Nonoptimal	2.61		2.99		45.07		55.23		68.07		74.70	
Birth wt (g)												
<750	4.78	.03	6.33	.04	43.33	NS	54.67	NS	56.00	.01	62.33	.01
750-1,500	2.19		2.35		45.72		55.92		69.88		76.72	
>1,500	3.00		3.14		43.71		54.95		68.81		73.95	

**TABLE 7.** Analyses of Variance: Griffith Developmental Quotients at 12 Months

Source of Variation	Locomotor		Personal/Social		Speech/Hearing		Eye/Hand		Performance	
	Mean	P Value	Mean	P Value	Mean	P Value	Mean	P Value	Mean	P Value
Group										
Experimental	109.6	NS	97.5	NS	95.3	NS	98.1	NS	97.3	NS
Control	112.0		102.3		98.5		116.1		112.9	
Prechtl Neurological Examination										
Optimal	118.1	NS	104.7	NS	103.9	NS	109.5	NS	106.7	NS
Nonoptimal	109.6		99.1		95.7		106.9		105.0	
Birth wt (g)										
<750	92.8	.01	85.7	.02	82.4	NS	82.1	NS	85.8	NS
750-1,500	113.2		101.5		98.6		111.2		108.1	
>1,500	109.1		100.0		96.3		102.4		102.0	

Ratings were based on the notebook recordings and on the rater's impressions of the parents' ability and commitment to follow through on the home program. Of the 56 ratings, the two raters disagreed on only ten cases. In these ten cases, the higher compliance rating was used. Sixty-eight percent of the parents were viewed as being excellent compliers, 27% as moderate, and 5% as poor.

Clinically important differences were unlikely to have been missed. Specifically, for the Griffiths

locomotor quotient, a difference of ten points between the experimental group and the control group would have been found 80% of the time, whereas a difference of 14 points would have been found 95% of the time, ie, if a true difference of 14 points in the locomotor quotient existed between the experimental and control groups, there was only a 5% chance of failing to reject the null hypothesis of no difference.

Results from the Neurological Examination of

**TABLE 8.** Twelve-Month Neurologic Assessment

Group	Normal	Suspicious	Abnormal
Experimental	35	14	7
Control	41	15	3

by the pediatric neurologist are given in Table 8. Of the ten children with neurologic abnormalities, four were blind with generalized developmental delays, one child was blind and had a shunted hydrocephalus, one child had a shunted hydrocephalus with accompanying development delay, one child had microcephaly, one child had spastic diplegia, and two had overall developmental delays. Of the five blind children, three were in the experimental group and two were in the control group; of the two children with hydrocephalus, one was in the experimental group and one was in the control group.

Subsequent analyses were performed excluding the five blind children. No significant main effects for the two factors, group, or optimality were noted. All previous birth weight category differences other than height and weight were eliminated.

Physical therapy was not completely withheld from the entire control group of children throughout the 12-month period. Although no control child received physical or occupational therapy before 6 months of age, seven of the control children were referred for treatment during the second half of the first year. The mean age of these "treated" control children at the time of referral was 8.25 months. To analyze the effects of the "treated" control children, two additional sets of analyses were performed. First, because no control child had received treatment prior to 6 months of age and because we had uniformly collected outcome data on all of the study children at 6 months, a complete series of analyses of variance were performed with all of the 6-month dependent variables. No significant main group effect at 6 months was noted for any of the dependent variables. Second, we removed the seven "treated" control children from the control group to reanalyze the 12-month outcome data. One-way analyses were conducted with all of the 12-month dependent variables comparing the performance of the three groups of children: experimental, control, and "treated" control. Significant differences between the three groups were found on three of the dependent variables: Wolanski Standing ( $P = .03$ ), Griffiths Locomotor Developmental Quotient ( $P = .03$ ), and Griffiths Personal-Social Developmental Quotient ( $P = .003$ ). Subsequent multiple comparison analyses (Scheffé) revealed that the control children performed significantly better than the "treated" control children on all three variables.

Also, the control children achieved significantly higher Personal-Social Developmental Quotient scores than the experimental children.

## DISCUSSION

Our findings fail to provide statistical evidence

as applied in this trial either prevents neuromotor dysfunction or promotes motor development in at-risk infants. The performance at 12 months of age by the experimental group was not superior to the control group in any of the assessed areas of development. Similarly, children in the experimental group were as likely to be categorized as neurologically suspicious or abnormal at 1 year of age as control children.

Unlike earlier studies that have reported positive responses to physical therapy with specific subgroups of children,<sup>4-6</sup> we were unable to demonstrate significant interaction effects with either of the two additional factors studied, Prechtl optimality scores and birth weight. Early physical therapy as provided in this clinical trial did not have a significant impact on any specific subgroup of experimental children. In other words, we were unable to demonstrate treatment effects in selective groups of infants.

Several explanations for these findings should be considered. The referral and subsequent treatment of control children was unavoidable due to ethical considerations and may, indeed, have contaminated the results. Clearly, however, this referral pattern and subsequent treatment cannot be considered to be early treatment, because children were only referred after the manifestation of a developmental problem. Accordingly, we believe that the study design still adequately addresses the question concerning the impact of a specific type of early physical therapy. Our 6-month analyses fail to demonstrate short-term early treatment effects. Although the 12-month comparison of "treated" controls with controls is difficult to interpret due to methodologic limitations, it is clear that the overall absence of treatment effects cannot be simply explained by the performance of the "treated" control group.

More intensive intervention than that offered in this trial may be required to effect developmental advances. It may be unreasonable to expect a one-hour weekly treatment session to have measurable impact on neurologic maturation or motor development. The program included individualized treatment, but it stressed parental education and encouraged home programming. More intensive, specialized treatment by highly skilled therapists may indeed be required to prevent neuromotor dysfunction.

tion. Previous early intervention studies with culturally disadvantaged children have shown that daily intensive intervention is required to derive positive outcomes.<sup>17,18</sup> Although this may be true as well with neurologically at-risk youngsters, we believe that the model evaluated in this trial closely represents the treatment pattern most emphasized in North America today for long-term chronic disability.

The timing of the initiation of the intervention may be questioned. Although we have considered this study to have assessed early physical therapy, it is still possible to intervene earlier within an infant's life. Many proponents of early intervention recommend intervening in the neonatal intensive care unit after the infant is medically stable but prior to term or discharge.<sup>19,20</sup> We chose to standardize the timing of treatment and, thus, only began treatment at 40 weeks of conceptional age. Perhaps earlier treatment would have elicited different results.

One might question whether a larger proportion of the more seriously involved children were randomly assigned to the experimental group. This reservation is largely based on the disproportionate number of experimental children who were considered to be neurologically abnormal at 12 months. Of the seven abnormal experimental children, six of them exhibited conditions that clearly demonstrate major CNS involvement. Only two of the three abnormal control children can be considered to be severely involved. Despite the convincingly similar of the two groups as measured by the various independent variables, one might argue that the apparent disparity in the numbers of severely involved children may, in fact, have diminished any true treatment effects. Few therapists would suggest that neurodevelopmental treatment programs will resolve major brain impairments. Perhaps of more relevance are the children who are deemed to be neurologically suspicious at 1 year. These children, although not categorically involved, are at risk for minimal to moderate levels of dysfunction. It might be implied that, whereas early physical therapy may not impact on the severely involved child, it should have measurable effects on the suspect children. These 29 children were evenly distributed between the treatment and control groups. This finding, perhaps more than any other, questions the role of this form of therapy on eventual outcome of the at-risk infant.

Although the assessment of compliance in this trial may be suspect, it is difficult to suggest, on the basis of the available data, that the lack of a treatment effect is due to the absence of parental compliance. On the other hand, it may be that control

parents assumed a more "active" role in the stimulation of their infants than the experimental parents. Because control parents were aware that they were not receiving the "treatment," they may have become more active participants in their child's daily care than the experimental parents, who believed that their child was being "treated" by someone else. If we accept the critical role of the parent in infant education, this participation factor may be of vital importance.<sup>21</sup>

Finally, the positive effect of early physical therapy may only be detectable with further maturation. It is possible that only with long-term follow-up will we be able to detect either a general treatment effect or specific subgroups of children who benefit from early physical therapy. It may be that treatment minimizes the motor disability in those infants who have been or will be diagnosed as having cerebral palsy. We intend to continue to monitor the developmental progress of the children as they age to better evaluate the long-term treatment effects.

As important as the clinical trial results are, the clear findings that were associated with the birth weight factor. Regardless of group assignment, children weighing <750 g at birth consistently exhibited physical, motor, and developmental delays at 12 months of age. And, all nine children who weighed <750 g at birth were assessed as being neurologically suspicious or abnormal at 1 year. Although the final developmental outcome for these nine children is still uncertain, this subgroup of very low birth weight infants represents a unique at-risk population.

## IMPLICATIONS

The failure to demonstrate benefits for the treated group of children is disappointing for those who advocate this form of early physical therapy as a means of enhancing the motor development of high-risk infants. Although the statistical findings are difficult to discount, we do not believe that the results of this one study should be interpreted as the final answer to this important question.

Specifically, the results of this one clinical trial with a specified treatment program and a carefully defined infant population should not be generalized to other treatment programs or different pediatric populations. In addition, by the measures used, we chose to assess certain motor and developmental outcomes. This, in itself, is a major limitation of the trial because the effects of early physical therapy may be quite varied and not limited to the parameters assessed in this study. Although the value of these additional potential benefits of ther-

apy should not be inferred from the results of this investigation, further work is required to objectively assess them.

Traditionally, physical and occupational therapists have been the primary care providers in the long-term management of these children. During the years, parents have looked toward therapists for valuable support and guidance for the care of their handicapped children. Given this long-standing commitment to the management of these children, physical therapists should view these findings as a challenge to search for and develop new treatment approaches. It may well be that an earlier, more intensive, or longer intervention than that provided in this study is required to significantly impact on developmental or motor outcome. Similarly, innovative techniques using different theoretical constructs and the latest technologic advances may have to be adopted to prevent dysfunction.

Clearly, the task at hand is to continue to identify and evaluate new therapeutic approaches for infants at risk for neuromotor dysfunction. It is only through careful, scientific investigation that we will be able to identify the components of efficacious treatment programs.

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