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THE EFFECTS OF PHYSICAL THERAPY ON CEREBRAL PALSY

A Controlled Trial in Infants with Spastic Diplegia

FREDERICK B. PALMER, M.D., BRUCE K. SHAPIRO, M.D., RENEE C. WACHTEL, M.D., MARILEE C. ALLEN, M.D., JANET E. HILLER, PH.D., SUSAN E. HARRYMAN, M.S., R.P.T., BARBARA S. MOSHER, M.S.W., CURTIS L. MEINERT, PH.D., AND ARNOLD J. CAPUTE, M.D., M.P.H.

Abstract Legislatively mandated programs for early intervention on behalf of handicapped infants often stipulate the inclusion of physical therapy as a major component of treatment for cerebral palsy. To evaluate the effects of physical therapy, we randomly assigned 48 infants (12 to 19 months of age) with mild to severe spastic diplegia to receive either 12 months of physical therapy (Group A) or 6 months of physical therapy preceded by 6 months of infant stimulation (Group B). The infant-stimulation program included motor, sensory, language, and cognitive activities of increasing complexity. Masked outcome assessment was performed after both 6 and 12 months of therapy to evaluate motor quotient, motor ability, and mental quotient.

After six months, the infants in Group A had a lower mean motor quotient than those in Group B (49.1 vs. 58.1, $P = 0.02$) and were less likely to walk (12 vs. 35 percent, $P = 0.07$). These differences persisted after 12 months of therapy (47.9 vs. 63.3, $P<0.01$, and 36 vs. 73 percent, $P = 0.01$, respectively). We noted no significant differences between the groups in the incidence of contractures or the need for bracing or orthopedic surgery. Group A also had a lower mean mental quotient than Group B after six months of therapy (65.6 vs. 75.5, $P = 0.05$).

The routine use of physical therapy in infants with spastic diplegia offered no short-term advantage over infant stimulation. Because of the limited scope of the trial, our conclusions favoring infant stimulation are preliminary. The results suggest that further study of the effects of both physical therapy and infant stimulation is indicated. (N Engl J Med 1988; 318:803-8.)

CEREBRAL palsy, a chronic neurologic condition due to nonprogressive brain injury, insult, or defect, results in abnormal motor development in children. Physical therapy is the most common intervention in cerebral palsy and is usually a component of mandated programs[1,2]; its purpose is to improve motor development and prevent musculoskeletal complications.

From the Clinical Research Unit of the Kennedy Institute for Handicapped Children, the Department of Pediatrics of the Johns Hopkins University School of Medicine, and the Department of Epidemiology of the Johns Hopkins University School of Hygiene and Public Health, Baltimore. Address reprint requests to Dr. Palmer at the Kennedy Institute for Handicapped Children, 707 N. Broadway, Baltimore, MD 21205.

Supported by a grant (17028) from the National Institute of Neurologic Disease, Communicative Disorders, and Stroke.

Despite periodic calls for scientific scrutiny of the effect of physical therapy in cerebral palsy,[3-8] only a few clinical trials have been undertaken to determine whether the goals of therapy are met.[9,10] It has been difficult to interpret such trials because of small, heterogeneous samples, substantial attrition among subjects, and nonrandom assignment of treatment.[11,12] Wright and Nicholson[9] found no consistent benefit of physical therapy. In a study of infants receiving physical therapy, Scherzer et al.[10] noted improvements in broadly defined motor and social skills and in the parents' ability to address the children's daily needs, but could not separate the influences of age, therapy, and cognitive level. In two recent controlled studies,[13,14] investigators evaluated the effects of physical therapy administered during the first year of life to infants deemed at risk for neurologic sequelae, and found the therapy to have no advantages.

Neurodevelopmental therapy is the most common type of physical therapy used in the United States[15] for the treatment of children with cerebral palsy. Our clinical trial evaluated the effects of neurodevelopmental therapy (applied by a physical therapist certified in that treatment) as compared with those of a similarly intense program of infant stimulation in infants with spastic diplegia, a form of cerebral palsy with prominent lower-extremity impairment but only mild upper-extremity involvement. Spastic diplegia was chosen for study because it is a prevalent type of cerebral palsy that can be diagnosed in infancy and is usually not associated with upper-extremity impairment or pharyngeal motor handicap, which are customarily treated with other interventions. This paper summarizes the motor and cognitive outcomes of the trial.

Methods

Population

Infants between 12 and 19 months of age with spastic diplegia, referred to the Kennedy Institute for Handicapped Children, were selected for enrollment after evaluation by a developmental pediatrician, psychologist, physical therapist, infant-stimulation therapist, and social worker. The inclusion and exclusion criteria (Table 1) defined a homogeneous group of infants with mild to severe spastic diplegia according to both neurologic and functional measures; the minimal level of postural stability, righting ability, and equilibrium required for participation in the planned physical therapy program; and an absence of potentially confounding variables, such as severe mental retardation. Of 90 infants evaluated for enrollment, 52 met the enrollment criteria. Forty-eight were enrolled after the informed consent of the parents was obtained according to procedures approved by the institutional review boards of the participating institutions. Initially, we had projected that a sample of at least 100 infants was necessary for a full evaluation of treatment differences across the entire range of outcomes. Despite aggressive efforts, however, enrollment was less than had been expected. This was attributed to the narrowly defined enrollment criteria essential to the study design. Therefore, the conclusions we report are preliminary.

Table 1. Enrollment Criteria.

Diagnosis: spastic diplegia of prenatal or perinatal onset
Age: 12–19 months
Neurologic measures
Lower-extremity hyperreflexia, hypertonus, and pathologic reflexes
Absence of sustained upper-extremity grasp reflex
Absence of moderate motor asymmetry or involuntary movements
Functional measures
Ability to roll over in at least one direction
Inability to come to a sitting position independently, cruise, or walk
Voluntary upper-extremity grasp and transfer
Potentially confounding variables
Absence of disorders posing a risk of degeneration (e.g., hydrocephalus)
No use of tone-altering drugs
Absence of contractures or hip subluxation or dislocation
Absence of severe pharyngeal impairment
No previous physical therapy or orthopedic surgery
No hearing or visual impairment that would interfere with therapy
Mental quotient of 40 or higher
Parents judged to be compliant
Measures of postural maturity
Effective righting of head
In prone position: effective head, trunk, and arm countermovements and facilitated pelvic countermovements; ability to shift weight with forearm support
In supported sitting position: effective anterior, and facilitated lateral, protective extension of the arm

Treatment Assignment

The selected infants were randomly assigned to receive either 12 months of neurodevelopmental therapy (Group A) or 6 months of neurodevelopmental therapy preceded by 6 months of stimulation (Group B). An untreated control group was not studied. To minimize the potentially confounding effects of mental retardation, randomization was stratified on the Bayley Scales of Infant Development[16] Mental Developmental Index, with separate schedules for infants scoring 70 or higher and those scoring lower than 70. At the time of enrollment there were no significant intergroup differences in chronologic or gestational age, sex, socioeconomic status,[17] family characteristics (Table 2), motor and mental levels (Table 3), or neurologic-examination results.

One infant in Group B dropped out of the study after the six-month evaluation. All the other infants completed the study. Both groups had over 90 percent compliance in attending the treatment visits. No infants received other therapies.

Description of Treatment

Physical therapy, defined before any of the infants were enrolled, was designed to improve the infants' expression of the postural responses of righting and equilibrium — abilities necessary for the continued development of gross motor skills (milestones).[18-21] The infant-stimulation treatment included *Learningames*,[22] a program that consists of 100 explicitly defined and illustrated cognitive, sensory, language, and motor activities of increasing developmental complexity appropriate for children from birth to three years of age. For example, fine motor activities include completing puzzles, using crayons, and performing form-matching and block-building tasks; word games are used to encourage linguistic development and social interaction. The motor activities do not focus on aspects of the abilities to right oneself and maintain equilibrium.

The treatment protocols for both physical therapy and infant stimulation were designed to provide identical amounts of outpatient contact with professionals and implementation at home. Individual therapy sessions were held at the Kennedy Institute every two weeks for one hour. The same physical therapist and child-development specialist gave all treatments for the duration of the study. Parents were trained in the daily administration of the home portion of the program, which was structured around checklists and specific behavioral objectives. Parental compliance was monitored at each treatment visit and through home visits by a supervising therapist. Treatment goals and therapeutic procedures were always reviewed with parents at the biweekly sessions. Progression in either program was determined according to the achievement of specific behavioral or motor objectives.

Infants receiving physical therapy, if not yet able to move independently from a prone to a sitting position, were enrolled in therapy that took place five days per week when they met objective criteria for stability in sitting and the ability to shift their weight in the sitting and prone positions. This therapy was provided until the infants could come to a sitting position independently. Only four infants received daily therapy — three in Group A and one (during the second six months) in Group B. None of the four required more than 20 days of therapy. The other infants were able to bring themselves to a sitting position at the time the aforementioned criteria were met and therefore did not receive daily therapy.

Outcome Measurement

After both 6 and 12 months of treatment, outcome was measured by examiners masked to group assignments and the interim results of this study. Outcome measures were the motor and mental quotient determined with use of the Bayley Scales, the observed attain-

Table 2. Description of Treatment Groups.*

Characteristic	Group A (N = 25)	Group B (N = 23)
Age at time of randomization (mo)	15.0	15.5
Gestational age (wk)	33.0	33.5
Percent <38 wk	72	70
Maternal age (yr)	28.1	26.8
Paternal age (yr)	30.8	28.2
Maternal socioeconomic status	4.0	4.2
Birth order	1.7	1.8
No. of persons in household	4.0	4.1
Sex (M/F)	20/5	16/7

*All values are means except those for sex and for the percentage with a gestational age less than 38 weeks.

ment of operationally defined motor-skill milestones, parental reports of an infant's age at the attainment of such milestones, neurologic examination, contractures and recommendations for bracing or surgery, and the social-development quotient determined with use of the Vineland Social Maturity Scale.[23] After 12 months of treatment, three infants were performing at levels that exceeded the cognitive range of the Bayley Scales and were assessed with use of the Stanford–Binet Intelligence Scale.[24]

The neurologic examination was performed by a developmental pediatrician according to a standard protocol. The pediatrician assessed muscle tone and examined each infant for the presence of characteristic clasp-knife spasticity, deep-tendon reflexes, and pathologic reflexes. For statistical comparisons between the groups, clinically quantified neurologic signs were assigned numerical scores; composite or summed scores were derived.

Statistical Analysis

Statistical analysis was performed with use of chi-square, Fisher's exact, Mann–Whitney, and t-tests adjusted for any base-line differences. The log-rank test[25,26] was used to analyze time-related differences in the achievement of milestones as reported by parents. Stepwise multiple regression techniques were used to examine the effects of treatment and potentially confounding variables on both motor and cognitive outcomes.

Results

Comparison of the groups after six months of treatment was intended to identify differences attributable to the effects of either physical therapy or infant stimulation. Comparison of the groups after 12 months of treatment was intended to identify differences attributable to physical therapy started earlier and thus of longer duration (Group A) or physical therapy started later and thus of shorter duration (Group B). Since each group received physical therapy during the second 6 months, differences between the groups after 12 months of treatment may be attributed partly to differences in treatment during the first 6 months.

Comparisons after Six Months of Treatment

The motor quotient showed no advantage for the infants in Group A, who received physical therapy only; instead, the data favored the infants in Group B, who received infant stimulation (motor quotient, 49.1 vs. 58.1; P = 0.02) (Table 3). This difference was due to a 3.8-point decline in the score for Group A and a 5.1-point increase in that for Group B over the six months of treatment. Data on observed motor skills also reflected no advantage for Group A; a higher percentage of infants in Group B attained most of the motor milestones. The greatest difference was in

Table 3. Motor and Cognitive Data on Both Groups.

Variable	Enrollment		6-Month Outcome			12-Month Outcome		
	Group A (N = 25)	Group B (N = 23)	Group A (N = 25)	Group B (N = 23)	P Value	Group A (N = 25)	Group B (N = 22)	P Value
Mean developmental quotients (SD)*								
Bayley motor quotient	53.0 (8.5)	53.0 (9.4)	49.1 (11.6)	58.1 (19.0)		47.9 (18.9)	63.3 (22.0)	
Change from enrollment			−3.8	+5.1	0.02	−5.0	+9.6	<0.01
95 percent CI†			−16.2 to −1.7			−24.2 to −5.1		
Bayley mental quotient	62.0 (15.6)	66.1 (18.3)	65.6 (16.3)	75.5 (14.9)		67.0 (18.4)	75.3 (15.3)	
Change from enrollment			+3.6	+9.4	0.05	+5.0	+9.0	0.30
95 percent CI†			−11.5 to −0.1			−11.9 to 3.8		
Vineland social quotient	60.9 (15.4)	65.2 (17.1)	67.8 (19.0)	72.5 (18.2)		67.5 (23.2)	76.6 (18.3)	
Change from enrollment			+6.9	+7.3	0.94	+6.6	+10.2	0.54
95 percent CI†			−10.6 to 9.9			−15.2 to 8.1		
Motor skill — % attaining‡								
Roll from supine to prone position	83	87	100	95	0.29	100	100	1.00
Sit tripod	70	78	92	96	0.58	100	100	1.00
Sit alone	61	65	83	91	0.41	92	91	0.89
Creep in prone position	56	56	96	96	1.00	100	95	0.28
Crawl on hands and knees	9	9	56	65	0.55	88	77	0.33
Come to sitting position	0	0	54	61	0.64	80	86	0.56
Pull to standing position	17	4	62	78	0.24	92	86	0.53
Cruise	9	9	58	74	0.26	84	86	0.82
Walk with one hand held	0	0	33	48	0.31	52	77	0.07
Walk independently	0	0	12	35	0.07	36	73	0.01
Walk backward	0	0	4	4	0.97	20	45	0.06

*Ratio of motor, mental, or social age to chronological age. Significance of mean differences from enrollment determined by t-test. Differences in 12-month outcomes calculated on the basis of N = 22 for Group B. This and the effects of rounding account for the apparent discrepancies between the quotients and the calculated changes from enrollment.

†95 percent confidence interval (CI) of the mean difference between treatment groups in change measured from enrollment. Intervals including 0.0 indicate no significant difference between groups. Data on certain skills were unavailable for a maximum of two subjects from Group A at enrollment and the six-month evaluation; data were unavailable for rolling from a supine to a prone position for one subject from Group B at the six-month evaluation.

‡Percentage of children attaining skill in each group. Significance was determined with use of Fisher's exact test or the chi-square test.

walking 10 steps independently (35 vs. 12 percent, P = 0.07). No intergroup differences were noted in the neurologic examination.

Cognitive outcome on the mental quotient also favored Group B (75.5 vs. 65.6 for Group A, P = 0.05). In regard to social development, no difference was noted between the two groups after six months of treatment.

Comparisons after 12 Months of Treatment

Differences in motor quotient continued to favor Group B (63.3 vs. 47.9 for Group A, P<0.01) (Table 3). These differences were due to a further decline in the scores for Group A and a further increase in those for Group B. The largest group difference in the observed attainment of a motor milestone was in walking independently; again, the data favored Group B (73 vs. 36 percent, P = 0.01). A trend favoring Group B was noted for the ability to walk with one hand held and to walk backward. As judged by parents' reports, the majority of the infants in both groups achieved the more fundamental skills, such as creeping or sitting alone, within one to four months of randomization. The reported achievement of the more advanced skills, however, paralleled the data on the observed attainment of milestones. Log-rank analysis revealed that infants in Group B were consistently earlier in walking with one hand held (P<0.01), walking alone (P = 0.01), and walking backward (P = 0.07). These differences were apparent within six months of randomization.

The scores for lower-extremity deep-tendon and pathologic reflexes were higher for Group A (P = 0.05 and 0.01, respectively, by the Mann–Whitney test). In addition, trends showed more lower-extremity spastic hypertonus in Group A (P = 0.08). No differences were noted between the groups in the number of infants requiring bracing for progressive joint limitation (10 in Group A, 6 in Group B) or surgery (0 in Group A, 2 in Group B). No appreciable intergroup differences in cognitive or social skills were noted after 12 months of treatment.

Stepwise multiple regression techniques were used to examine the effects of treatment and other variables on motor and mental outcomes both 6 and 12 months after randomization (Table 4). Variables were selected for entry into the regressions after the exploration of univariate data, nonstepwise multiple regressions, and the clinical importance of various factors. The factors included in the final reduced models were the treatment group, age at randomization, gestational age, and mental and motor quotients at base line. Interaction terms were examined but did not contribute and were excluded from the final model. After both 6 and 12 months, the most important determinant of the motor quotient was the motor quotient at the time of enrollment (P<0.0001). A smaller treatment-group effect was also seen after six months (P = 0.02) and 12 months (P<0.01). The beta values for the treatment-group factor indicated that when compared with infants in Group A after adjustment for other variables in the model, infants in Group B had increases in motor quotients averaging 8.93 and 14.19 points at 6 and 12 months, respectively. In a separate regression analysis of 12-month motor outcome on 6-month motor and mental quotients, only the motor quotient at the 6-month evaluation contributed; no effect of the treatment group was seen.

Regression analyses for mental quotients revealed a similar pattern, although the difference favoring Group B, apparent at the 6-month evaluation (beta, 6.92; P<0.01), was not seen at the 12-month evaluation. Gestational age made a significant contribution throughout. The negative signs before the beta values for this variable indicate that infants of higher gestational ages had poorer mental outcomes.

Discussion

The goals of any motor therapy in cerebral palsy include the improvement of motor development and the prevention of complications. The routine use of such therapy in a population with cerebral palsy can be advocated if success can be demonstrated in meeting one of these goals, or in improving nonmotor development, without concurrent deleterious side effects.

In our study, the evaluation of outcomes after six

Table 4. Variables Contributing Significantly to 6-Month and 12-Month Motor and Mental Quotients in Stepwise Multiple Regression Equations.*

Variables	Beta	P Value
Motor quotient		
Enrollment variables contributing to 6-month motor quotient (42% variance explained)		
Motor quotient at enrollment	1.06	<0.0001
Treatment group	8.93	0.02
Enrollment variables contributing to 12-month motor quotient (50% variance explained)		
Motor quotient at enrollment	1.53	<0.0001
Treatment group	14.19	<0.01
6-Month variable contributing to 12-month motor quotient (57% variance explained)		
Motor quotient at 6-month evaluation	1.01	<0.0001
Mental quotient		
Enrollment variables contributing to 6-month mental quotient (76% variance explained)		
Mental quotient at enrollment	0.83	<0.0001
Treatment group	6.92	<0.01
Gestational age	−0.85	<0.01
Enrollment variables contributing to 12-month mental quotient (62% variance explained)		
Mental quotient at enrollment	0.83	<0.0001
Gestational age	−1.34	<0.001
6-Month variables contributing to 12-month mental quotient (77% variance explained)		
Mental quotient at 6-month evaluation	0.92	<0.0001
Gestational age	−0.52	0.05

*The beta value for the treatment-group variable is the average increase in the outcome variable for subjects in Group B as compared with those in Group A after adjustment for other independent variables in the model. The beta values for the other variables represent the average change in the outcome (mental or motor quotient) per unit of increase in that independent variable.

months of treatment demonstrated no motor, cognitive, or social advantage for infants receiving physical therapy. The trends that we noted favored infant stimulation. Evaluation after 12 months of treatment did not support the tenet that physical therapy started earlier is more effective in the treatment of cerebral palsy.[27] The motor outcome of the group receiving 12 months of physical therapy (A) was no better than that of the group receiving 6 months of physical therapy after 6 months of infant stimulation (B). In fact, the motor differences after 12 months favored Group B. Time-dependent analysis of historical data from parents corroborated the masked evaluations of motor outcome.

The motor data favoring infant stimulation were unexpected. After adjustment for any base-line motor, cognitive, and demographic differences, the effect of the treatment group on motor outcome persisted. This effect represented a relative advantage of infant stimulation over physical therapy. Further studies should include a control group receiving no treatment, so that it will be possible to determine the degree to which either intervention provides any advantage or disadvantage over no treatment.

Beneficial effects of infant stimulation have been suggested previously, but usually when stimulation was applied with other interventions in socioeconomically disadvantaged, not physically handicapped, infants.[28] The positive effects of infant stimulation in this trial may be due to better or broader understanding by the parents of the infants' development and capacities, which may have improved their ability to cope and interact with their infants.[29,30] Infant stimulation may also enhance the infant's motivation to explore his or her environment and thereby have a positive influence on motor development.

Alternatively, physical therapy structures motor experiences so as to produce more normal patterns of movement, and it may thereby delay the infant's attainment of motor skills. If so, the short-term differences in milestone attainment observed in this trial would not be expected to persist. In addition, quantitative measures based on motor skills alone may not reflect qualitative differences in movement patterns. To be meaningful, however, any qualitative differences would have to produce long-term benefits that outweighed the observed short-term results favoring Group B.

More frequent contact between therapist and patient may be necessary to make physical therapy more beneficial to infants with cerebral palsy. If so, costly changes in program emphasis may be necessary.

The minor differences between groups observed on neuromotor examination after 12 months of treatment may be of concern when viewed with the other motor data favoring Group B. They may indicate subtle deleterious effects of sustained physical therapy on lower-extremity spasticity. Alternatively, they may reflect neurologic differences between the groups that were not apparent at the time of enrollment but were manifested clinically only 12 months later because of the infants' neurologic maturation.[31] Patterns of the evolution of signs are not evaluated when enrollment criteria are assessed at a single point.

The magnitude of the cognitive difference favoring Group B after 6 months did not persist until the 12-month evaluation. This may indicate that infant stimulation has a true benefit that diminishes when stimulation is withdrawn. Alternatively, because of possible similarities between the Bayley cognitive items and any infant-stimulation program, these differences may reflect a practice effect that had diminished by the 12-month evaluation.

The power to detect a difference between treatments across the broad range of motor outcomes was limited by the sample size. However, considerable differences between groups in motor quotient and walking ability after 12 months and consistent trends favoring Group B in regard to other motor variables made an undetected benefit of physical therapy unlikely.

In conclusion, this clinical trial offers no support for the idea that neurodevelopmental physical therapy, as applied in this study, is a preferred intervention in infants with mild to severe spastic diplegia. The lack of differences in outcome between groups favoring physical therapy was not due to identifiable differences between the treatment groups at enrollment, differences in the intensity of treatment or in compliance, or unmasked measurement of outcome. Although it is possible that there are longer-term benefits of physical therapy or benefits in domains not reported in this study, the goal of improved motor development was not achieved in infants receiving physical therapy as compared with infants receiving infant stimulation. Furthermore, physical therapy applied earlier offered no advantage over physical therapy applied six months later. Because of the small size of the sample, the apparent benefit of infant stimulation should be interpreted cautiously. Indeed, the regression analyses showed that motor and mental abilities at the time of enrollment were the most powerful determinants of motor or mental outcome, strongly outweighing any effect of treatment. Nevertheless, the findings underscore a fundamental issue in developmental pediatrics and public policy affecting developmentally disabled children: the immediate and long-term effectiveness of traditional interventions must be examined critically. Alternative, less costly therapies may improve outcomes. The mechanisms of action, timing, sequence, and duration of interventions and the use of multiple interventions should be explored systematically in multicenter clinical trials with well-defined cohorts of adequate size.

We are indebted to Diane R. Nemett, M.S., R.P.T., and Georgette Evler, B.A., for administering the therapies; to Barbara Andreasson, M.S., and Susan Tonascia, Sc.D., for assistance in preparing the study protocol; to Stacey Bilker, M.P.H., for computer analysis; to Pasquale J. Accardo, M.D., for vital assistance in study design; to Vernon T. Tolo, M.D., and Charles E. Silberstein, M.D., for orthopedic care; and to Hugo W. Moser, M.D., for advice and support.

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