A comparison of intensive neurodevelopmental therapy plus casting and a regular occupational therapy program for children with cerebral palsy

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The purpose of this research was to evaluate the combined effect of intensive neurodevelopmental therapy (NDT) and casting in improving hand function, quality of upper-extremity movement and range of motion in children aged between 18 months and 4 years with cerebral palsy (CP). A randomized crossover design was used to evaluate the difference between intensive NDT plus casting and a less intensive regular occupational therapy (OT) program. Blinded assessments of hand function, quality of upper-extremity movement, and parents' perception of hand-function performance were carried out at baseline, 4 months (end of first intervention period), 6 months (after a 2-month 'washout' period), and 10 months (end of second intervention period). Analysis of the outcomes revealed no significant differences in hand function, quality of upper-extremity movement, or parents' perception of hand-function performance between the two treatment groups – intensive NDT plus casting or regular OT programs. There does not appear to be any beneficial effect of an increased amount of therapy for the children in this study.

Children with cerebral palsy (CP) typically receive ongoing physical and occupational therapy (OT) to facilitate motor development and to enhance independence in movement, self-care, play and leisure. The most common current therapy approach is based on neurodevelopmental therapy (NDT) (Harris 1990, Bly 1991, VanSant 1991, DeGangi and Royeen 1994). In this approach, intervention focuses on improving motor-based activities by changing the child's underlying impairments in motor control through the inhibition and integration of primitive postural patterns and the facilitation of more normal quality of movement (Bly 1991).

Clinical evaluation studies have raised questions about the efficacy of NDT. Eight group-comparison studies of neurodevelopmental, physical, and occupational therapy for children with CP have been conducted over the past 20 years. In these studies, this approach has been compared with no therapy (Wright and Nicholson 1973), functional therapy (Carlsen 1975, Scherzer et al. 1976, Sommerfeld et al. 1981), infant stimulation (Palmer et al. 1988), Vojta therapy (D'Avignon 1981) and differing intensities of therapy (Law et al. 1991a, Mayo 1991). The results of these trials are mixed, with three demonstrating no difference (Wright and Nicholson 1973, Sommerfeld et al. 1981, Law et al. 1991a), three supporting NDT (Carlsen 1975, Scherzer et al. 1976, Mayo 1991), and two supporting alternative interventions (D'Avignon 1981, Palmer et al. 1988). Randomized clinical trials have not supported the efficacy of this approach in reducing disability and handicap (Piper 1990).

Inhibitive casting, in which a cast is applied to maintain a specific joint in a functional position, is used for children with CP to decrease the effects of increased tone and increase functional movement. Casting in combination with NDT has recently been shown to increase range of motion and upper-extremity movement quality (Law et al. 1991a). Reid and Sochaniwskyj (1992) also studied the effects of a hand-positioning device on upper-extremity control, muscle activity, and visual–motor performance in 10 children with CP. Each child was tested with the splint on and the splint off. There were no statistically significant differences found in upper-extremity movement control, muscular activity, or on visual–motor performance between the splinted and non-splinted condition. The authors did comment, however, that it was their impression that some children with mild to moderate upper-extremity hypertonicity or fluctuating tone showed improvement in the quality of motor performance as measured by increased speed and accuracy on pencil–paper tasks.

The efficacy of the most beneficial frequency or intensity of direct therapy is unclear, with conflicting evidence. Based on her detailed analysis of the intervention literature, Piper (1990) concludes – albeit from limited evidence (Carlsen 1975, Scherzer et al. 1976) – that therapy 'must be offered a minimum of two times per week'. Bower and McLellan (1992), in a small before–after study, also seemed to demonstrate the short-term benefit of bursts of 'intensive' treatment on the acquisition of motor skills, and many of these skills regressed when the intensity of therapy decreased. On the other hand, evidence from a clinical trial (Law et al. 1991a) found no demonstrable effect of twice-weekly compared with once-weekly NDT-based therapy in children aged between 18 months and 8 years. The results of the study by Law et al. (1991a) did indicate the possibility that intensive NDT was more effective than weekly NDT for a cohort of children under 4 years of age.

The purpose of the present study was to evaluate the combined effect of intensive NDT and casting in improving hand function, quality of upper-extremity movement and range of motion in children, aged between 18 months and 4 years, who have CP. The primary research question in this study was: what are the effects of intensive NDT and upper-extremity inhibitive casting compared with a less intensive regular OT program on hand function, quality of upper-extremity movement and parents' perception of hand-function activities in young children with spastic CP?

Method

SUBJECTS

Participants for the study were selected from children attending therapy at eight children's rehabilitation centers in Ontario, Canada. All children in the study were between 18 months and 4.0 years of age. They were diagnosed with CP with limb involvement of diplegia (with upper-extremity involvement), hemiplegia, or quadriplegia. Upper-extremity involvement for all children ranged from moderate to severe, with the wrist in a flexed posture. Children were not able to isolate hand function from wrist function and thumb-in-palm deformities were often present. All children experienced difficulties in manual dexterity, coordination, isolated finger movement, and in-hand manipulation activities.

Children were excluded if they demonstrated a skin sensitivity to casting materials; had a fixed permanent contracture at the wrist; had recent or planned upper-extremity surgery; used antispasticity medications; or had a cognitive impairment severe enough to preclude improvement in hand function. The last criterion was assessed using the therapist's judgment. More formal methods of assessment were not suitable because of cost and lack of reliability and validity of available tests for young children with disabilities.

In total, 52 children met the inclusion criteria and their parents consented to their participation. Two children were not available for all assessments: one because the parents decided to drop out of the study and another because they moved out of the country. Thus, 50 children completed the study.

STUDY DESIGN

A randomized crossover design with a 'washout' period was used to evaluate the differences between intensive NDT and casting versus regular OT. The primary reason for using a crossover design was to enable children to receive both interventions under study, and thus make the study more acceptable to parents who were concerned about their children receiving the best available intervention. The crossover design is an efficient method of comparing therapies because a smaller sample size is usually required (Fleiss 1986). It allows each child to act as his/her own control; this leads to an increase in precision in the estimated treatment effect for response variables where there is a strong component of variation due to individual subjects (Brown 1980). Data from a trial previously conducted (Law et al. 1991a) confirmed that there was a great deal of variation between subjects.

Children entered into the study were randomly assigned to one intervention for 4 months, followed by a 2-month washout period, and then 4 months on the other intervention. Two measurements for each period were made to allow for estimation of the carry-over effect, which could be constant or differential over the two measurements for the second intervention period.

INTERVENTION

Stratified randomization was used to improve baseline equivalency of groups with respect to age and severity of hand-function impairment. Each child was stratified by age (young, 18 to 33 months; and old, 33 to 48 months) and hand-function severity as measured using the Peabody Fine Motor Scales (Folio et al. 1983) (mild, less than 6 months below chronological age; severe, 6 months or more below chronological age). The randomization was not stratified by center since a previous study showed no important center effects (Law et al. 1991a). Randomization to treatment sequence groups was completed immediately after baseline assessment and stratification. Children were assigned initially to intensive NDT and casting or regular OT using a blocked randomization design with blocks of four. All outcomes were measured by trained evaluators who were blind to the random assignment of the child. After the first 4-month intervention period, children had a 2-month therapy 'holiday' as a washout period, followed by the alternative intervention for 4 months.

The major differences between intensive therapy plus casting and regular OT were the focus during therapy, quantity of therapy, and the application of a cast. In the intensive therapy plus casting intervention, therapists used facilitation and handling, using the principles of NDT, to focus on changing impairments and improving upper-extremity quality of movement. The regular OT program focused on task analysis and facilitating changes in functional skills such as skills in self-care, feeding, and play. Children in the intensive treatment group received twice-weekly therapy for 45 minutes, plus a 30-minute daily home program. In addition, they received a bivalved upper-extremity cast which covered the wrist and was intended to be worn for a minimum of 4 hours daily, on at least two separate occasions. The casts were fibreglass and extended from below the elbow to the palm of the hand. The wrist was held in a position of neutral to 10° extension and the thumb and fingers were free so that their movement was not affected. Children receiving regular OT received therapy a maximum of once weekly for 45 minutes or a minimum of once monthly, keeping their previous therapy schedule.

All occupational therapists involved in the study attended a training workshop on the development of guidelines for therapy and the methods to apply and use inhibitive casting. Detailed guidelines were developed to define acceptable treatment practices for each phase of the study. A complete record of therapy goals and attendances for each child was kept. Home programs were given for the casting period only and consisted of NDT therapy activities to be carried out at home. Parents kept records of home program completion and amount of cast wear. Records were also kept of other treatments received in OT or elsewhere during the study period, so that cointervention could be evaluated.

MEASUREMENT OF OUTCOME

The primary outcome of this study was hand function as measured by the Peabody Fine Motor Scales. Secondary outcomes were a measure of quality of upper-extremity movement and a measure of parents' perception of their child's ability in hand-function activities. Range of motion at the wrist was to have been included as an outcome but was discontinued because of the difficulty in getting accurate measures from young children. Assessments were performed at baseline, 4 months, 6 months, and 10 months. Independent evaluators who were trained in the use of the measures and who were unaware of treatment allocation administered all outcome measures.

The Peabody Fine Motor Scale is a standardized measure of fine motor function in children from birth to 7 years (Folio et al. 1983). Test–retest and interrater reliability and validity of the Peabody Fine Motor Scales have been well-established (Folio et al. 1983, Russell et al. 1994). Quality of upper-extremity movement was measured using the Quality of Upper Extremity Skills Test (QUEST) (DeMatteo et al. 1993). Interrater and test–retest reliability as well as criterion validity of the QUEST with other measures of hand function have been shown to be excellent (DeMatteo et al. 1993).

The Canadian Occupational Performance Measure (COPM) (Law et al. 1991b), was added as a secondary measure; it is a measure of parents' perception of their child's performance and satisfaction with performance in specific, individualized activities. Through an interview, the parents identified specific activities involving hand function with which they felt their child was having difficulty. Parents then rated their child's performance and satisfaction with performance on a 1 to 10 scale. These data enable us to measure the parents' perception of children's change in areas of hand function identified as important to them during each study treatment period.

Adherence to therapy was assessed using a standardized assessment which asked parents about their understanding, ability to carry out, and skill in carrying out a home program. This assessment had been previously validated and the reliability found to be 0.7 using weighted κ statistics (Cadman et al. 1986).

ANALYSIS

The crossover design was selected for this study because it presents the opportunity for all participants to experience both therapies, which was a desirable objective in this context. Despite these advantages, there were certain difficulties which arose in the analysis of the crossover design for this study because of the nature of the outcome variables. In traditional uses of the crossover design, it is assumed that the outcome experiences a relatively short-term effect following the initiation of treatment, and that it returns approximately to baseline level when the effect of therapy or intervention wears off after a suitable washout period has elapsed. Typical examples of this include those where drugs are administered to induce physiological or symptomatic response.

If the washout period is not sufficiently long to allow the effect of the intervention to have worn off, the possibility of differential carry-over effects exists. In this circumstance, some of the responses observed in the second period of the crossover design may be partly due to residual effects of the treatments administered in the first period. If these residual effects are unequally distributed between study groups, the subsequent estimate of the difference in effectiveness of treatments becomes biased.

Conventional analyses of crossover designs are able to examine the possibility of carry-over bias before the evaluation of treatment effects. If it is determined that carry-over effects have been unimportant, then fully efficient estimates of the treatment effect can be derived using data from both treatment periods, and exploiting the within-subject control feature of the design.

In the context of this study, the implementation of the crossover design was not achievable in the standard way, because many of the outcome variables were not expected to revert to baseline following cessation of the interventions. Indeed, the objective of the therapy in this study was to achieve long-lasting benefit. Examples of outcome variables with this pattern include measures of motor skills or activities of daily living. Here, we expected that the effect of treatment would, ideally, carry over well beyond its immediate period of administration. The objective was to achieve a therapeutic effect that would be cumulative, building on improvements in earlier time periods.

The use of outcome variables that were expected to show a cumulative response required the development of special techniques for data analysis. Accordingly, special analysis of variance (ANOVA) techniques were derived with the objective of obtaining unbiased and efficient estimates of the treatment effect, while also allowing for carry-over effects. In this study, there were baseline measurements prior to each of the two interventions (at 0 months and 6 months after enrolment into the study) and postintervention measurements (at 4 months and 10 months). Under this design, it was assumed that carry-over could be characterized into first- and second-order components. The first-order component was assumed to be the residual effect of the first treatment, being felt at 6 months and subsequently for a given subject. The second-order component was assumed to be an additional residual effect, but which was felt only at the 10-month observation. It was assumed that first-order carry-over was inherently more likely to occur than second-order carry-over.

An estimator of the treatment effect was developed which used the observations at 0, 4, 6, and 10 months. This estimator is biased only if the second-order carry-over effect is non-zero. Thus, even if first-order carry-over exists, an unbiased estimator of the treatment effect can be obtained, under the relatively weak assumption that the second-order carry-over effect is zero. Additionally, estimators were obtained for the first- and second-order effects. Standard errors of all of the estimators were obtained analytically. The results of the entire analysis can be summarized as an ANOVA table, with appropriate tests of statistical significance.

The first effect that is to be examined is the second-order carry-over effect because of the bias that it may introduce. Next, one can evaluate the effect of first-order carry-over, although, as mentioned above, this effect does not bias the estimate of the treatment effect. The demonstration of significant first-order carry-over would suggest that the 2-month washout period had not been sufficient to allow all of the benefits of the first treatment to accrue before the posttreatment measurement had been made.

The final effect to be examined is that of the treatment, which is the variable of primary interest. Statistical significance in this effect indicates a relatively superior effect of one treatment compared with the other; this estimate and test is achieved by examining within-subject changes, and allowing for all other relevant effects. In particular, the treatment is assessed after taking account of between-subject variation, the effects of possibly differential responses in the first and second time period, and overall differences between the randomized study groups.

In the ANOVA, between-subject variation is known to be an effect usually of large magnitude, so it is not required to test it for statistical significance. This is because the treatment effect is examined on a within-subject basis. The effect of time in the ANOVA indicates whether responses of all subjects might have been systematically different at the various observation points (0, 4, 6, and 10 months after randomization). Such an effect might occur, for instance, if there had been improvement in all participants over the course of the study. Another possible reason for a time effect is because the subjects have aged, and may have changed their abilities as a group, on average, irrespective of differential effects of therapy. An example of a variable subject to this kind of phenomenon would be the Peabody scores prior to adjustment for age. Even the age-adjusted Peabody scores might be subject to a time effect, if the adjustment for age were imperfect, in the sense that all such effects had not been accounted for.

Data from each outcome measure were collected and summarized for each treatment group. Descriptive statistics were calculated for all demographic variables. The cumulative response model in the crossover design was used for the Peabody and QUEST outcome measures, which were expected to show a cumulative response pattern. The third outcome, the COPM score, measures the parents' perception of the child's performance and satisfaction with performance in particular activities. It is likely to reflect satisfaction in the parents with relatively recent achievement, and is not necessarily expected to show a cumulative response. Accordingly, for the COPM outcome, standard crossover analyses were carried out, assuming the transient response, rather than the cumulative response model.

Results

Demographic information about the study sample is summarized in Table I. Fifty children completed the study and were assessed at all four assessment times. The intervention groups were equivalent in sex, previous frequency of therapy, CP distribution, use of lower-extremity orthoses, maternal education, and age.

Data from the parent and therapist log books were extracted by a trained occupational therapist. Analysis of the therapy log books indicated that therapists were successful in differentiating NDT treatment from regular OT. Goals for therapy using NDT were based on changing impairments and improving quality of movement. The most prevalent goals included achievement of dissociated movements, improvement of head control, decreased retraction of shoulders, promotion of active grasp, resisted movements, promotion of equilibrium responses, improvements in bringing hands to midline, trunk elongation, improvements in shoulder control, weight shifting, weight bearing, and decreased associated reactions. For regular OT, the goals were fewer, more global and functionally

Table I: Description of study sample N=50

	Treatment order				*Total*	
	Intensive NDT/ casting first (%)		*Regular OT first (%)*			
Sex						
Female	15	(30)	13	(26)	28	(56)
Male	11	(22)	11	(22)	22	(44)
Frequency of therapy before beginning of study						
2 times/wk	5	(12)	1	(2)	6	(14)
1 time/wk	12	(29)	9	(21)	21	(50)
2 times/mo	5	(12)	7	(17)	12	(29)
Monthly	0		3	(7)	3	(6)
Missing data	4	(8)	4	(8)	–	
Cerebral palsy distribution						
Quadriplegia	11	(22)	11	(22)	22	(44)
Hemiplegia	9	(18)	10	(20)	19	(38)
Diplegic (with upper-extremity involvement)	6	(12)	3	(6)	9	(18)
Wears lower-extremity orthoses						
Yes	11	(26)	11	(26)	22	(52)
No	10	(22)	11	(26)	21	(48)
Missing data	4	(8)	3	(6)	7	(17)
Mother's education level						
High school	17	(37)	13	(28)	30	(65)
Training program	1	(2)	0		1	(2)
College or university	7	(15)	8	(18)	15	(33)
Missing data	1	(2)	3	(6)	–	
Chronological age at baseline (mo)	Mean 33.38	SD (9.94)	Mean 32.42)	SD (12.26)	Mean 32.92	SD (11.01)

Table II: Therapy attendances and adherence to home programs N=50

	Treatment order				*Total*	
	Intensive NDT/ casting first		*Regular OT first*		*Mean*	*(SD)*
	Mean	*(SD)*	*Mean*	*(SD)*		
Total parent adherence score (max=20)	15.38	(3.55)	16.16	(2.59)	15.72	(3.15)
Total therapist adherence score (max=20)	15.58	(3.22)	16.20	(2.89)	15.86	(3.05)
Attendance for regular OT	8.38	(3.33)	9.48	(3.03)	8.91	(3.20)
Attendance for intensive NDT/casting	24.42	(3.34)	23.05	(6.04)	23.81	(4.73)
Parent report: average time in cast (h)	275.27	(132.52)	323.73	(160.83)	297.19	(146.20)
Parent: home program						
All completed (d)	48.00	(35.54)	46.05	(31.50)	47.10	(33.33)
Some completed (d)	22.71	(18.39)	26.00	(25.25)	24.23	(21.59)
None completed (d)	11.00	(13.08)	9.82	(9.63)	10.43	(11.38)

based. The most prevalent goals for regular OT included improvement in self-care skills, improvement in oral–motor and feeding skills, improvement in play skills, and provision of adaptive equipment.

Information about adherence to the treatment schedule and home program is presented in Table II. The average number of therapy attendances was 24 for the intensive NDT intervention (out of a potential 32) and 9 for the regular therapy intervention. Scores for adherence during the intensive therapy period as reported by parents and therapists were very similar to each other and across therapy order (means of 15 to 16 out of a possible score of 20). When children were in the intensive therapy plus casting group, parents were asked to complete a daily home program (maximum 120 days). Information extracted from the parent log books revealed that the logs were kept for an average of 82 days (range 0 to 118 days). Mean cast wear was 297 hours (range 13.45 hours in total to 704.45 hours in total). Parents indicated that they were able to complete all of the prescribed home program in an average of 47 days and some of the home program in an average of 24 days.

Analysis of the results for hand function measured using the Peabody Fine Motor Scales revealed no statistically significant or clinically important differences between children receiving intensive NDT plus casting or regular OT (Table III). Since the pattern for the total raw scores for the Peabody Scales was the same as age-equivalent change, the scores are reported as changes in age-equivalent months as these scores are easier to interpret clinically. Power calculations completed after the study indicated that based on N=50, the power to find a 2.6 month clinically important difference on the Peabody scales was 81%.

There were no statistically significant or clinically important differences as measured by the QUEST between children receiving intensive therapy plus casting versus children receiving regular OT. As well, there were no statistically significant or clinically important differences between treatment groups on parents' perception of hand function activities as measured using the COPM.

There were statistically significant and clinically meaningful differences over time for children in each treatment group on the Peabody scale (P=0.0001), the QUEST (P=0.007). Performance (P=0.0001) and Satisfaction scores (P=0.0001)

Table III: Outcomes by treatment group

	Mean (SD)							
	Baseline		*4 months*		*6 months*		*10 months*	
Peabody Fine Motor Scales (N=50)								
Intensive NDT/casting first	20.4	(9.0)	21.8	(8.5)	23.4	(10.4)	24.9	(12.3)
Regular OT first	19.2	(8.6)	20.9	(9.0)	21.9	(10.9)	24.7	(13.4)
QUEST (N=50)								
Intensive NDT/casting first	51.3	(22.3)	53.3	(22.9)	53.8	(24.6)	53.3	(25.1)
Regular OT first	41.5	(25.3)	47.3	(27.7)	48.2	(28.0)	49.0	(24.4)
COPM (N=35)								
Performance score								
Intensive NDT/casting first	3.2	(1.5)	6.5	(1.6)	3.2	(1.1)	6.1	(1.6)
Regular OT first	3.4	(1.0)	5.7	(1.4)	3.2	(1.2)	5.5	(1.7)
Satisfaction score								
Intensive NDT/casting first	3.6	(1.9	7.1	(1.9)	3.8	(1.8)	6.7	(1.8)
Regular OT first	3.6	(1.4)	5.8	(1.8)	3.5	(1.6)	5.8	(1.7)

Table IV: Estimated treatment and primary carry-over effects and confidence intervals for study outcomes

	Estimate of treatment effect	*Standard error*	*95% CI*	
Peabody Fine Motor Scales				
Treatment	−0.50	0.92	−2.30	1.29
Primary carry-over	0.17	0.92	−1.62	1.97
Quality of upper-extremity skills test				
Treatment	1.21	2.17	−3.05	5.46
Primary carry-over	2.98	2.17	−1.27	7.24
Canadian occupational performance measure (using standard crossover analysis)				
Performance score: treatment	−0.05	0.10	−0.24	0.14
Satisfaction score: treatment	−0.11	0.13	−0.36	0.14

Note: all treatment and primary carry-over values were not statistically significant.
CI = confidence intervals.

on the COPM, measured from baseline to 4 months and 6–10 months, also showed statistically significant and clinically meaningful differences over these time periods.

The ANOVA table for study outcomes, including estimated treatment and primary carry-over effects and confidence intervals for all outcomes are listed in Table IV. There were no significant second-order carry-over effects. As well, first-order carry-over effects did not achieve statistical significance.

To determine if there was an effect of the length of time a cast was worn each week, the sample was divided into two groups, those below and above the median cast-wear time (19.6 hours per week). Results for each group were compared using an analysis of variance procedure. Those children who wore the cast for a number of hours greater than the median demonstrated significantly more changes on the Peabody age equivalent scores and COPM Performance and Satisfaction scores.

Discussion

The results of this study indicate that, in this young population, there were no differences in hand function, quality of upper-extremity movement, or parents' perception of the child's hand-function activities when children are receiving intensive NDT plus casting or regular OT. There did not appear to be any beneficial effect of increasing the amount of therapy for the children in this study. Children when receiving regular OT focused on functional activities achieved very similar outcomes compared with those same children receiving more intensive therapy based on NDT principles and primarily focused on changing quality of movement.

During the more intensive treatment period, children attended therapy 24 times during 16 weeks (an average of 1.5 times weekly). There were a variety of reasons for absences, and no specific pattern appeared. The ratio of attendances between the intensive and regular treatment times was 3:1, indicating that children who received three times as much therapy did not make more gains during the study period. While it is possible that an even greater intensity would have led to differential improvements, the practicality of such a level of service delivery is doubtful, both because of difficulties for parents to attend therapy and because of required therapy resources.

The results of this study are different from a previous study (Law et al. 1991a) which found that casting in the presence of at least regular amounts of NDT significantly improved quality of upper-extremity movement. One explanation for these differences could be the ages of the children in each study. In the Law et al. (1991a) study, children ranged in age from 18 months to 8 years of age, compared with 18 months to 4 years in the current study. It may be that changes in quality of movement due to therapy occur more often in children who are older. Recent research using the Gross Motor Performance Measure, a measure of quality of movement for gross motor skills, has found that quality of movement does improve more in children who are over 4 years of age (Boyce et al. 1995).

If casting is used, those children who wore the cast over a threshold of hours of casting (19.6 hours per week) demonstrated improved hand function and perceived improvements in performance on selected hand-function goals. These results can only be applied to the type of cast used in this study – a bivalved, fibreglass cast. Splints, which do not provide the same degree of positional control as casts, may not be effective in changing function (Reid and Sochaniwskyj 1992).

It is important to examine the statistical power of this study so that the possibility of a type II error can be ruled out. A type II error occurs when a clinically important difference between treatment groups exists but the sample size is too small to detect it. The sample size for this trial was calculated based on a predetermined value of a clinically important change in 2.6 months on the Peabody Fine Motor Scales. Although we did not achieve the calculated sample size of 62 children, post hoc power analyses using variability estimates from this study revealed that the study had a power level of 81% to find a difference of 2.6 months on the Peabody scales. Therefore, we can conclude that a type II error is a relatively unlikely occurrence in this trial.

The outcomes of two different therapy regimens were compared in this study. Since both groups received some therapy, no conclusions can be made about the effect of no therapy. It is interesting to note that, on average, scores on all outcome measures in both treatment groups changed significantly over time. Whether these effects are due to developmental progress or are influenced by therapy cannot be determined within this study design.

What are the clinical implications of the results of this study? There appears to be no immediate benefit from more intensive therapy based on neurodevelopmental principles in improving hand function, upper-extremity quality of movement, or parent-identified goals in young children with CP. This finding should alleviate some of the anxiety which parents, therapists and other clinicians have about not having as much therapy as they believe is needed. Casting to improve upper-extremity quality of movement appears to be more effective in children who are older than this group. If casting is undertaken, our results indicate that improvements are associated with hours of casting over the median of 19.5 hours per week. The largest improvements in this study occurred in the scores for the COPM, a measure based on changes in parent-identified functional goals. Parents perceived that their children improved significantly when therapy was directed at goals important to them, irrespective of the type or amount of therapy that was delivered. This suggests that therapy should be more focused, concentrating on the functional goals that parents believe are important for their child within the environment that they live. Further research to determine the effectiveness of such a therapeutic approach is warranted.

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References

Bly L. (1991) A historical and current view of the basis of NDT. *Pediatric Physical Therapy* **3:** 131–5.

Bower E, McLellan DL. (1992) Effect of increased exposure to physiotherapy on skill acquisition of children with cerebral palsy. *Developmental Medicine and Child Neurology* **34:** 25–39.

Boyce W, Gowland C, Rosenbaum P, Lane M, Plews N, Goldsmith C, Russell D, Wright V, Zdrobov S, Harding D. (1995) The gross motor performance measure: validity and responsiveness of a measure of quality of movement. *Physical Therapy* **75:** 603–13.

Brown BW. (1980) The crossover experiment for clinical trials. *Biometrics* **36:** 69–79.

Cadman D, Rosenbaum P, Walter S, McNamee J. (1986) Community professionals compliance with consultants' recommendations for developmentally disabled children. *Developmental and Behavioural Pediatrics* **7:** 21–6.

Carlsen PN. (1975) Comparison of two occupational therapy approaches for treating the young cerebral-palsied child. *American Journal of Occupational Therapy* **29:** 267–72.

D'Avignon M. (1981) Early physiotherapy and modum Vojta or Bobath in infants with suspected neuromotor disturbance. *Neuropediatrics* **12:** 232–41.

DeGangi GA, Royeen CB. (1994) Current practice among neurodevelopmental treatment association members. *American Journal of Occupational Therapy* **48:** 803–9.

DeMatteo, Law M, Russell D, Pollock N, Rosenbaum P, Walter S. (1993) The reliability and validity of the quality of upper extremity skills test. *Physical and Occupational Therapy in Pediatrics* **13:** 1–18.

Fleiss JL. (1986) *The Design and Analysis of Clinical Experiments.* New York: J. Wiley & Sons.

Folio R, Fewell R, DuBose RF. (1983) *Peabody Developmental Motor Scales.* Toronto: Teaching Resources.

Law M, Cadman D, Rosenbaum P, Walter S, Russell D, DeMatteo C. (1991a) Neurodevelopmental therapy and upper-extremity inhibitive casting for children with cerebral palsy. *Developmental Medicine and Child Neurology* **33:** 379–87.

— Baptiste S, Carswell-Opzoomer A, McColl M, Polatajko H, Pollock N. (1991b) *Canadian Occupational Performance Measure Manual.* Toronto: CAOT Publications.

Mayo NE. (1991) The effect of physical therapy for children with motor delay and cerebral palsy. *American Journal of Physical Medicine and Rehabilitation* **70:** 258–67.

Palmer FB, Shapiro BK, Wachtel RC, Allen MC, Hiller JE, Harryman SE, Mosher BS, Meinert CL, Capute AJ. (1988) The effects of physical therapy on cerebral palsy: A controlled trial in infants with spastic diplegia. *New England Journal of Medicine* **318:** 803–8.

Piper MC. (1990) Efficacy of physical therapy: rate of motor development in children with cerebral palsy. *Pediatric Physical Therapy* **2:** 126–30.

Reid DT, Sochaniwskyj A. (1992) Influences of a hand positioning device on upper-extremity control of children with cerebral palsy. *International Journal of Rehabilitation Research* **15:** 15–29.

Scherzer AL, Mike V, Ilson J. (1976) Physical therapy as a determinant of change in the cerebral-palsied infant. *Pediatrics* **58:** 47–52.

Sommerfeld D, Fraser BA, Hensinger RN, Beresford CV. (1981) Evaluation of physical therapy service for severely mentally impaired students with cerebral palsy. *Physical Therapy* **61:** 338–44.

van Sant AF. (1991) Neurodevelopmental treatment and pediatric physical therapy: a commentary. *Pediatric Physical Therapy* **3:** 137–41.

Wright T, Nicholson J. (1973) Physiotherapy for the spastic child: an evaluation. *Developmental Medicine and Child Neurology* **15:** 146–63.