Effect of intensive neurodevelopmental treatment in gross motor function of children with cerebral palsy

Nikos Tsorlakis* MSc PT, Physical Educator, Hellenic Society for Care and Rehabilitation of Children with Disabilities, Thessaloniki;
Christina Evaggelinou PhD, Assistant Professor;
George Grouios PhD, Associate Professor;
Charalambos Tsorbatzoudis PhD, Associate Professor, Department of Physical Education and Sport Science, Thessaloniki-Serres, Aristotle University of Thessaloniki, Greece.

**Correspondence to first author at* 73 Dimokratias Street, Pefka, GR 57010, Greece.
E-mail: lemamou@in.gr

This study examined the effect of neurodevelopmental treatment (NDT) and differences in its intensity on gross motor function of children with cerebral palsy (CP). Participants were 34 children (12 females, 22 males; mean age 7y 3mo [SD 3y 6mo], age range 3 to 14y) with mild to moderate spasticity and hemiplegia (n=10), diplegia (n=12), and tetraplegia (n=12). Gross Motor Function Classification System levels were: I (n=10), II (n=10), and III (n=14). The paired sample, which was obtained by ratio stratification and matching by sex, age, and distribution of impairment from a total of 114 children with CP, was assigned randomly to two groups: group A underwent NDT twice a week and group B five times a week for 16 weeks. The outcome measure used was the Gross Motor Function Measure, which assessed the performance of the children before and after intervention. The paired-sample t-test revealed that gross motor function of children from both groups improved significantly after intervention (p<0.05). Children in group B performed better and showed significantly greater improvement than those in group A (p<0.05). Results support the effectiveness of NDT and underline the need for intensive application of the treatment.

Cerebral palsy (CP) is a common, non-progressive, but not necessarily unchanging, neurological disorder of childhood. The primary problem in CP is gross motor dysfunction (Scherzer and Tscharnuter 1982). An important treatment approach for children with CP is neurodevelopmental treatment (NDT), a neurophysiological approach that aims at maximizing the child's potential to improve motor competence and to prevent musculoskeletal complications (Ottenbacher et al. 1986, Mayston 1992, Barry 1996). NDT is based on a conceptual model devised by the Bobaths in 1940 (Bobath 1980; Bobath and Bobath 1972, 1984) and has achieved popular acceptance through its empirical appropriateness.

Studies of the effectiveness of NDT have reported conflicting or inconsistent findings and have not resulted in any empirical consensus (Ottenbacher et al. 1986, Royeen and DeGangi 1992, Butler and Darrah 2001). The influence of physical therapy is not easy to evaluate because there are many inherent difficulties. Researchers also face inevitable methodological problems and practical constraints, such as small and heterogeneous samples, non-random assignment into groups, lack of a control non-treatment group, and inappropriate outcome measures (Simeonsson et al. 1982, Bower and McLellan 1994b, Hur 1995, Butler and Darrah 2001).

Some of the studies have shown that the NDT approach is effective in improving measures of motor performance in children with CP, especially in gross motor ability, postural control, and stability (Carlsen 1975, Campbell 1990, Barry 1996, Ketelaar et al. 2001). In contrast, other investigators have found little or no difference in motor function (Herndon et al. 1987, Butler and Darrah 2001). Other studies examined the effect of NDT in CP in interaction with variables such as age, type and severity of CP, intellectual level, parental participation, goal setting, child's co-operation, and intensity of therapy (Law et al. 1991, 1997; Bower and McLellan 1992, 1994a; Bower et al. 1996).

Other investigators tried to document the influence of the intensity and duration of intervention because proponents of NDT claim that children who receive intensive therapy achieve greater independence. Bower and McLellan (1992) and Bower et al. (1996) demonstrated that programmes providing a higher intensity of therapy (a mixture of different types of therapy) yielded better results. Conversely, Law et al. (1991, 1997) and Herndon et al. (1987) did not support these findings. Further, Bower et al. (2001) found that more intensive daily treatment produced only a limited and temporary improvement. Intensive therapy for a long period seemed to be very demanding and was considered tiring and stressful by the children, who showed low compliance. Recently, Trahan and Malouin (2002) demonstrated that an intermittent intensive NDT programme was less tiring and led to improvements in motor function.

The purpose of the present study was to evaluate the effectiveness of NDT on gross motor function of children with CP, and particularly to investigate the effect of intensive NDT intervention. The hypothesis was that the children in the intensive therapy group would improve more over time than the children in the reference non-intensive therapy group.

Method

PARTICIPANTS

Thirty-eight children participated (14 females, 24 males; age range 3 to 14y; mean age 7y 3mo,SD 3y 6mo), with an

established diagnosis of CP which had been confirmed by a consultant developmental paediatrician and a neurologist. Participants were recruited from a total of 114 children from the Hellenic Society for Care and Rehabilitation of Children with Disabilities, Thessaloniki, Greece. Inclusion criteria were: (1) mild to moderate spastic hemiplegia, diplegia, or quadriplegia; (2) Gross Motor Function Classification System (GMFCS; Palisano et al. 1997) levels I to III; (3) age 3 to 14 years; (4) no other severe abnormalities, such as seizures, learning disability*, or sensory deficits; (5) no orthopaedic remedial surgery, nor medication to reduce spasticity for the previous 6 months; and (6) no participation in other therapeutic programmes except for physical therapy. It is understood that before this study all the children had been having normal weekly NDT therapy according to their level of severity. Only 34 children (12 females, 22 males) completed the study as four children dropped out: one male because of absence, another due to orthopaedic surgery, and two females because they started medication. Data for these four children were not included in the data analysis.

Ethical approval was granted for the study and an informed consent statement was signed by all the parents.

RESEARCH DESIGN

Sample size was calculated at 26 participants per group – 52 in total – with an alpha level of 0.05 and a power of 80%, with two-tailed tests of significance. However, it was only possible to recruit 38 participants, and finally 34 after four dropped out.

Before randomization, from the total of 114 children, 38 were selected through proportional stratification on the basis of age, sex, and distribution of motor impairment (i.e. hemiplegia, diplegia, and quadriplegia). After stratification, the selected sample was matched for age, sex, and distribution of impairment and then randomly assigned into two equal treatment groups ($n = 19$; 12 males, seven females), depending on the intensity of the NDT intervention (Tables I, II and III; these tables show only the 34 children who finally completed the study). A person not otherwise involved in the trial undertook the assigning to groups. Group A (mean age 7y 1mo SD 3y 6mo) was designed to receive NDT treatment for 16 weeks, twice weekly, for 50 minutes each session. Group B (mean age 7y 5mo, SD 3y 7mo) was the intensive group and followed the NDT programme for 16 weeks, five times weekly, for 50 minutes each session.

Throughout the trial, NDT intervention for both groups was based on the fundamental and current principles of the approach, as it has evolved more recently (Bobath and Bobath 1984; Bly 1991; Mayston 2001a, 2001b). In Greece there might be some slight differences of interpretation of NDT, because it has evolved independently in different countries. However, the concept remains the same and the cited treatment is what is usually encompassed by the Bobath approach.

Therapy was individualized for each child's condition and was dictated by the child's unique clinical needs. Differences in therapy were influenced by variations in the children's severity level and not by differences in therapists' techniques. Each child had a therapist (instead of one therapist for all children) who administered the therapy and set the intervention goals, in accordance with the principles of NDT, thereby minimizing the danger of personal bias. This was preferred for reasons of internal validity, because the children would be unfamiliar with their therapist, which could affect their cooperation and performance. All the therapists had been NDT-certified for at least 5 years, with clinical experience for more than 10 years. A prerequisite for the completion of the trial was that each child should complete at least 90% of the programmed NDT sessions. Absences for any reason resulted in exclusion from the study. Parents had the responsibility for, and a justifiable interest in, ensuring their children complied with the programme. The difference (two or five sessions) in intensity of the therapy between the two groups was, therefore, maintained over the whole study.

The lack of a true – in its narrow sense – non-treatment control group was a limiting factor of this study. This was inevitable for ethical reasons (Simeonsson et al. 1982, Bower and McLellan 1994b, Barry 1996), and because parents refused to break

*US usage: mental retardation.

Table I: Matched pairs for age, sex, and distribution of impairment

Matched pairs	*Sex*	*GMFCS level*	*Distribution of impairment*	*Age (y)*	
				Group A	*Group B*
1	Males	I	Hemiplegia	6	7
2		II	Hemiplegia	7	8
3		II	Diplegia	4	3
4		I	Diplegia	6	7
5		III	Diplegia	3	4
6		I	Diplegia	9	9
7		II	Diplegia	3	3
8		III	Quadriplegia	5	6
9		III	Quadriplegia	14	13
10		III	Quadriplegia	11	11
11		III	Quadriplegia	5	4
12	Females	II	Hemiplegia	5	3
13		I	Hemiplegia	6	8
14		I	Hemiplegia	10	12
15		II	Diplegia	5	4
16		III	Quadriplegia	9	10
17		III	Quadriplegia	14	14

Group A, non-intensive treatment; Group B, intensive treatment.

Table II: Participants' characteristics

Group	*n*	*Males*	*Females*	*Hemiplegia*		*Diplegia*		*Tetraplegia*	
				Males	*Females*	*Males*	*Females*	*Males*	*Females*
A	17	11	6	2	3	5	1	4	2
B	17	11	6	2	3	5	1	4	2
Total	34	22	12	4	6	10	2	8	4

Group A, non-intensive treatment; Group B, intensive treatment.

up their children's therapy. Similar studies faced the same problems (Carlsen 1975, Hur 1995, Fetters and Kluzik 1996). In the present study the reference non-intensive treatment group played the role of the control group for the intensive treatment group.

INSTRUMENTATION

Acquisition of motor function over the 16-week period was assessed with the Gross Motor Function Measure (GMFM). The GMFM is an evaluative, standardized, criterion-referenced observational instrument that was developed to measure change in gross motor function over time in children with cerebral palsy. This measure has been studied for its reliability (intrarater, test–retest, and interrater) and validity (Russell et al. 1989, 1993).

Table III: Participants' distributions by age and sex

Age	*Group A*		*Group B*	
(years)	*Males*	*Females*	*Males*	*Females*
3	2	–	2	1
4	1	–	2	1
5	2	2	–	–
6	2	1	1	–
7	1	–	2	–
8	–	–	1	1
9	1	1	1	–
10	–	1	–	1
11	1	–	1	–
12	–	–	–	1
13	–	–	1	–
14	1	1	–	1
Total	11	6	11	6

Group A, non-intensive; Group B, intensive.

Table IV: Characteristics of 5-children sample for reliability study

No.	*Sex*	*Age (y)*	*Distribution of impairment*	*GMFCS level*
1	Male	10	Diplegia	II
2	Male	7	Hemiplegia	II
3	Female	6	Quadriplegia	III
4	Female	14	Quadriplegia	III
5	Female	8	Hemiplegia	I

GMFCS, Gross Motor Function Classification System (Palisano et al. 1997).

MEASUREMENT

Assessments for all children were made in accordance with the GMFM guideline manual (Russell et al. 1993). Assessments before and after treatment were undertaken by an independent assessor blind to the group assignment and to the amount of therapy being given. The assessor was an experienced NDT-certified physical therapist who had practised administering and scoring the GMFM before the start of the trial. The assessor achieved a high level of intrarater reliability, with an intraclass correlation coefficient of 0.997 ($p<0.001$), by using a camera in a small study with five children with CP, who were not included in the main sample, randomly selected from the total of 114 children (Table IV). Furthermore, an interrater reliability study on the use of the GMFM between the assessor and the researcher (first author) was undertaken with the same five children before the main study. This study showed a significant intraclass correlation coefficient of 0.994 ($p<0.001$). In the end, for the reliability of the outcome measure (test–retest reliability) one more assessment, within 3 or 4 days of the first one, was administered by the assessor to the five children, before the main study. Intraclass correlation coefficient was 0.996 ($p<0.001$).

STATISTICAL ANALYSIS

It was necessary to transform the raw scores (ordinal scaling) of GMFM-88 into interval scaling scores in order to use parametric statistics and for better scoring and interpretation of data (Russell et al. 2000). The transformation was achieved through Rasch analysis, via a software program, the Gross Motor Ability Estimator (*CanChild* Center for Child Disability Research, Ontario, Canada) and was used for the development of GMFM-66 to improve interpretability and clinical usefulness (Russell et al. 2000, Avery et al. 2003, personal communication L Avery 2000). The new GMFM-66 scores were used for the statistical analysis.

Pretreatment differences in gross motor function between the two matched pair groups were analyzed with a paired-sample *t*-test, to find out whether the groups were equivalent. Differences in the ages of the children assigned to the two groups were also analyzed with a paired-sample *t*-test, to establish whether the groups were matched for age.

The pre-NDT and post-NDT intervention mean scores for each of the two groups were analyzed with a paired-sample *t*-test, to determine whether any significant differences existed. Finally, a paired-sample *t*-test was used to determine the possible significant differences between the two groups' mean change scores before and after treatment. This was performed to find out whether the mean change between pretreatment and posttreatment assessment for group B was

Table V: Descriptive statistics

Group	*Assessment*	*GMFM-88*				*GMFM-66*			
		Mean	*SD*	*Min.*	*Max.*	*Mean*	*SD*	*Min.*	*Max.*
A	Before treatment	80.31	15.15	52.46	98.65	65.85	14.47	45.91	87.99
	After treatment	82.00	14.54	53.68	98.93	67.04	14.24	46.91	89.70
B	Before treatment	77.36	15.89	44.43	97.07	62.17	12.24	44.03	84.05
	After treatment	79.99	15.80	46.93	97.58	64.54	12.86	45.32	85.23

GMFM, Gross Motor Function Measure (Russell 2002). Min, minimum; Max, maximum. Group A, non-intensive; Group B, intensive.

significantly greater than the mean change for group A.

The alpha level was 0.05 for all statistical tests (two-tailed). Statistical analysis was performed with SPSS (version 10.0).

Results

The NDT sessions were completed in more than 90% of the programmed sessions for both groups. Mean treatment each week was 32.8 therapies for group A and 80.1 therapies for group B.

Mean, standard deviation (SD), minimum and maximum scores for the GMFM-88 and GMFM-66 pretreatment and post-treatment measures for both groups are given in Table V. The change between the two measurements for both groups is shown in Figure 1.

The paired *t*-test between the initial measurements in the two groups revealed no significant difference ($t=1.648$, $df=16$, $p=0.119$, 95% confidence interval [CI] –1.05 to 8.41). The mean difference was 3.67 (SD 9.2). Consequently, before the intervention the two groups were equivalent in gross motor function. Similarly, the paired *t*-test for the age equivalence of the two groups showed no significant difference ($t=0.719$, $df=16$, $p=0.483$, 95% CI –1.16 to 0.57); mean age difference was 0.29 (SD 1.69).

The paired *t*-test between the initial and final measurements for group A revealed significant differences in GMFM-66 scores ($t=4.449$, $df=16$, $p<0.001$, 95% CI –1.75 to –0.62). Mean change score was 1.18 (SD 1.09; Fig. 1). The paired *t*-test between the initial and final assessments for group B revealed significant differences in GMFM-66 scores ($t=5.433$, $df=16$, $p<0.001$, 95% CI –3.29 to –1.44); mean change score was 2.36 (SD 1.79; Fig. 1). Therefore, as initially hypothesized, NDT intervention had a significantly positive effect on gross motor function in the children of both groups.

Analysis with the paired *t*-test revealed that the improvement in gross motor function for the children of group B was significantly greater than that for those in group A ($t=2.644$, $df=16$, $p=0.018$, 95% CI –2.13 to –0.23). This result confirmed the hypothesis that intensive versus non-intensive NDT treatment would cause greater progress in children's gross motor function. The mean difference between change scores, before and after treatment, for the two groups was 1.18 (SD 1.84). Figure 2 shows a comparison of the mean change in GMFM-66 scores for both groups, before and after the treatment programme.

For a better interpretation of the difference in GMFM-66 scores between the two groups, an effect size (Cohen's *d*) was calculated (Cohen 1988). The effect size was found to be 0.794. Following Cohen's guidelines, this should be interpreted as almost large (close to 0.8). This effect size was in accord with the statistically significant results and supported a high level of statistical power. It also showed that intensive provision of NDT was effective.

Because the age range of the children was large, it was decided to examine the effect of age on the progress made by the children in both groups. The age range was divided into three subgroups: 3 to 5 years ($n=13$), 6 to 9 years ($n=12$), and 10 to 14 years ($n=9$). The one-way analysis of variance revealed a significant difference ($F_{[2,31]}=3.443$, $p=0.045$). Through further post-hoc analysis with a Scheffe test a significant difference was found between the first (3 to 5 years) and third (10 to 14 years) age groups ($p=0.046$, 95% CI 0.024 to 3.322). Younger children improved more than older ones (mean difference score on GMFM-66 was 1.67; Fig. 3). This finding was in accordance with earlier evidence (Russell et al. 1989, 2000; Ketelaar et al. 2001; Knox and Evans 2002).

Discussion

NDT intervention, which was administered for 16 weeks in

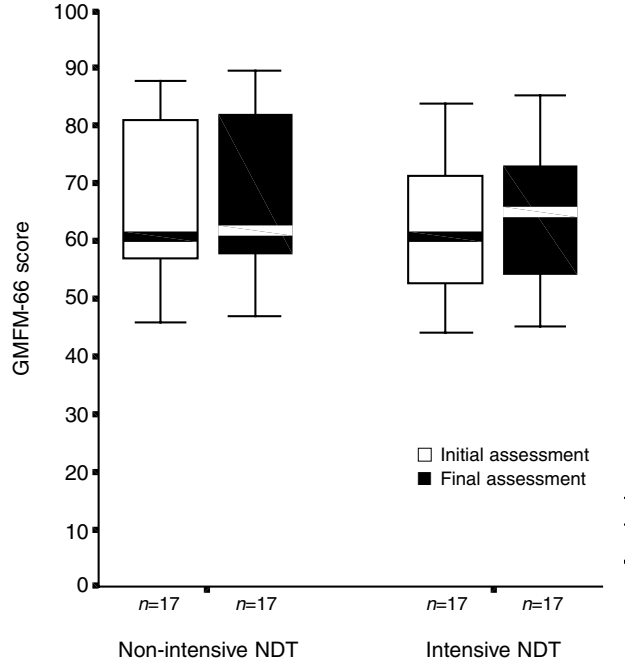

Figure 1: *Mean change in GMFM-66 scores for both groups between initial and final assessments.*

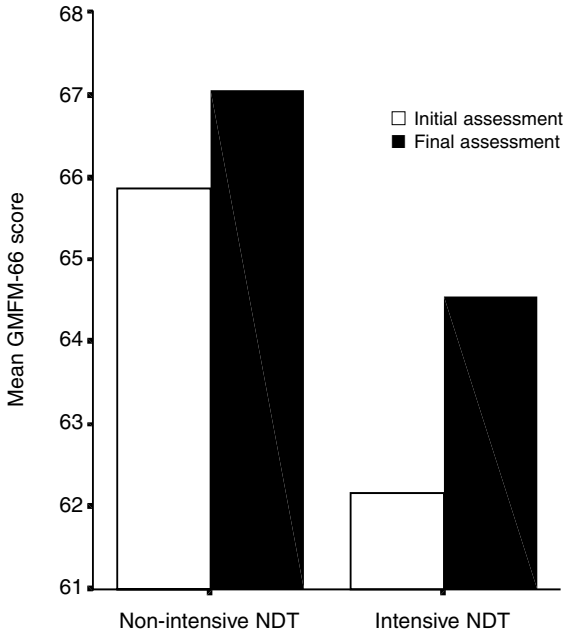

Figure 2: *Mean change in GMFM-66 scores for both groups between initial and final assessments.*

children with mild to moderate spasticity and a distribution of hemiplegia, diplegia, and quadriplegia improved their gross motor function as measured with the GMFM. This improvement was significant for both groups. Furthermore, intensive NDT intervention had a greater effect on children's motor function than reference non-intensive intervention (Figs 1 and 2). This conclusion justifies the notion for more intensive NDT in CP.

To our knowledge, there have been only a few studies in the English-language literature with the GMFM as an outcome measure for the effectiveness of intervention in gross motor function (Bower and McLellan 1992; Bower et al. 1996, 2001; Ketelaar et al. 2001). In two further studies the use of the GMFM is cited as a measure for the effectiveness of NDT which is provided either normally (Knox and Evans 2002) or intensively (Trahan and Malouin 2002). Only one of these studies (Knox and Evans 2002) used the improved scaling of GMFM-66. Because our study used GMFM-66 for the intensive provision of NDT, no direct comparison of our results can be made with the findings of previous studies.

The results support the efficacy of NDT. Of the 34 children who participated, only four remained static (children 6, 12, 16, and 17 in group A); all the others showed an improvement (Table I). It must be highlighted that even a lack of change in motor function has clinical importance for children with CP. Often there is a levelling-off or regression in motor development, especially in older children with severe spasticity, in whom the movement patterns are fixed and no more improvement is expected (Scherzer and Tscharnuter 1982, Herndon et al. 1987). In that sense, NDT intervention must be held to be effective in cases in which the level of motor function is at least retained (see also Parette and Hourcade 1984).

It is important to examine the statistical power of this study. Although the calculated total sample size of 52 children was not achieved (the actual sample was 34 after the four dropouts), a post-hoc power analysis revealed that the study had a power level of 99.43% to find a significant difference ($p<0.05$) with an effect size of 0.794. It can be concluded, therefore, that a type II error was a relatively unlikely occurrence in this trial.

The size of the statistically significant advantage for group B

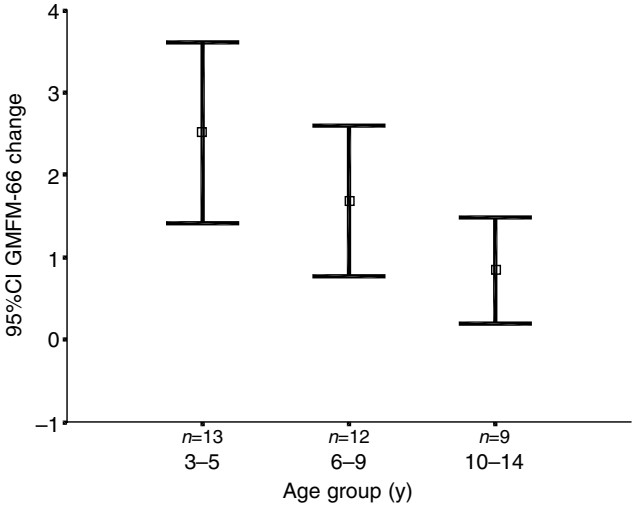

Figure 3: *Change in GMFM-66 score by age group.*

mate from about 62.17 to 64.54) and 2.63 percentage points on GMFM-88. For group A, although it reached significance, the advantage was of smaller degree: a mean change score of 1.18 points on GMFM-66 (mean ability estimate from about 65.85 to 67.04) and 1.69 percentage points on GMFM-88. The clinical significance of changes can be assessed from the GMFM manual (Russell et al. 1993), in which an increase of 1.825 percentage points on GMFM-88 was suggested to be the smallest change of clinical importance according to the parents. Seven of the children in group A and 10 in group B showed increases in their total GMFM-88 scores greater than this.

In relation to GMFM-66 scores, there is limited information on how to interpret the clinical significance. However, examination of the manual of the GMFM-66 (Russell et al. 2002) suggests that children from 4 to 6 years old in GMFCS level I could change 2.77 points over 6 months with a wide range of treatment. In the present study there were children of different ages and levels who accomplished a change of more than 2.77 points over 16 weeks. In group A, two males, 3 years old (level I) and 5 years old (level III), demonstrated a change of 3.47 and 2.83 points respectively. In group B, four males and two females, 3 to 9 years old (levels I to III) demonstrated a change score ranging from 3 to 6.77 points.

It could be argued that these changes might have been due to maturation and not to therapy. A possible answer should be grounded on the basis of the practical advantages of therapy for the children with CP, something that therapists and parents can assess straight away. For example, we observed differences in the gross motor abilities of a 5-year-old male with spastic diplegia (level III) in group A, who initially achieved a GMFM-66 score of 51.56 points; on retesting 16 weeks later he achieved a score of 54.15. This magnitude of change demonstrated an accomplishment of a score from 1 to 2 on GMFM item 55, from 1 to 3 on item 84, and from 0 to 1 on items 56, 63, 64, and 69. The child was able to perform actual activities that he could not do before treatment (such as better standing on one or both legs with little support, independent walking for a few steps, and climbing stairs by holding with one hand). In another example, in group B, a 3-year-old female with spastic left hemiplegia (level II) initially achieved a GMFM-66 score of 61.51 points and finally a score of 64.98. The improvement in gross motor function was seen with a score from 0 to 1 on items 58, 79, 80, and 81, from 1 to 2 on items 54, 60, 84, and 85, and from 2 to 3 on items 62 and 63. In fact, after treatment, the child improved her functionality (that is, walking up stairs alone, jumping, and kicking a ball) because she could stand with better balance and for longer on her affected left leg. Using the item difficulty map of GMFM-66 (Russell et al. 2000, 2002) should enhance the interpretation of a child's GMFM-66 score.

In the present trial, the NDT approach was found to be effective in children with spastic CP. This should not, therefore, be generalized to children with other types of CP (such as athetoid or ataxic). Future studies should investigate the efficacy of NDT, intensive or not, in these children with CP with the use of the GMFM.

Conclusions

The benefits of intensive NDT demonstrated here are encouraging for those who advocate this approach and its more intensive provision. Of course, we do not consider that the results of this one study should be interpreted as the final

answer to the above important questions, given that some of the earlier studies have reported no responses to NDT intervention. Future evaluative research is required to assess objectively the effectiveness of NDT in CP.

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