Comparison of efficacy of Adeli suit and neurodevelopmental treatments in children with cerebral palsy

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This study compared the efficacy of Adeli suit treatment (AST) with neurodevelopmental treatment (NDT) in children with cerebral palsy (CP). Twenty-four children with CP, Levels II to IV according to the Gross Motor Function Classification System (GMFCS), were matched by age and functional status and randomly assigned to the AST or NDT treatment groups. In the AST group (n=12; eight males, four females; mean age 8.3y [SD 2.0]), six children had spastic/ataxic diplegia, one triplegia and five spastic/mixed quadriplegia. In the NDT group (n=12; nine males, three females; mean age 8.1y [SD 2.2]), five children had spastic diplegia and seven had spastic/mixed quadriplegia. Both groups were treated for 4 weeks (2 hours daily, 5 days per week, 20 sessions). To compare treatments, the Gross Motor Function Measure (GMFM-66) and the mechanical efficiency index (EI_{HB}) during stair-climbing were measured at baseline, immediately after 1 month of treatment, and 10 months after baseline. The small but significant time effects for GMFM-66 and EI_{HB} that were noted after 1 month of both intensive physiotherapy courses were greater than expected from natural maturation of children with CP at this age. Improvements in motor skills and their retention 9 months after treatment were not significantly different between the two treatment modes. Post hoc analysis indicated a greater increase in EI_{HB} after 1 month (p=0.16) and 10 months (p=0.004) in AST than that in NDT, predominantly in the children with higher motor function (GMFCS Levels II and III). The results suggest that AST might improve mechanical efficiency without a corresponding gain in gross motor skills, especially in children with higher levels of motor function.

See end of paper for list of abbreviations.

New approaches for the therapy and management of children with cerebral palsy (CP) have been emphasized in the past two decades. Rosenbaum (2003) addressed the subject of alternative therapies and the difficulties encountered in evaluating these new approaches. He advocated sound scientific inquiries into their potential benefits. It is necessary to consider whether meaningful improvement can be attributed to the type or intensity of the intervention and whether performance is improved by permanently raising the child with CP to a higher level of function.

TREATMENT INTENSITY

Physiotherapy for children with CP is often provided as a continuous process from the time of risk or pathology identification. Bower et al. (1996) administered short intensive bouts of physiotherapy to 44 children with CP, emphasizing motor skills acquisition measured by the Gross Motor Function Measure tool (GMFM-88). Intensive physiotherapy resulted in significantly improved skills acquisition when compared with conventional amounts of physiotherapy. This advantage declined over the subsequent 6 months when therapy reverted to its usual intensity. Increasing the treatment frequency over a period of 6 months was demanding for children and their families (Bower et al. 2001). In a pilot study of intensive physiotherapy treatment over a short period for very young quadriplegic children, Trahan and Malouin (2002) found improvement in motor performance, measured by GMFM-88, which was retained in the subsequent non-treatment period. The 4-week period of treatment was well tolerated by the children.

STRENGTH AND ENDURANCE TRAINING

Impairments of CP affect muscle strength and cause motor deficits. Lieber et al. (2003, 2004) reviewed evidence that muscles from patients who develop spasticity are greatly altered. Spastic muscles have an increased concentration of collagen (Booth et al. 2001) and markedly decreased collagen quality in comparison with healthy muscles (Lieber et al. 2003). Elder et al. (2003) suggested that weakness of spastic muscles is based on the inability to produce torque levels that are commensurate with the muscle's cross-sectional area. Failure to maximally activate muscles contributes to this weakness, with further contribution from co-activation of synergic muscle groups. Damiano and Abel (1998) addressed muscle weakness in a 6-week muscle-strengthening programme, achieving positive functional outcomes for an ambulatory population. Blundell et al. (2003) developed an intensive training programme (twice a week for 4 weeks) for ambulatory children with CP, including repetitions of functional tasks with increasing difficulty. They found improved strength and functional performance that was maintained over time. Strength training is now an accepted therapeutic approach in patients with CP (Damiano et al. 2002). Muscle strengthening programmes can improve the patient's ability to compensate for gait disabilities (Bar-Or 1996), and specific interventions can reduce the metabolic cost of locomotion. Patients with an increased cardiovascular fitness are able to maintain a more normal walking speed (Waters and Mulroy 1999).

THE ADELI SUIT

The Adeli suit and associated treatment (AST) was introduced in 1991 and refined by Semenova (1997). The treatment incorporates a device developed in Russia in the late 1960s to

maintain neuromuscular fitness during weightlessness experienced by cosmonauts. This treatment is based on three principles: (1) the effect of the suit (working against resistance loads, increased proprioception and realignment); (2) intensive daily physical therapy for 1 month; and (3) active motor participation by the patient. Semenova (1997) argued that this method, termed 'dynamic proprioceptive correction', would reduce pathological synergies, restore normal muscular synergies, and apply loads to antigravity musculature that would normalize the afferent vestibulo-proprioceptive input. A variety of functional tasks were evaluated and scored, but tests and scales were not detailed. Shvarkov et al. (1997) studied the clinical efficacy of AST in an assorted adult population with movement disorders due to brain lesions, using clinical observational tools and assessment questionnaires. They found 'clinical effects in all patients that were transient in the hyperkinetic syndrome, but maintained in patients with spastic paralysis for longer periods'.

As described by the developers of AST, the treatment should influence both muscle strength (working against resistance) and the level of physical fitness (prolonged exercise). Scepticism persists about the relative effectiveness of this treatment and its long-term effects (retention), when compared with other conventional therapies and techniques, because no comparative studies have been done.

AIMS

The objective of this study was to evaluate the efficacy of AST by comparing it with neurodevelopment treatment (NDT) in children with CP. Specifically investigated were the effects of AST on gross motor functions and energy cost quantified by mechanical efficiency. The following two hypotheses were tested: (1) that children treated for 1 month with AST would have a significantly greater improvement in motor functions and mechanical efficiency than a corresponding group of children treated for 1 month with NDT; and (2) that 10 months after treatment the children treated with AST would have a significantly higher motor function score and mechanical efficiency (indicating a smaller decline or a greater improvement) than the group treated with NDT.

Method

PARTICIPANTS

The study was advertised in national and local newspapers. A letter explaining the aims and requirements of the study was sent to interested parents. Parents of 40 children with CP from various regions in Israel applied for the programme. All children were on continuous programmes of physical therapy of varying intensities in their local community or school.

The inclusion criteria were as follows: (1) diagnosis of CP; (2) 6 to 12 years of age; (3) level II, III, or IV of the GMFCS; (4) no orthopaedic surgery or spasticity-reduction intervention in the previous 6 months; (5) not a candidate for surgery or other interventions for at least 1 year; and (6) parents' agreement for child allocation to either group by randomization.

Exclusion criteria according to the contraindications for AST were as follows: (1) hip dislocation or scoliosis; (2) high degree of spasticity; (3) poorly controlled epilepsy; and (4) hydrocephalus and progressive encephalopathies and myopathies.

The local Institutional Review Board approved the study. Written consent to participate was obtained from the parents after a detailed explanation to them and the children of the research project. A paediatric neurologist screened the patient's medical history before soliciting their participation. A paediatric orthopedic surgeon determined each child's orthopaedic status. In their first visit to determine their study eligibility, a paediatric physiotherapist with 25 years of experience with children with CP classified the children according to the GMFCS (Palisano et al. 1997).

Twenty-four children, 17 males and 7 females, met the requirements. The 16 excluded children had one or more of the AST contraindications or were found to be at GMFCS level V. The GMFCS levels of participants are shown in Table I. These 24 children were randomly divided into two groups by using the Ranuni function (SAS 6.12 software). The randomization list was divided into six blocks, each block containing four patients: two were from the ATS (experimental) group, and two from the NDT (comparison) group. Each pair of patients in the same block was matched by age (to within 1y) and GMFCS level. The sex, age, anthropometric measures, type of CP, and limb distribution by group are shown in Table II. There was no significant difference in anthropometric measures between the two groups at the beginning of the study. Their mean age was 8 years 2 months (range 5y 11mo–12y 11mo).

PROTOCOL

Both groups were tested at baseline and after 1 month of AST or NDT therapy, and again 9 months later after they had returned to their regular pre-study therapy. Both groups received daily treatment sessions for about 2 hours, 5 days per week for 4 weeks (20 sessions). During this time they stopped routine physiotherapy treatments, but continued educational and recreational activities.

AST

This treatment approach includes the suit and an intensive, well-structured treatment protocol. Adeli suits were obtained from Zvezda Corporation, Moscow, Russia, and sized in accordance with the anthropometrical measures. AST was conducted in accordance with the original Russian protocol that included the following: (1) massage before fitting the suit; (2) passive stretching of all limb muscles; (3) application of the suit by placing the body into proper alignment and restricting limb positions, thereby loading the patient's musculature; and (4) rigorous exercises in the suit, following an individual programme based on functional weight-bearing gross motor activities primarily related to locomotion. Each session included walking activities suited to individual abilities, standing up from sitting, playing with a ball while standing, walking on different terrains, jumping on a trampoline, and climbing stairs and ladders. Russian physical therapists, expert in AST application, treated the children in the experimental group and the treatment was performed in the same environment for all 12 children.

NDT

This treatment approach for CP is the one most widespread and clinically accepted to target the central nervous and neuromuscular systems and 'teaching' the brain to improve motor performance skills and achieve 'as near normal function as possible', in view of the specific lesion in the central nervous system. The NDT method does not follow a strict protocol of treatment, being oriented to reacting in real time to

the tone and movement patterns of the patient. After a precise determination of the treatment's individual functional aims (e.g. improved stability while sitting) and goals (e.g. walking or riding tricycles), a structured programme was set for each child. This programme included passive stretching of lower limb muscles (e.g. hamstrings, gastrosoleus), followed by techniques of reducing spasticity and facilitating more normal patterns of movements while working on motor functions. Functional motor activities included in each session were walking, standing up from sitting and sitting on a bench. Children in the NDT group were treated by physical therapists with at least 7 years of experience and trained by NDT basic and advanced courses. The treatment was conducted in the same rehabilitation centre for the 12 participants in this group.

MEASUREMENT TOOLS

GMFM-66

The GMFM tool was used to evaluate and compare functional status before and immediately after 1 month of treatment, and again approximately 9 months later. The GMFM is an ordinal measure designed to evaluate changes in gross motor function in children with CP in five dimensions: (1) lying and rolling; (2) crawling and kneeling; (3) sitting; (4) standing; and (5) walk–jump–run activities (Russell et al. 1989). Each item is scored on a four-point ordinal scale, as outlined in a manual (Russell et al. 1993). All scoring procedures were videotaped. The scores were subsequently analyzed with the Gross Motor Ability Estimator computer-scoring program to obtain a GMFM-66 score, outlined in another manual (Russell et al. 2002). All tests were performed by the same trained and certified physiotherapist, who was unaware of the treatment group to which the children were assigned and was not provided with scores or videos from their previous assessments. All tests were performed in the same room with identical equipment.

Metabolic cost of stair-climbing

The mechanical efficiency of a stair-climbing task was chosen as an ambulatory function measurement to compare the efficacy of interventions. This measure was adopted to circumvent the difficulties of achieving a metabolic steady state in individuals with gait impairments (Boyd et al. 1999). A steady state is required for most indices, such as the physiological cost index (Butler et al. 1984) and the energy expenditure index (Rose et al. 1985). In populations with motor impairments, the physiological strain can be assessed by calculating the effort required to accomplish measured external work in Watts (W). The mechanical efficiency, or energy cost, during stair-climbing constitutes a comprehensive expression incorporating mobility components. These components include body and limb mass, range of movement, step height, and the relationship between walking velocity and step length. Mechanical efficiency can, therefore, represent a global and objective assessment of the mobility efficiency among and within individuals. Mechanical efficiency during stair-climbing is significantly lower in children with CP (one-seventh) than in normally developing children (Bar-Haim et al. 2004).

Because heart rate is related to O_2 uptake during exercise, it is convenient to estimate the metabolic energy cost from heart rate during stair-climbing. Although this increases scatter between individuals (Bar-Haim et al. 2004), in a study such as this, where participants are serially measured over time, it is not unreasonable, especially because heart rate is more convenient to measure than O_2 uptake in children. For validation of the relation between heart rate and and O_2 uptake these parametres were obtained simultaneously during one of the three checkups in 20 of the 24 participants. The regression equation of mechanical efficiency (100 × total work in W/metabolic cost in W) against mechanical efficiency index (EI_{HB}), calculated as 100 × total work in kg.min per beat, was mechanical efficiency=$0.44+0.077\ EI_{HB}$ ($n=20, r=0.96, p<0.001$).

Heart rate was monitored continuously by a Polar Pulsimeter (model S-810; Polar Electro Co., Kempele, Finland). The Dynamic Stair Trainer (DPE Medical Ltd., Shoeva, Israel) was used for stair-climbing and measuring external work. It has five stairs, adjustable from 0 to 17cm, with adjustable handrails. The stair height was set according to each child's climbing ability during two pre-test trials. The distance component of the work over a finite time period is calculated from the summed vertical displacement of the body (m). The force applied is the body weight (kg) and the work is calculated as the product (kg.m), namely external work=body weight×number of stair ascents×stair height. Each child was given a detailed explanation of the equipment and practised stair-climbing. When the child felt comfortable, baseline measurements were made while the child was sitting on a chair

Table I: Distribution of 24 participants in study by age according to GMFCS level

Age, y:m	*GMFCS*			
	Level II (n=4)	*Level III (n=11)*	*Level IV (n=9)*	*Total (n=24)*
5:11–6:11	2	3	4	9
7:0–7:11	–	3	1	4
8:0–8:11	1	2	–	3
9:0–9:11	1	2	–	3
10:0–10:11	–	1	1	2
11:0–11:11	–	–	1	1
12:0–12:11	–	–	2	2

GMFCS, Gross Motor Function Classification System.

Table II: Characteristics of NDT and AST groups at baseline

Characteristic	*NDT group (n=12)*	*AST group (n=12)*
Sex, M/F	9/3	8/4
Age, y:m	8:1 (2:2)	8:3 (2:0)
Height, cm	119.3 (15.0)	119.2 (11.9)
Weight, kg	22.2 (7.2)	21.9 (7.5)
Right leg length, cm	61.7 (9.5)	61.9 (7.6)
Diplegia, spastic	5	5
Diplegia, ataxic	–	1
Triplegia, spastic	–	1
Quadriplegia, spastic	5	1
Quadriplegia, mixed	2	4
GMFCS II	2	2
GMFCS III	6	5
GMFCS IV	4	5

Mean (SD) values are shown; no difference was statistically significant ($p \geq 0.05$). NDT, neurodevelopmental treatment. AST, Adeli suit treatment; GMFCS, Gross Motor Function Classification System.

with a backrest for 5 minutes and being told a story. Children then walked up and down the stairs continuously for 4 to 5 minutes at a self-chosen pace comfortable for them, using the handrails for assistance if they desired. After ascending to the top step they turned and descended in the opposite direction, the number of ascents being counted. The children were encouraged to maintain a regular pace.

STATISTICAL ANALYSES

A mixed-effects model with repeated measures (SAS version 9.1) was used to test the effect of time and group differences. This model accounts for nonlinear correlation between repeated measures and missing data. GMFM-66 and EI_{HB} were the dependent variables, and groups (NDT and AST) and time (baseline, 1mo, 10mo) were the fixed independent variables. Both main effects and their interaction were evaluated within and between groups. In addition, Tukey's post hoc analysis, corrected for unequal *n*, was used to test specific differences (Spatz 1993).

The two main treatment groups were subdivided into two subgroups of six participants each, based on rank order of baseline GMGM-66 scores, to estimate whether the magnitude of change induced by either treatment might be related to the level of gross motor function. The GMFM-66 classification was used to rank the children into high and low motor function categories because the GMFCS is not sensitive to minor changes in motor function. For example, two children that were classified to level III by GMFCS differed in their GMFM-66 scores by 10 units.

Results

Twenty-one children completed the 20-session course in 4 weeks; three were allowed an extra week to make up one to three sessions lost for health reasons. The baseline scores and those taken after 1 month of treatment and 9 months later for GMFM-66 are shown in Table III, a higher score indicating higher motor function. A significant time effect was found, but the group effect and interaction were not significant. On the

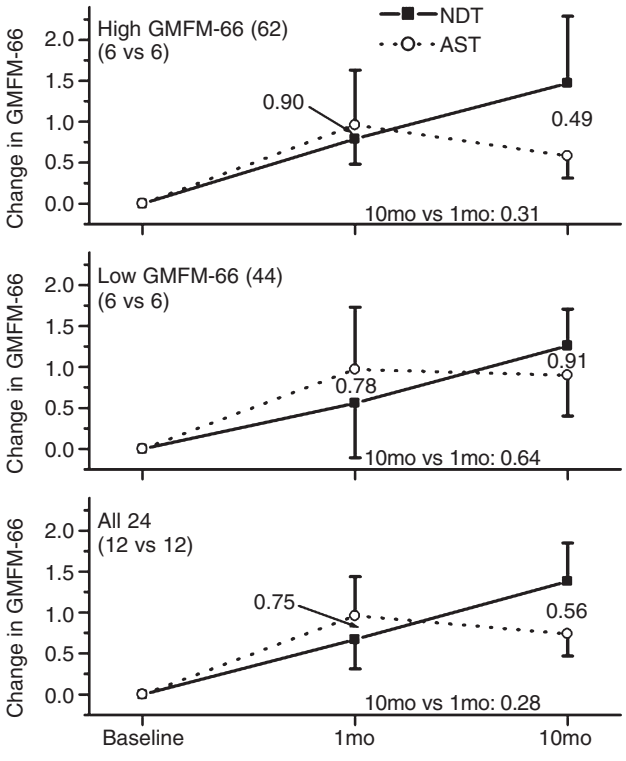

Figure 1: *Change in Gross Motor Function Measure (GMFM-66) from baseline after 1 month of treatment and 9 months after treatment. Top and middle: changes from baseline for 6 participants with highest and lowest GMFM-66 baseline scores respectively (in parentheses) in each group. Bottom: means and SEM for change in GMFM-66 from baseline after 1 month of treatment and 9 months later for all participants in each group. p-values are shown for Tukey's post hoc analyses. NDT, neurodevelopmental treatment; AST, Adeli suit treatment.*

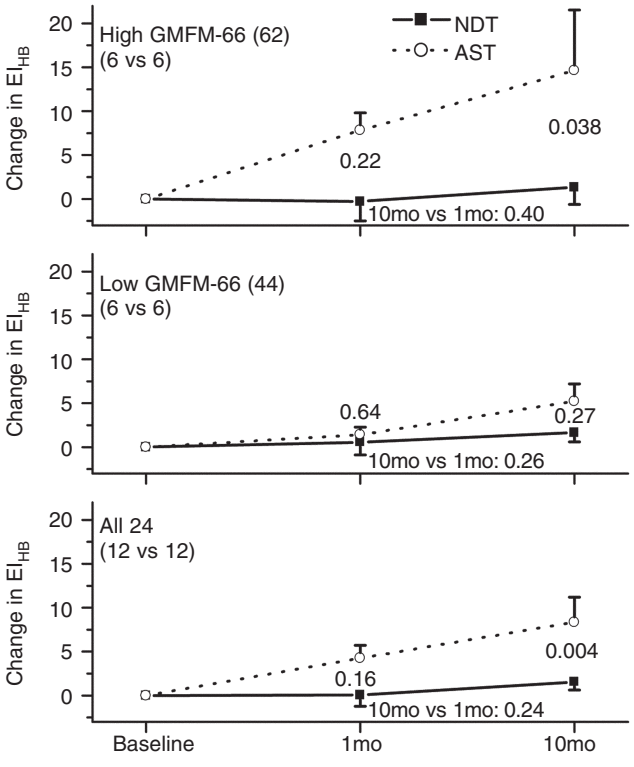

Figure 2: *Change in mechanical efficiency index from baseline after 1 month of treatment and 9 months after treatment. Top and middle: changes from baseline for 6 participants with highest and lowest Gross Motor Function Measure (GMFM-66) baseline scores respectively (in parentheses) in each group. Bottom: means and SEM for change in mechanical efficiency index (EI_{HB}, 100×kg.m per beat) from baseline after 1 month of treatment and 9 months later for all participants in each group. p-values are shown for Tukey's post hoc analyses. A change of 7 EI_{HB} units is equal to 1% change in mechanical efficiency. NDT, neurodevelopmental treatment; AST, Adeli suit treatment.*

baseline test the groups' scores on the GMFM-66 were similar and the difference remained insignificant at 1 month and 10 months. The analysis showed a significant improvement in GMFM-66 scores after 1 month of treatment in both groups combined, and this was sustained for 9 months after treatment. Within the NDT group there was a significant difference between baseline and 10-month scores ($p<0.006$) and within the AST group there was a significant difference between baseline and 1-month scores ($p<0.037$). Post hoc testing revealed no differences between groups in the time-related differences of the scores. In addition, as shown in Figure 1, the change in GMFM-66 did not differ significantly between children with lower and higher motor function, as estimated by baseline scores.

For EI_{HB} a higher score represents increased efficiency. As shown in Table III, there was also a significant overall time effect and no significant group effect or interaction, as with GMFM-66. Within the NDT group there was no significant change over time, but within the AST group the increase from baseline to 1 month approached significance, and after 10 months the increase was significant. This same significance was reflected in the post hoc analysis of changes between the two groups, shown in Figure 2, with the AST group showing a significantly greater increase over 10 months after baseline. It is apparent that improvement in AST predominated in the six participants who had the highest level of motor function before treatment began.

Discussion and conclusions

The aim of this study was to investigate whether children with CP receiving physical therapy in accordance with the original intensive AST approach would have greater improvement in motor function and mechanical efficiency than children receiving therapy based on the neurodevelopmental approach with similar intensity. Two reports of AST studies are available in English (Semenova 1997, Shvarkov et al. 1997), the former on children with CP and the latter on adults with acute brain damage and hyperkinesis. Semenova (1997) reported on 60 children with spastic diplegia and 34 children with hyperkinetic diplegia who underwent traditional and AST treatments. Details regarding the age and severity of impairments were limited. The measured domains were maintaining sitting and standing posture, independent walking, self-care, and speech. Major improvements were reported in these domains with AST in comparison with the traditional treatment (protocol not specified), but statistical methods and analysis were unclear. Although our research was conducted in accordance with the original Russian protocol (Semenova 1997), the lack of reported details make a quantitative comparison impossible.

The marginal, but significant, time effect for GMFM-66 and EI_{HB} that was noted in Figure 1 in all participants after 1 month of intensive physiotherapy treatment was greater than expected from the natural development of children with CP at that age (Rosenbaum et al. 2002). Therefore, these findings support the idea that more intensive therapy (either NDT or AST) can generally accelerate the acquisition of motor abilities in children with CP and agrees with other reports (Bower et al. 1996, Trahan and Malouin 2002). When administered with equal intensity, the AST did not show superior motor skills retention in comparison with NDT. No participant had a change in GMFCS status after either intervention.

Because muscle-strengthening programmes and increased cardiovascular fitness may help compensate for gait disabilities (Bar-Or 1996, Waters and Mulroy 1999), we also chose to measure energy cost or mechanical efficiency, as represented by EI_{HB} of the stair-climbing task, for evaluating the efficacy of AST. The mechanical efficiency of children with CP is low as a result of a loss of motor control, co-contraction, spasticity of muscles, and reduced range of motion (Waters and Mulroy 1999). The metabolic cost of a task is affected by speed of movement, work rate, and fiber type recruitment. Climbing the stairs at a self-selected pace serves to equate these factors between participants. The EI_{HB} results indicate that children in the AST group who had higher GMFM-66 scores at baseline improved their

Table III: GMFM-66 scores and mechanical efficiency index for stair-climbing in two groups of participants

Measure	*Treatment*	*Value*	*Test point*		
			Baseline	*1mo*	*10mo*
GMFM-66	NDT	Mean	52.2	52.9	54.1[a]
		SEM	3.0	3.0	3.1
		Range	36.4–72.6	39.0–73.6	37.4–74.8
	AST	Mean	54.0	55.0[a]	54.7
		SEM	4.0	4.1	4.0
		Range	36.4–85.2	40.2–88.0	36.4–85.2
EI_{HB}	NDT	Mean	11.1	12.5	13.1
		SEM	5.0	5.3	5.4
		Range	2.1–55.0	2.9–48.4	2.4–59.8
	AST	Mean	12.7	15.1	19.6[a]
		SEM	3.5	4.1	5.3
		Range	1.2–30.6	1.9–43.9	2.0–55.2

Mechanical efficiency index (EI_{HB}) units are 100×kg.m per beat. For Gross Motor Function Classification System-66 (GMFM-66), mixed-effects p: time=0.006; group=0.73; interaction=0.38. For EI_{HB}, mixed-effects p: time=0.013; group=0.86; interaction=0.28. [a]Significantly different ($p<0.05$) from baseline. NDT, neurodevelopmental treatment; SEM, standard error of mean; AST, Adeli suit treatment.

EI_{HB} more than children with lower gross motor function.

The strength-building effect of AST was not measured for any specific muscle or muscle groups, but if AST resulted in any strengthening it should be evident in an increase in EI_{HB} within the AST group (Fig. 2). These results suggest a trend in the improvement of EI_{HB} or a reduction in metabolic cost for a given amount of external work after AST compared with NDT. Also indicated is that improvement is better maintained after the programme in children having a higher level of motor function.

The significant improvement in GMFM-66 in the AST group after 1 month can be attributed to the improved EI_{HB}. This advantage in AST declined after the treatment reverted to its routine amount (Fig. 1, Table III). The slower, but significant, time effect within group NDT between baseline and 10 months reflects the acquisition of motor skills of these children under regular treatment.

In summary, the results suggest improved EI_{HB} in the AST group, especially for children with higher levels of motor function, without the gain of additional gross motor skills. This implies that AST can serve to optimize these skills in children with a higher level of gross motor skills, as reflected by a reduced metabolic cost of external work.

Future studies on the efficacy of AST should measure changes in metabolic efficiency and fitness level, as well as motor skills. It is also important to determine changes induced by the suit itself, by having two groups perform the same physical training, with and without the suit. Future studies should increase the number of participants and homogenize the participants with CP to reduce variability. It is apparent from this study that the intensity of treatment was a principal factor in the improvement of function. Anecdotal comments from parents of children in both groups showed satisfaction with intensive treatment, regardless of type. The high compliance indicates that intensive treatment programmes over a short period are well tolerated by children with CP and by their families.

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List of abbreviations

AST	Adeli suit treatment
EI_{HB}	Mechanical efficiency index
NDT	Neurodevelopmental treatment