Efficacy of intensive therapy program using therasuit method for pediatric rehabilitation patients compared to conventional in-patient NDT therapy

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BACKGROUND

Pediatric patients with the neurologic disorder showed functional deficits and developmental delays. The severity and range of these impairments represent variable conditions depending on the diagnosis or lesion of site. Compromised integrity of the brain due to pediatric brain injury has been associated with gross and fine motor, language, and cognitive impairment, in addition to somatic and emotional symptoms and reduced everyday function.

In children with congenital or acquired motor deficits caused by neurologic disorders, intense motor activity can re-establish and reinforce neuronal pathways and enhance neuronal plasticity. Furthermore, additional requirement is a goal-oriented and task-specific training program. Motor function in pediatric patients with motor dysfunction can be improved using targeted functional training. Variations in repeated movements especially play an important role in improving patient motivation and thus the intensity and efficacy of training.

Neurodevelopmental treatment (NDT) is one of the earliest specific therapies and the most common approach, which is being used by physiotherapists and occupational therapists. The essential concepts in NDT are facilitation (using sensory inputs to improve motor performance), management of compensatory motor behavior and an overall management strategy. Despite being the most frequently used intervention to treat pediatric patients with the neurologic disorder or developmental delay, there is no conclusive evidence that neurodevelopmental treatment promotes functional improvement of children with the neurologic deficits. As a result, alternative approaches such as suit therapy, robot-assisted therapy, and hippotherapy, etc have been provided to patients with neurologic deficits.

The therasuit was originated from a prototype developed for Russian astronauts to resist the effects of zero-gravity on the body during prolonged space travel. The therasuit is a soft dynamic proprioceptive orthotic that regulate the body in position by exerting pressure on specific regions using a bunch of interconnected elastic cords. Intensive therapy program using therasuit method (ITP) is a stretching and strengthening program based on individual`s level and need, during which the patient wears therasuit. Use of therasuit may able to modify joint alignment and reinforce certain muscle groups. ITP included multiple movements combined with the wearing of a fitted suit, which provided resistance during activity. In addition, each patient`s therapeutic program was individualized with the goal of advancing the patient to the next level of function or physical activity. Two major differences between ITP and in-patient NDT therapy were as follows: (1) one continuous session versus three intermittent sessions, (2) using therasuit and universe exercise unit versus no additional device Researches and meta-analysis on suit therapies for pediatric patients with neurologic deficits have appeared to show positive trends in terms of gross motor function, proximal stability, and gait. However, due to the heterogeneity of included studies, additional studies must be conducted in order to draw a final conclusion on the effects of the suit therapies. This study evaluated the efficacy of intensive therapy program using therasuit method for pediatric patients with neurologic deficits.

Materials & Method

In this study, we used a case crossover design. As cases serve as their own controls, there is less risk of confounding. Each participants had one case period (ITP therapy) and other control period (NDT therapy) in random sequence. In order to eliminate a carryover effect, we set up “washout phase” of 1 month.

Each patient has received in-patient NDT therapy for a period of 12 weeks, 5 times per week, in three half hour sessions per day, and after a period of time, after a period of time (at least 5 weeks later) same patients admitted again and underwent ITP for a period of 8weeks, 5 times per week, in a one and half hour session per day or vice versa(Fig 1).

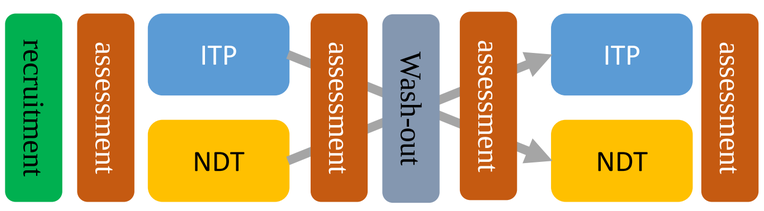

Figure 1. Study design. Two-period, controlled crossover design.

Inclusion criteria were: (a) unilateral spastic cerebral palsy; (b) ability to walk independently (level I or II according to GMFCS); (c) age range from 5 to 10 years old; (d) cognitive level and emotional state facilitating understanding and cooperation of the participant; (e) no prior experience with this type of dynamic orthosis (TS) before this study.

Exclusion Criteria were: (a) another medical diagnosis, types and sub-types of spastic CP; (b) congenital heart disease and cardiorespiratory problems; (c) presence of structural deformities at the lower limbs and trunk, or instability in the ankle joint, which could compromise the child’s safety and performance of the motor task; (d) uncontrolled epilepsy; (e) treatment with botulinum toxin in the calf muscles within the previous 6 months; (f) surgical intervention (e.g. tendon lengthening in lower limb) within the previous 12 months; (g) severe affective or psychiatric impairments; (h) serious vision or hearing problems.

Outcome measures were gross motor function measure (GMFM-88), pediatric balance scale (PBS). Outcome measures were assessed at beginning and end of treatment.

Changes on the GMFM-88, PBS were compared between ITP and in-patient NDT therapy. Difference within and between groups were assessed with paired T-test and analysis of covariance (ANCOVA), respectively.

RESULTS

Fifty-six patients with CP or other acquired brain injuries were included in our study, from June 2016 to December 2018. Among 56 patients, 44 patients completed both ITP and NDT therapies, but 9 patients accomplished only ITP therapy, 3 patients NDT therapy. The washout phase was

Demographic and baseline characteristics of the participants were displayed on Table 1. No significant differences were found between groups at baseline with regard to gender, diagnosis, duration of therapy, GMFCs, and baseline GMFM-88 and PBS scores, except age(ITP group 7.91 ± 2.66, control group 5.69 ± 3.42, p-value 0.08).

Of 37 patients in the ITP group, 27 were diagnosed with cerebral palsy, 10 were diagnosed with other brain diseases. Of 25 patients in the control group, 18 were diagnosed with cerebral palsy, 7 were diagnosed with other brain diseases, such as brain tumor, intracranial hemorrhage, etc.

Table 1. Demographic and baseline characteristics

	Total (N=54)	ITP (N=31)	Control (N=23)	P-value[2]
Age, mean ± SD	6.97 ± 3.18	7.91 ± 2.66	5.69 ± 3.42	0.008
Gender, n (%)				
Male	26 (48.15%)	15 (48.39%)	11 (47.83%)	>0.990
Female	28 (51.85%)	16 (51.61%)	12 (52.17%)	
Diagnosis, n (%)				
CP	42 (77.78%)	24 (77.42%)	18 (78.26%)	>0.990
Non-CP	12 (22.22%)	7 (22.58%)	5 (21.74%)	
Duration of therapy, mean ± SD	67.64 ± 21.95	65.6 ± 23.18	70.7 ± 20.16	0.463
GMFCS, n (%)				
1	9 (16.98%)	5 (16.13%)	4 (18.18%)	>0.990
2	25 (47.17%)	15 (48.39%)	10 (45.45%)	
3	9 (16.98%)	5 (16.13%)	4 (18.18%)	
4	8 (15.09%)	5 (16.13%)	3 (13.64%)	
5	2 (3.77%)	1 (3.23%)	1 (4.55%)	
Baseline GMFM-88, mean ± SD	70.38 ± 21.18	71.45 ± 18.88	68.93 ± 24.32	0.965
Baseline PBS mean ± SD	25.47 ± 18.05	25.1 ± 17.35	26.2 ± 19.99	0.914

Between groups

The mean difference of GMFM-88 and PBS scores between groups are presented in Figure 2. Statistically significant differences were found between groups on both the GMFM-88 (ITP: 8.69 ± 7.93, Control: 2.85 ± 5.82, p-value 0.005) and PBS (ITP: 7.67 ± 6.49, Control: 1 ± 4.05, p-value <0.001).

ANCOVA with baseline score of both outcome measures as a covariate also found differences in endpoint score between groups (Table 2).

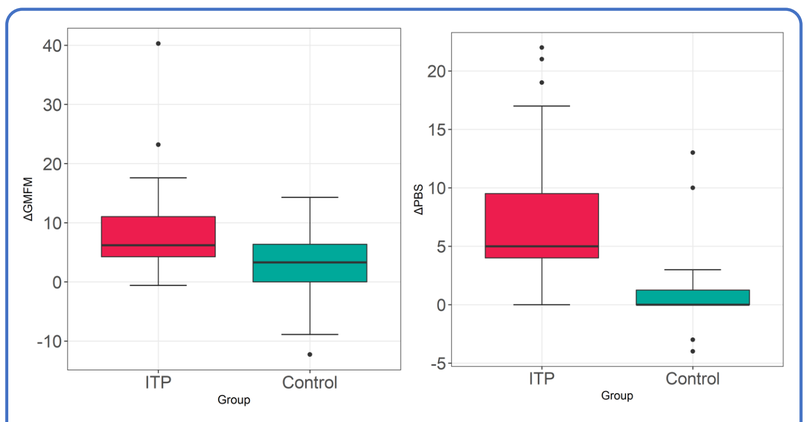

Figure 2. Differences of outcome measures between groups.

Table 2. ANCOVA comparing ITP and control group in post-test scores with pre-test as covariate

	ITP group		Control group		ANCOVA (pre-test as covariate)		
	mean	SD	mean	SD	F	p-value	partial η2
GMFM-88	79.21	1.19	73.04	1.38	11.5	0.001	0.184
PBS	32.37	1.11	26.16	1.69	9.420	0.004	0.191

Within groups

Results of the paired samples T-test within each group demonstrated significant differences for the ITP group on both outcome measures, GMFM-88 (baseline: 71.45 ± 18.88, endpoint: 80.15 ± 16.90) and PBS (baseline: 25.10 ± 17.35, endpoint: 33.16 ± 17.76), and control group on the GMFM-88 (baseline: 68.93 ± 24.32, endpoint: 71.28 ± 22.92)at endpoint versus baseline.

As confirmed by our study results, suit therapy can help the patients to improve balance function. This is observed in figure 3 in which a series of photos shows the changes in the standing posture during suit therapy. After suit therapy, static standing balance and spine alignment improved.

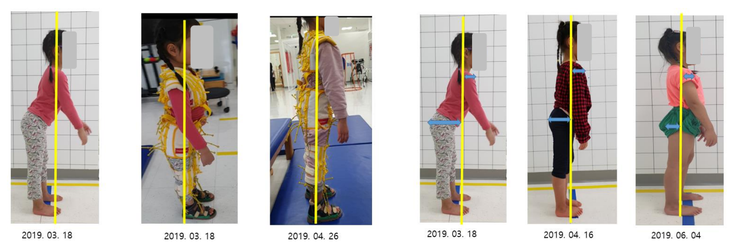

Figure 3. changes in the standing posture during suit therapy

CONCLUSION

This study shows that the effect of ITP superior to those of in-patient NDT therapy on gross motor and balance function. Although the findings have been verified by previous studies, this is the first trial applying crossover design. Our study also included a large number of participants and provided almost equivalent intensity and duration of therapy session to the participants. These have been pointed out major limitations of previous studies. As our study failed to blind both patient and therapist, it is not usually available to blind the therapist or the participants.

Implicit in this conclusion is the importance of intensive, goal-directed repetition of movement toward the improvement of motor function. Further study should be performed to achieve consensus on the details (frequency, duration, etc) of ITP.

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