

Quality of Life and Functional Independence of TheraTogs in Children with Spastic Diplegic Cerebral Palsy: A Randomized Controlled Clinical Trial

Hatem A Emara^{1,2,*}, Eman Sobh^{3,4,*}, Raid Homoud Almohammadi⁵, Emad Abdullah Alamri⁵, Marwan MA Aljohani¹, Ayman Abdullah Alhammad¹

¹Physical Therapy Department, College of Medical Rehabilitation Sciences, Taibah University, Medina, Saudi Arabia; ²Department of Physical Therapy for Growth and Developmental Disorders in Children and Its Surgery, Faculty of Physical Therapy, Cairo University, Cairo, Egypt; ³Respiratory Therapy Department, College of Medical Rehabilitation Sciences, Taibah University, Medina, Saudi Arabia; ⁴Chest Diseases Department, Faculty of Medicine for Girls, Al-Azhar University, Cairo, Egypt; ⁵Department of Physical Therapy, Medical Rehabilitation Hospital, Ministry of Health, Medina, Saudi Arabia

*These authors contributed equally to this work

Correspondence: Hatem A Emara, Physical Therapy Department, College of Medical Rehabilitation Sciences, Taibah University, Medina, Saudi Arabia, P.o 344, Medina, 41411, Saudi Arabia, Tel +966564156262, Fax +966148618888, Email drhatem_emara@yahoo.com

Purpose: Children with cerebral palsy (CP) have limited postural control and functional ability. TheraTogs was reported to improve postural stability. However, studies involving the functional ability and quality of life are limited. We aimed to investigate the effects of TheraTogs use as an orthotic garment and strapping system on the balance and functional ability of children with spastic diplegic CP and if wearing TheraTogs improves their quality of life.

Patients and Methods: A total of 34 children (aged 5–8 years) with spastic diplegic cerebral palsy participated in this study. The control group received conventional physical therapy (CPT), whereas the study group received CPT in addition to wearing TheraTogs. Balance, lower limb strength, and functional abilities were examined using the Biodex balance system, 30-s chair rise test, and Pediatric Evaluation of Disability Inventory-PEDI).

Results: The measured parameters of postural stability significantly improved in both groups post-treatment ($p < 0.05$). The study group showed significant improvement in balance and lower limb strength compared to the traditional physical therapy group ($p < 0.05$). Both groups showed significant improvement in functional skill mobility (0.001 and 0.01 for control and study groups respectively) and caregiver assistance mobility scores ($p = 0.001$ and < 0.001 for control and study groups respectively); however, there was no significant improvement in self-care ability with TheraTogs. The 30s sit-to-stand showed increased number of sit to stands in both groups post treatment ($p < 0.001$ for both groups) and the study group showed significant improvement compared to the control group ($p = 0.01$).

Conclusion: The findings in this study suggest that both conventional physical therapy and TheraTogs are beneficial in improving balance and functional ability. TheraTogs could be utilized as a useful posture orthosis to help improve the balance and functional strength of children with spastic diplegic cerebral, palsy indicating improved quality of life.

Keywords: children with cerebral palsy, TheraTogs, functional ability, 30-s Sit-to-Stand Test, pediatric evaluation of disability inventory

Introduction

Children with spastic diplegic cerebral palsy (CP) usually have limitation of daily life activities and self-independence.^{1,2} This may be attributed to musculoskeletal and neurological abnormalities³ resulting in deficient muscle control due to excessive spasticity, abnormal flexibility, muscle weakness, and abnormal reflexes, which cause instability.⁴ These

abnormalities impair postural control during sitting and standing, and affect gait,⁵ which is considered a significant problem in children with CP.⁶

Children with spastic diplegic CP have poor trunk muscle control, leading to anterior tilt of the pelvis, which limits movements of the hip and knee joints, specifically flexion and adduction during walking. They attempted to overcome the deficiency of antigravity by raising the upper body segment. All these factors lead to impaired daily life activities and self-independence.⁷ Daily life activities and mobility are crucial requirements for the quality of life of children with CP and their families.⁸ These factors can affect the performance and participation at home and in community activities.⁹ This limitation is one cause of impaired quality of life in CP children and their carers.⁷ Interventions focusing on improving mobility and postural control are encouraged to support children with CP in participating and engaging in several activities, and to have good functioning in their daily life activities.⁸ Rehabilitation is one of the interventions aimed at improving postural control and mobility. Orthoses have been suggested for improving posture, gait, and balance.¹⁰ The application of a customized external strap orthosis affects plantar pressure and gait.¹¹ Additionally, it improves proprioception and postural alignment.^{12–14} Therapeutic suits have been reported to improve gait.¹³ It can be used to correct posture in real time and promote normal movement patterns in children with CP.¹² More studies are needed to generate evidence to support the use of therapeutic suits to improve gait and postural control.¹⁵ TheraTogs have been developed to overcome the challenges faced in therapeutic suits, such as discomfort while wearing and enabling their use for longer durations and daily life activities.¹⁶ It has a positive effect on postural alignment and lower-limb function.¹⁷ Studies have examined the positive effect of TheraTogs on balance, gait, and postural control in children with spastic diplegic CP are scarce. Health-related quality of life has been understudied in patients with CP, and there are discrepancies in the results of published studies.¹⁸ Thus, this study aimed to investigate the effects of TheraTogs use as an orthotic garment and strapping system on the balance and functional ability of children with spastic diplegic CP and if wearing TheraTogs improves their quality of life.

Materials and Methods

Study Design

This was a single-blinded randomized controlled clinical trial (RCT) involving 34 children (17 study and 17 control) between March 2022 and June 2022.

Participants

The study included children with spastic diplegic CP (spasticity grade 1 or 1+¹⁹ Gross Motor Function Classification System (GMFCS) scores I and II).²⁰ The child was able to stand and walk independently. Children with visual, auditory, or mental disabilities; uncontrolled epilepsy; fixed skeletal deformities; those who had surgical or local pharmacologic interventions related to muscles or bones of the lower limbs or spine; and those who had lower limb bone fractures in the past six months were excluded from the study.

A pilot study was carried out to determine the sample size using the Pediatric Evaluation of Disability Inventory (power 80%, confidence level 95%, margin of error 5%) revealing a sample size of 34 children.

Children were randomly allocated to one of the groups (1:1) using the sealed envelope method after baseline measurements were taken, and a blinded independent examiner performed all measurements.²¹

Intervention

The control group received conventional physical therapy (CPT) based on neurodevelopmental approaches and proprioceptive training involving training for weak muscles and stretching of tight muscles. Besides, exercise to improve postural control and gait. Each session lasts one hour, three times/week.

The study group, in addition to CPT, wore an orthotic undergarment strapping system (TheraTogs™ Inc., Telluride, USA). The guardians or parents of children were educated about wearing TheraTogs orthosis and received a video explaining the fitting of TheraTogs. Markings were made in TheraTogs to facilitate and improve fitting. The child wore 8–10 hours/day during daily life activities. A monitoring scheme for the application was applied and any emerging issues for fitting the orthosis were resolved. The program was administered for 12 weeks to both groups.²¹

Outcome Measures

Postural Stability Evaluation

The Biodex balance system (Balance System SD, Shirely, NY, US) was used to evaluate postural stability. The system measures the ability to maintain postural stability on an unsteady surface and neuromuscular control. It involves 12 stability levels (12 is the most stable and one is the least stable).²² An examiner (blinded to the children's assignment) tested all children for postural stability at baseline and 12 weeks post-treatment. During the assessment, the children were asked to maintain a centered position on a slightly unstable surface by shifting their feet until they could easily keep the cursor centered on a high-resolution color touch screen while standing. The child was instructed to keep his or her foot in place until the platform stabilized. The test started after the foot angles and heel coordinates were entered into the system. The child was instructed to keep their eyes focused on the visual feedback screen directly in front of them, keep both arms at their sides without grasping the handrails, and keep the cursor in the middle of the bull's eye. The test lasted 30s and was determined as the average of three tests. The results were printed after completion of the test. The overall, anteroposterior, and mediolateral stability indices were all included in the results. Higher values indicated a balance problem.²³

Functional Strength of Lower Limbs

We used the 30-s Sit-to-Stand Test²⁴ to evaluate the number of sit-to-stand movements the child could perform in 30 seconds. The test was performed on a child-sized chair with a height-adaptable seat (no backrest or armrest). The upper legs were parallel to the floor, the feet parallel to the ground (as flat as possible), and the trunk erect. The child was asked to stand up as erect as possible with a symmetric hip strategy ("flex hips and move the trunk forward until the shoulders are above the knee joint and then stand up"). Full movements (standing up and sitting down) were counted as one correct repetition.

Pediatric Evaluation of Disability Inventory (PEDI)

The PEDI is a clinical instrument used to evaluate functional abilities in children. The data were recorded through judgment-based parent-structured interviews. The PEDI measures capability (what a child can do) and performance of routine childhood activities in self-care, mobility, and social function domains. Six raw subscale scores were obtained: functional skills and self-care (FS-sc), Functional Skill mobility (FS-mo), Functional Skill social function; (FS-sf), caregiving assistance self-care (CA-sc), caregiving assistance mobility (CA-mo), and caregiving assistance social function (CA-sf).²⁵

Statistical Analysis

Subsequently, data were cleaned and coded. The normal data distribution was tested using the Shapiro–Wilk test. Group comparisons were performed using the Unpaired *t*-test for numerical variables and Chi-Square test for categorical variables. Paired and Unpaired *t*-tests were used to compare within- and between-group effects. All statistical analyses were performed using SPSS version 25 for Windows (IBM Corp., Armonk, NY, US). Statistical significance was set at $p < 0.05$.

Ethical Issues

The study was conducted following the Declaration of Helsinki and approved by the Research Ethics Committee of the College of Medical Rehabilitation Sciences, Medina, Saudi Arabia (CMR-PT-2022-09). Informed consent was obtained from the parents or guardians of all children involved in the study. This clinical trial has been registered at ClinicalTrials.gov (NCT05271149).

Results

Subject Characteristics

We enrolled 34 children (17 in each group) in this study. Both groups showed no statistically significant differences in demographic data and spasticity grades. Their mean age (8.3 ± 0.6 for the control group and 8.6 ± 0.7 for the study group, $p = 0.3$). Male: female (11/6 in the control group and 9/8 in the study group; $p = 0.5$). Body mass index (BMI) (17.52 ± 1.41 for the control group 18.4 ± 1.22 and for the study group, $p = 0.07$). Modified Ashworth Scale (1/ 1+) (10/7 for the control group and 9/8 for the study group, $p = 0.7$). GMFCS (I/II) scores (9/8 in the control group and 10/7 in the study group; $p = 0.7$).

Postural Stability Evaluation

There was a statistically significant improvement in the measured parameters of postural stability in both groups when the pre- and post-treatment mean values were compared. The mean values of the postural stability indices obtained from the baseline and post-treatment evaluations were statistically significant ($P < 0.05$) in both groups (Table 1). Significant differences were observed between the groups post-treatment in the stability indices of the postural stability test. These significant differences favored the study group.

30-s Chair Rise (Number of Sit to Stands)

The mean sit-to-stand values showed a statistically significant improvement following treatment ($p < 0.05$) in both groups. The TheraTogs group showed significant improvement in the number of sit-to-stand movements compared to the control group (Table 2).

Pediatric Evaluation of Disability Inventory (PEDI)

Both groups showed no statistically significant improvement when comparing their pre- and post-treatment mean values of PDEI scores except in the mobility domains. Both groups showed statistically significant improvement in the functional skill mobility score and the caregiver assistance mobility scores with no significant difference between the study and control groups (Table 3).

Discussion

The main results of this study showed that the postural stability (Table 1) and functional ability scores (functional self-care skills and caregiver mobility scores) (Table 3) improved in both groups following a 12-week rehabilitation program. Moreover, the number of sit-to-stands significantly increased in both groups (Table 2).

Compared to the CPT program, TheraTogs combined with the CPT program resulted in better muscle endurance seen as a significantly higher number of sit-to-stands post-treatment compared to the control group (Table 2).

It is well-established that physical therapy based on a neurodevelopmental approach improves balance and muscle strength.²⁶ The exercise program emphasizes developing weight shift and providing postural adaptations and alignment. Hence, improving equilibrium in all positions and normalizing mobility patterns, particularly in the trunk and lower limbs. The approach reinforces

Table 1 Biodex Balance Score in Children with Diplegic Cerebral Palsy Pre and Post-Intervention Results

Variable	Control Group				Study Group			
	Pre-treatment	Post-treatment	Mean difference (% of change)	p-value	Pre-treatment	Post-treatment	Mean difference (% of change)	p-value
Overall stability index	3.37 ± 0.17	2.76 ± 0.16	0.61 (18.1%)	0.001	3.39 ± 0.20	2.26 ± 0.17	1.13 (33.3%)	0.0001
Antero-posterior stability index	2.79 ± 0.15	2.27 ± 0.20	0.52 (18.63%)	0.001	2.86 ± 0.17	1.91 ± 0.16	0.95 (33.21%)	0.0001
Medio-lateral stability index	2.25 ± 0.29	2.02 ± 0.19	0.23 (10.22%)	0.001	2.33 ± 0.30	1.66 ± 0.117	0.67 (28.75%)	0.0001

Table 2 Comparison of the Mean Values of the 30-s Chair Rise (Number of Sit to Stands) in Both Groups

	30-s Chair Rise (Mean±SD)		t.	p-value
	Pre-Treatment	Post-Treatment		
Control group	8.88±1.866	9.71±1.79	14.22	<0.001
Study group	8.059±1.68	10.76±1.52	7.49	<0.001
t.	0.29	2.74		
p-value	0.774	0.010		

Table 3 Pediatric Evaluation of Disability Inventory (PEDI) Scores Pre and Post-Intervention in Both Groups

PEDI Scores	Control Group				Study Group				Control Group vs study Group			
									Pre-Treatment		Post-Treatment	
	Pre-Treatment	Post-Treatment	t.	p-value	Pre-Treatment	Post-Treatment	t.	p-value	t.	p-value	t.	p-value
FS_SC	38.55±6.45	39.01±6.42	1.49	0.156	41.03±5.30	41.29±5.57	1.42	0.17	1.47	0.62	3.55	0.49
FS_MO	35.31±7.49	41.83±5.63	3.64	0.001	37.08±6.01	45.47±7.63	4.46	0.01	0.75	0.26	1.58	0.41
FS_SF	44.59±8.55	45.85±8.01	1.24	0.116	44.32±8.76	44.83±6.32	0.98	0.23	0.93	0.51	1.02	0.27
CA_SC	25.977±6.638	25.98±6.64	0.207	0.839	25.52±7.26	25.96±6.83	1.37	0.18	0.19	0.79	0.23	0.18
CA_MO	22.68±5.07	26.34±4.33	1.27	0.001	25.76±4.03	30.05±4.43	4.49	<0.001	1.96	0.34	2.48	0.53
CA_SF	19.18±3.14	20.67±4.0	1.84	0.085	22.05±3.45	22.54±3.42	1.96	0.68	2.53	0.46	1.46	0.88

Note: Significance $p < 0.05$.

Abbreviations: PEDI, Pediatric Evaluation of Disability Inventory; FS-sc, Functional Skill self-care; FS-mo, Functional Skill mobility; FS-sf, Functional Skill social function; CA-sc, Caregiver Assistance self-care; CA-mo, Caregiver Assistance mobility; CA-sf, Caregiver Assistance social function; p-value, probability value. Pretreatment and posttreatment are presented as mean±standard deviation.

the muscle function and works through the inhibition of abnormal muscle tone and abnormal reflexes. Postural correction exercises work to restore the equilibrium between agonists and antagonists which recovers symmetry.²⁷

Previous studies reported similar results, Jung et al in their cross-over RCT investigated the immediate effects of TheraTogs on balance and gait and reported significant improvement of all balance variables (Sway path, sway velocity, and sway area) after wearing TheraTogs.²⁸ TheraTogs was reported to decrease trunk sway and increase trunk stability in a patient who had delayed healing of hip fracture.²⁹ Increased hip abduction and hence gait speed in stroke patients was also reported.³⁰ Flanagan et al found that TheraTogs improved joint alignment (pelvis, hip joint, and knee). Strapping the abdominal and back extensors provided core trunk stabilization and hence improved functional skills, in addition to balance and gait.³¹ El-Shamy et al studied the effect of electrical stimulation versus TheraTogs on balance and gait and reported that improvement with both treatments with electrical stimulation was more significant.²³

TheraTogs strappings exert tension, leading to improved extension of the trunk, knee, and hip joints, and inducing improvement in postural alignment.³² Improved trunk stability is crucial for trunk muscle coordination and the ability to maintain postural alignment and muscle control.²⁸ Wrapping the trunk and pelvic muscles with the TheraTogs garment continuously stimulated the antigravity muscles, while connecting the strap to induce symmetrical alignment of the trunk and lower limbs affected postural control, resulting in significant differences in the balance variables.²⁸

One of the essential objectives of rehabilitation programs is to improve quality of life and ensure participation in activities of daily life and social involvement, which maintain physical, psychological, and social balance.³³

In the current study, we found improved functional self-care skills and caregiver mobility scores posttreatment in both groups, which indicated improved functional abilities and a decreased need for assistance (Table 3).

Ehlert et al reported similar results. In their study, TheraTogs improved the posture, gait, and functionality.³² The improvement in PEDI mobility domain scores (functional skills and caregiver assistance) have also been reported in previous studies.³¹

This improvement in functional ability may be attributed to the trunk stabilization generated by TheraTogs, which helped maintain appropriate postural alignment and efficient movement control.³⁴ Improvement of mobility scores can be attributed to the reduction of spasticity which is prevalent in children with CP that passively affects motor learning and the acquisition of functional skills.^{35,36}

Wearing TheraTogs for a long time may exert a continuous inhibitory reflex over the hip's odd internal rotation and abduction. This effect works to facilitate the action of the antagonists of these muscles³⁷.

Our previous results indicated an increased six-minute walking distance post-treatment with TheraTogs.²¹

In this study, we did not observe any significant changes in independence (Table 3). Similarly, Ehlert et al reported that the child lost independence and required assistance while wearing TheraTogs and in toilet tasks, compared to that without wearing TheraTogs.³² Independence problems were associated with orthotic garments. These problems are attributed to the time required for fitting and unfitting as well as the heat generated using TheraTogs.^{31,38–40} A systematic review and meta-analysis reported that the physical components of QOL were more affected in children with CP, whereas the psychological components showed inconsistent results.¹⁸

A cross-sectional study in Sudan found that QOL was severely affected in children with CP and their caregivers. Overall scores and individual domains were affected.⁴¹ Rehabilitation programs aim to improve all domains of QOL, including the physical and social components.³³ Improved functional ability and decreased need for assistance are important factors for improving quality of life.⁴² Several studies have reported impaired QOL in caregivers of children with CP.^{43,44} Physical disabilities in children with CP are the main factors behind impaired QOL in children and their families due to functional disabilities and decreased participation in social life.⁴³ The improved functional ability and caregiver assistance found in this study, even in mobility scores, is a good indicator that rehabilitation programs could be a factor in improving the quality of life of children with diplegic CP.

Conclusion

This study found that following treatment both groups showed improvement in postural stability and the PEDI functional skill mobility and caregiver assistance mobility sub-scores. There were no significant improvements in self-care or social functioning. The study group showed significant improvement in muscle endurance that is observed as a higher number of 30s sit-to-stands.

Future studies evaluating long-term impact and individual QOL domains including mental and cognitive function with a detailed analysis of daily life activities are warranted.

Data Sharing Statement

The datasets generated and/or analyzed during the current study are available from the corresponding author upon reasonable request.

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Disclosure

The author(s) report no conflicts of interest in this work.

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