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Efficacy of TheraTogs orthotic undergarment on modulation of spinal geometry in children with diplegic cerebral palsy

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Abstract

Background: The use of TheraTogs orthotic undergarments has been suggested to improve the ability to stabilize the posture, to correct or prevent deformities, to improve functionality, and to enable the user a more appropriate functional pattern. The aim of this study was to investigate the efficacy of TheraTogs orthotic undergarment on modulation of spinal geometry in children with diplegic cerebral palsy. Forty children with diplegic cerebral palsy, with ages ranging from 6 to 9 years, were selected for this randomized controlled study. They were randomly assigned to (1) an experimental group that received TheraTogs orthotic undergarment (12 h/day, 3 days/week) plus traditional physical therapy for 3 successive months and (2) a control group that received only traditional physical therapy program for the same time period. Spinal geometry was measured at baseline and after 3 months of intervention using the Formetric system.

Results: Children in both groups showed significant improvements in the spinal geometry ($P < 0.05$), with significantly greater improvements in the experimental group than the control group. The post-treatment mean values of lateral deviation (mm), pelvic tilt (mm), trunk imbalance (mm), and surface rotation (mm) were 5.45, 6.35, 8.8, and 3.65 and 8, 8.9, 11.2, and 5.9 for the experimental and control group, respectively.

Conclusions: TheraTogs orthotic undergarment may be a useful tool for improving spinal geometry in children with diplegic cerebral palsy.

Trial registration: This study was registered in the [ClinicalTrial.gov](https://clinicaltrials.gov/ct2/show/study/NCT04271618) PRS (NCT04271618).

Keywords: Cerebral palsy, Diplegia, TheraTogs, Orthotic undergarment, Spinal geometry

Background

Cerebral palsy (CP) describes a group of permanent disorders of movement and posture that result from non-progressive disturbances in the developing fetal brain. Although the pathophysiology of CP is nonprogressive, musculoskeletal structures often deteriorate with advancing age. Tightness of spastic muscles, spinal mal-

alignment, and joint contractures are common and significant CP-related problems in children [1].

Spastic diplegia is the most prevalent type of CP, and it accounts for about 44% of the total incidence of CP and represents 80% of affected preterm infants [2]. Children with spastic diplegia have significant weakness in the trunk and spasticity of the extremities. The primarily functional problem includes difficulty with mobility and posture. Other problems include postural deviations such as inability to sit without support, inability to stand, and difficulty in movement transition [3, 4].

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The development of spinal deformities is very common in children with CP with prevalence proportionate to the degree of neurological involvement. The deformity can cause back and rib pain, as well as affect the children's sitting balance and ability to function [5].

Spinal deformities are often flexible in the early stages, but may rapidly become fixed. Deformities which start in early childhood are liable to become more severe and more rigid and result in greater cardiopulmonary compromise than those develop in late childhood. Spinal deformities in CP have a greater risk of curve progression after skeletal maturity than non-neuromuscular spinal deformities [6].

The objective of the management of spinal deformities in children with CP is to maintain or improve the children's functional abilities, as well as the quality of life. The decision-making for treatment must be tailored to the individual patient and should be based on a meticulous risk-benefit assessment depending on the severity of co-existing medical morbidities. The treatment protocols include both conservative management and surgical treatment. Conservative treatment includes seating adaptations as well as the use of spinal braces. The tight fitting of a conventional firm spinal brace may cause skin irritation, respiratory compromise, exacerbation of gastro-esophageal reflux, and feeding disorders, as well as lead to poor child compliance [5, 6].

TheraTogs™, an orthotic undergarment invented from Delta-flex, a lightweight, breathable fabric that is Velcro-sensitive, has been advanced to provide a soft, passive force to gain balance or restore normal alignment through a mix of a chest and shorts system along with a customized external strapping system. TheraTogs strapping system could modify and manipulate components of the musculoskeletal and sensory systems to accomplish corrected biomechanical alignment, increase proprioceptive input which improve percept of correct spatial orientation, and increase trunk stiffness, which improved proximal stability and reduce the number of body segments needed to coordinate when trying to balance and move [7, 8]. Therefore, from the previously mentioned claimed theoretical effects of TheraTogs on postural alignments, the aim of this study was to evaluate the effects of TheraTogs orthotic undergarment and strapping system on modulation of the abnormal spinal geometry in children with diplegic CP.

Methods

Design

This randomized controlled study was approved by the Ethical Committee of the Faculty of Applied Medical Sciences, Umm Al Qura University (19-MED-1-01-0005). Parents signed a consent form approving the children participation. Participating children were enrolled from

the physical therapy department, Maternity and Children Hospital, Makkah, Saudi Arabia. This trial was registered in the [ClinicalTrials.gov](https://www.clinicaltrials.gov) PRS (NCT04271618).

Participants

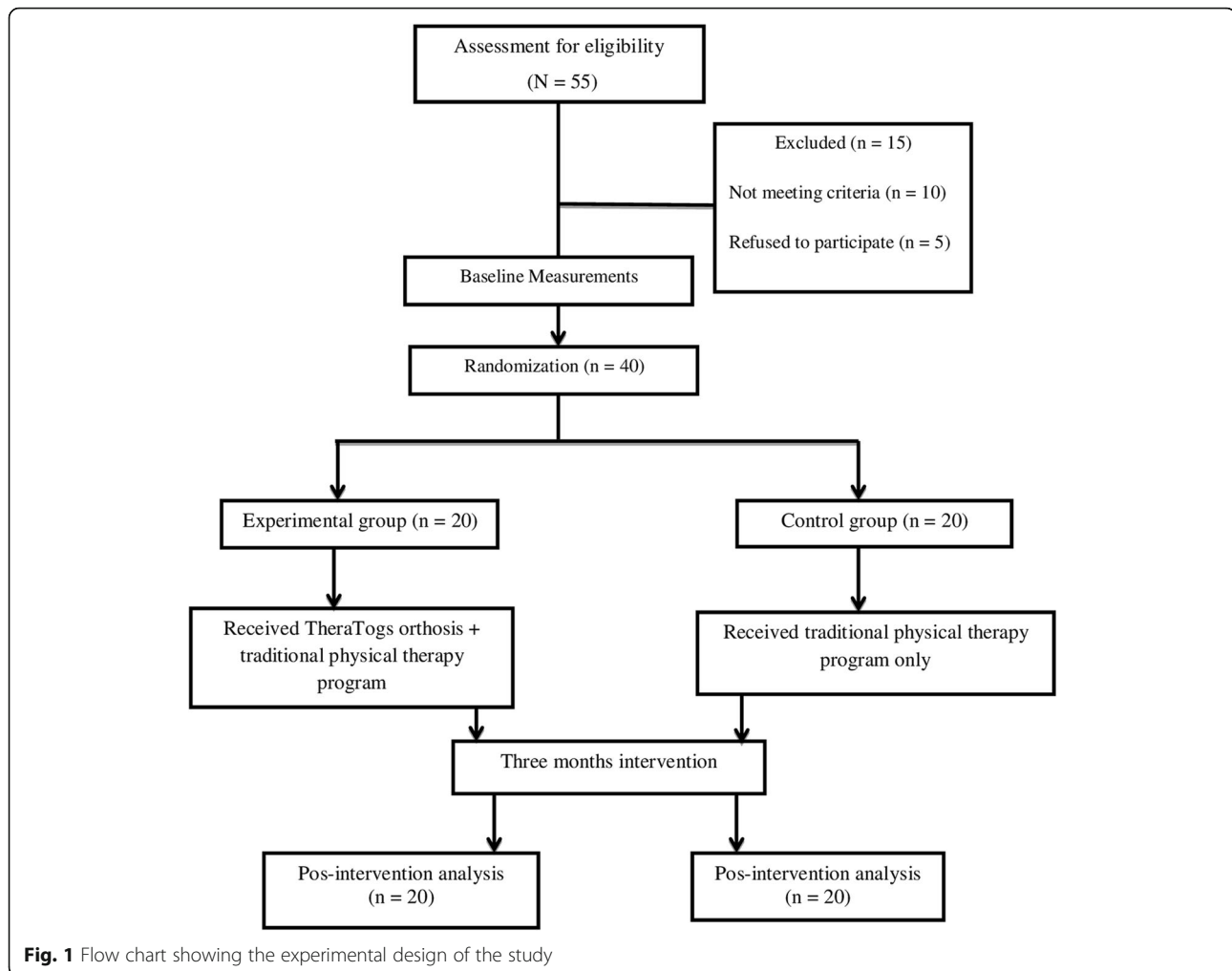
This study included 40 children diagnosed with spastic diplegic CP and classified as level I or II on the Gross Motor Function Classification System (GMFCS). A sample size of 40 was determined to avoid type II error in a preliminary power analysis (power = 0.8, α = 0.05, effect size = 0.5). The criteria for inclusion in this study were age between 6 and 9 years, ability to stand alone, spasticity scores were ranging between 1 and 2 on Modified Ashworth Scale (MAS), the ability to understand and follow simple verbal instructions, and their height should be more than 100 cm to fit with the Formetric system that will be used in this study to evaluate the geometry of the back surface. The exclusion criteria were children who have skin diseases or allergic reactions to adhesive tape or any other materials used in this study; children with visual, auditory, or perceptual deficits; children with surgical interference for the lower limb and spine in the preceding 12 months; children with seizures or epilepsy; children with fixed spinal deformities; and use of medications (e.g., steroids) known to affect growth or body composition. During the study, children did not receive any treatment to improve the sagittal geometry of the back surface other than the study intervention. They did not participate in any previous trials with orthotic undergarment, adhesive tape, or spiral strapping to the lower limbs and axial trunk.

Randomization

Fifty-five children with diplegic CP were recruited for this study. Ten children failed to meet the inclusion criteria, and the parents of five children refused to participate in this study. The randomization process was performed using sealed envelopes. The investigator prepared 40 sealed envelopes, which contained a piece of paper indicating whether each participant was in the experimental group (TheraTogs) or the control group (traditional treatment). The randomization process was carried out by a registration clerk who was not involved in any part of the study. The experimental design of this study is shown in Fig. 1.

Procedures

All children were evaluated for spinal geometry before the treatment and at the end of 3 months of treatment by the same examiner, who was blinded in regard to the group to which each child was assigned.



Spinal geometry evaluation

Spinal geometry evaluation was conducted using the Formetric 4D dynamic system (DIERS Medical Systems Inc., Chicago, IL, USA) (Fig. 2). The DIERS Formetric 4D analysis system permits rapid static and dynamic optical measurement of the human back and spine. It has high validity and high intraclass correlation coefficient (ICC) in measuring spinal deviations [9]. The procedure is radiation-free and operates without contact. Numerous clinical parameters for objective analysis of body statics, posture, scoliosis, and all forms of spinal deformities can be shown. The new 3D technology leads into functional clinical measurement technology, to increase measurement precision (4D averaging) and to avoid postural variances [10].

Spinal geometry evaluation was conducted in a warm and quiet room before and after 3 months of treatment. Child data were entered in his/her file on the computer including date of birth, name, sex, height, and weight. Each child was asked to stand facing the black background screen at a distance of 2 m away from the scan

system on the ground. The horizontal line of the scan system should lie below the inferior angles of scapulae. It is important that the child's back was completely bare to avoid disturbed image structures. Each child was asked to assume the usual natural standing attitude with chin in to improve the presentation of the vertebral prominence. The child was also asked to keep his/her both upper extremities freely extended beside the body as much as possible. Height adjustment of the optical column was done before capturing to obtain the suitable image. When the camera was ready for image recording, a green horizontal line appeared on the computer screen and the projector lamp was automatically switched. The scanning time was very short (30 ms); in order to eliminate movement artifacts during capture, the child was asked to hold on breath.

Full back shape 4D analysis was recorded and printed out for each child. Through one capture, the following parameters were measured: lateral deviation (represents the root mean square lateral deviation of the spinal midline from the line VP-DM), trunk imbalance (represents



Fig. 2 Formetric 4D body scan system

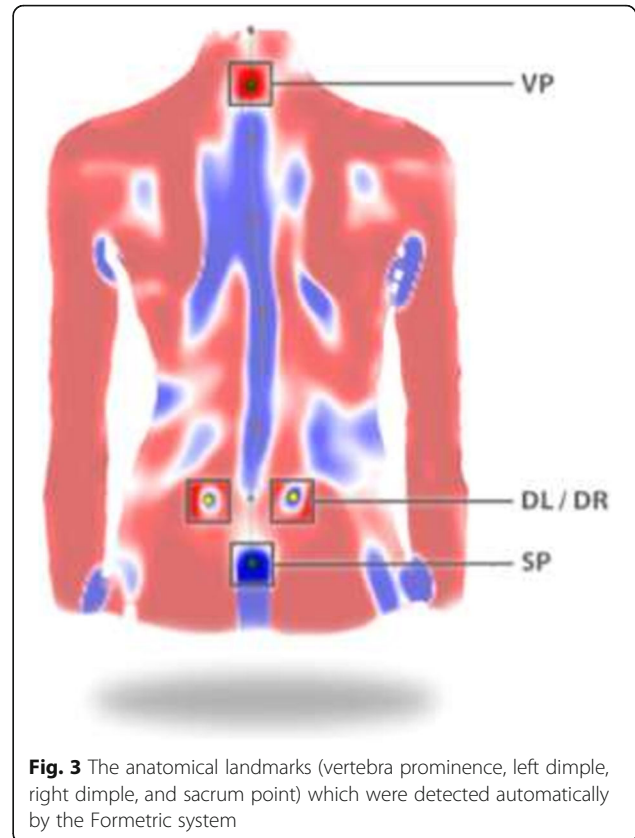


Fig. 3 The anatomical landmarks (vertebra prominence, left dimple, right dimple, and sacrum point) which were detected automatically by the Formetric system

the lateral deviation of the VP from DM), pelvic tilt (refers to a height difference of the lumbar dimples relative to a horizontal plane (DL-DR), and surface rotation (represents the root mean square of the surface rotation on the symmetry line) (Fig. 3). All values are measured in millimeters; in a healthy child, it should be zero [11, 12].

Interventions

The control group received the traditional physical therapy training program, which includes exercises without any orthotic intervention. The experimental group received the same program as the control group, plus TheraTogs orthotic undergarment and strapping system. The traditional physical therapy training program included reflex-inhibiting patterns for both lower limbs; stretching exercises for both hip flexors and adductors, knee flexors, and ankle plantar flexors; strengthening exercises for muscles of the trunk and both lower limbs; facilitation of postural reactions (righting, equilibrium, and protective reactions); proprioceptive training; and gait training (2 h/day, 3 days/week for 3 consecutive months).

TheraTogs orthotic application

Children in the experimental group received the strapping technique using TheraTogs orthotic undergarment

strapping system (TheraTogs™ Inc., Telluride, USA) (Fig. 4). TheraTogs are made of a patented, proprietary, machine washable, compose fabric consisting of nylon and spandex with an inner foam that gently grips the skin and the underlying soft tissues and a Velcro-sensitive outer layer to which therapist can affix elastic strapping to effectively influence the patient's movement, stability, posture, and gait. A TheraTogs orthotic undergarment consists of a sleeveless tank-top and two shorts (Hipster) each with two thigh cuffs and limb cuffs. All parts are fabricated from nylon and spandex with a foam layer made of aqueous-based elastomeric urethane and a variety of elasticized straps. They are designed to be worn directly on the skin as undergarments that allow unimpeded toileting.

A properly fitted TheraTogs system gives the wearer a comfortable, breathable Latex-free "second skin" on his torso and thighs, providing vertical stiffness to reinforce postural stability and horizontal stretch for child compression and a comfortable fit. The following precautions should be considered when applying this strapping technique: the child should be comfortable without feeling constriction, itching, or circulatory impairment. The garments should be snug against the skin, with no significant gaps, folds, or loose material. Well-fit garments are snug enough that they effectively grip the wearer's



Fig. 4 TheraTogs Orthotic undergarment and strapping system

skin, without slipping. Each child will have his own TheraTogs orthotic undergarment and it will not be allowed for any child to share his orthosis with others for several reasons: to avoid any infectious disease transformation; each child has its special size which may not fit with other; the way of fitting and strapping technique will differ from one child to other according to his case and degree of spinal deformity and angulations.

The wearing schedule for this study was adopted and modified from Flanagan et al. [7]. Children in the experimental group wore TheraTogs orthotic undergarment and strapping system under their usual clothes so it was not annoying or disturbing. One week before starting the training program, only the experimental group wore their TheraTogs as a preparatory stage without application of any exercise program with gradually increasing the worn time till reaching the 12 h per day, to allow the children to become acclimated to it.

The TheraTogs was applied in the experimental group after appropriate and accurate pre-treatment evaluation. Throughout this week also, the therapist properly educated at least one of the family members on how to fit the TheraTogs orthosis to the child and how to apply the strapping technique for the involved limb. Written and photographic instructions were provided. TheraTogs suits were marked to ensure consistent application of strapping attachments.

Statistical analysis

For all measured parameters, a comparison of assessments before and immediately after the treatment in each group (experimental or control) was performed using a paired *t*-test. The comparison of assessments between both groups before and immediately after the treatment program was carried out using an unpaired *t*-test. The Statistical Package for the Social Sciences (SPSS) version 20.00 was used for data analysis. *P* values less than 0.05 were considered to be statistically significant.

Results

Forty children with diplegic CP (21 boys and 19 girls) were included in this study. The children were randomly assigned to one of two equal-sized groups ($n = 20$ each). The demographic and clinical characteristics of the children were similar in both groups (Table 1).

Pre-treatment measurements revealed no significant differences in the mean values of spinal parameters (lateral deviation, trunk imbalance, pelvic tilt, and surface rotation) between the experimental and control groups ($P = 0.34$) (Table 2). However, there was a significant difference between the mean values of spinal parameters obtained pre-treatment and post-treatment assessments ($P < 0.001$). The children in the experimental group exhibited improvement in their spinal geometry compared to the improvement in the control group (Table 2).

The percentage of change between the pre- and post-treatment values of spinal parameters for the experimental and control groups indicated that the experimental group showed a higher significant improvement than the control group in spinal geometry as shown in Fig. 5.

Discussion

The results of this study indicated that a program of combined TheraTogs orthotic undergarment and physical therapy produced better improvement in spinal geometry compared with a 3-month program of physical therapy alone. Improvement was noted in both groups in spinal geometry after 3 months of treatment. However, higher improvement was achieved in the experimental group.

The intervention used in this study was designed to be used 12 h/day and, thus, could be incorporated into the many functional activities that the child encountered in everyday life [7]. The aim was to quantitatively determine the effects of TheraTogs orthotic undergarment on spinal geometry in children with diplegic CP.

TheraTogs is a new aids material and therapy concept for correction of trunk and extremities with moderate mal-alignment. The fabric can be arranged between pure proprioceptive bandages and firm cotton fabrics with

Table 1 Pre-treatment characteristics of participants

Characteristics	Experimental group (n = 20)	Control group (n = 20)
Age (yr), mean (SD)	8.12 (0.88)	7.85 (1.06)
Weight (kg), mean (SD)	29.15 (2.13)	28.5 (2.18)
Height (m), mean (SD)	1.30 (2.28)	1.29 (2.20)
Gender		
n male (%)	12 (60%)	9 (45%)
n female (%)	8 (40%)	11 (55%)
MAS, n (%)		
1	7 (35%)	5 (25%)
1+	8 (40%)	9 (45%)
2	5 (25%)	6 (30%)
GMFCS, n (%)		
I	11 (55%)	8 (40%)
II	9 (45%)	12 (60%)

MAS Modified Ashworth Scale, GMFCS Gross Motor Function Classification System

elastic elements. The utilization requires training and time [13].

The significant improvement in the spinal geometry in the experimental group could be explained by the effect of TheraTogs and the strapping system in managing spinal deviations. This dynamic splinting is certainly a viable and useful physical therapy intervention tool for the management of mechanical mal-alignment and poor postural control in children with CP. Many researchers proposed that TheraTogs would provide the foundation for increasing proprioceptive and tactile facilitation, controlling trunk movement in the frontal and sagittal planes, restoring optimal muscle length to provide a foundation for normal firing and recruitment patterns,

orienting the muscle force along more normal vectors, and finally assisting with static and dynamic balance [14–18].

Wearing TheraTogs orthotic undergarment during physical therapy treatment assists the muscle action by helping the correction of the soft tissues and muscle imbalance, and realigned the position of the joints [19]. This comes in agreement with previous studies [20, 21]; they stated that the use of soft orthosis can assist weak muscles and correct abnormal body positions or movement patterns from non-structural sources.

The results of this study come in agreement with Flanagan et al. [7], who found that TheraTogs worn for a

Table 2 Pre- and post-treatment mean values of lateral deviation, pelvic tilt, trunk imbalance, and surface rotation within each group and between groups

Parameters		Experimental group	Control group	95% confidence interval of the difference		P-value
				Lower	Upper	
Lateral deviation (mm)	Pre	8.95 (1.9)	9.47 (1.55)	-1.63	0.58	0.34
	Post	5.45 (1.14)	8 (1.25)	-3.31	-1.78	<0.001
	P-value	<0.001	<0.001			
Pelvic tilt (mm)	Pre	10.8 (1.47)	11.4 (1.63)	-1.59	0.39	0.23
	Post	6.35 (1.18)	8.9 (1.25)	-3.32	-1.77	<0.001
	P-value	<0.001	<0.001			
Trunk imbalance (mm)	Pre	15.25 (1.33)	14.75 (1.55)	-0.42	1.42	0.281
	Post	8.8 (1.15)	11.2 (1.47)	-3.24	-1.55	<0.001
	P-value	<0.001	<0.001			
Surface rotation (mm)	Pre	6.6 (1.42)	7.25 (1.83)	-1.7	0.4	0.218
	Post	3.65 (1.03)	5.9 (1.37)	-3.02	-1.47	<0.001
	P-value	<0.001	<0.001			

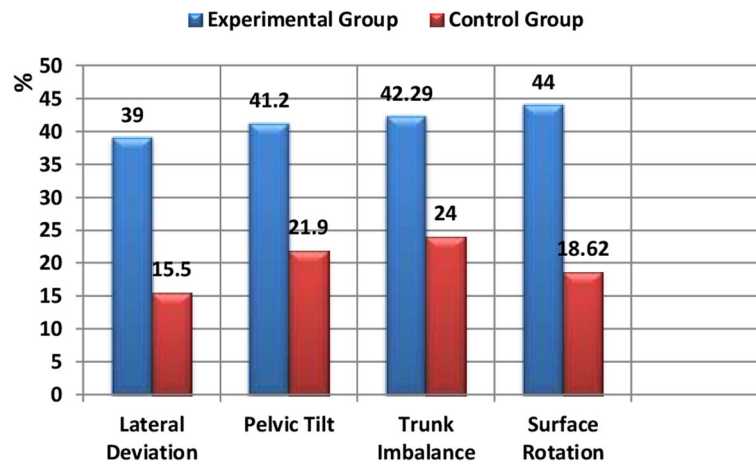


Fig. 5 Percentage (%) of change between pre- and post-treatment values of spinal geometry for the experimental and control groups

successive 12-week period, 12 h daily could improve gait and functional skills in some children with diplegic CP. This also agrees with Ehlert et al. [22], who reported that TheraTogs soft garment with the strapping system could improve temporal/distance gait factors, functional abilities, and range of motion in some children with diplegia when applied over an 8-week time period [23, 24].

The results of this study come in agreement with that of Abd El-Kafy and El-Shemy [25]; they concluded that wearing TheraTogs orthotic undergarment and strapping system during standing and walking might be helpful in minimizing the future development of rotational deformities of affected lower extremities and in improving gait parameters in children with diplegic CP. They also agree with Abd El-Kafy [26], who concluded that using TheraTogs spiral strapping during treatment of children with CP over 12 weeks leads to a greater improvement in their gait than using conventional treatment without TheraTogs.

Maguire et al. [27] reported the benefits of using TheraTogs in decreasing the trunk sway and increasing the trunk stability in a patient with delayed healing post-hip fracture. In this patient, the function and recovery rate of all measured parameters increased more in the TheraTogs phase than in the crutches or no-aids phase. This may be because muscle activity was facilitated enabling active support of recovering structures.

The findings of this study agree with that of El Fiky et al. [16]; they revealed that using TheraTogs for a long period might act as a continuous reflex-inhibiting pattern for the abnormal internal rotation and adducted hip pattern of the involved spastic limb. This inhibitory mechanism might help in dampening the continuing reciprocal inhibiting pattern of these overexcited groups on the antagonist groups facilitating their action [16].

Limitations of this study include the lack of follow-up data, which restricts the applicability of our findings on the long-term effects of TheraTogs. The effect of physical therapy program in both groups limits the ability to isolate the contribution of the TheraTogs alone. The age (6–9 years) and height (more than 100 cm) of the selected children limit the generalization of the results of this study. The lack of assessment of functional impacts is another limitation of this study. The results of the present study are encouraging but other studies with larger samples, long-term findings, and possible comparisons with other conservative interventions are needed. Future studies investigating the effect of TheraTogs and its role in improving gait and balance in children with CP may be useful to guide clinical practice.

Conclusions

TheraTogs orthotic undergarment in combination with traditional treatment may increase improvements in spinal geometry in children with diplegic CP.

Abbreviations

CP: Cerebral palsy; GMFCS: Gross Motor Function Classification System; MAS: Modified Ashworth Scale; ICC: Intraclass correlation coefficient; VP-DM: Lateral deviation (represents the root mean square lateral deviation of the spinal midline from the line); DL-DR: Pelvic tilt (refers to a height difference of the lumbar dimples relative to a horizontal plane)

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Authors' contributions

EMA and SME conceived and designed the study and conducted the data collection. EMA and SME analyzed and interpreted the data in addition to reviewing the final results. EMA and SME provided logistical support and wrote the initial and final drafts of the article. EMA and SME are responsible for the findings and have critically reviewed and approved the final draft of the article. All authors have read and approved the final manuscript.

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Availability of data and materials

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

Declarations**Ethics approval and consent to participate**

The study was approved by the Ethical Committee of the Faculty of Applied Medical Sciences, Umm Al-Qura University (19-MED-1-01-0005). Parents of all participants signed a written informed consent before starting the study.

Consent for publication

N/A

Competing interests

The authors declare that they have no competing interests.

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