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Combined effect of orthotic intervention and conventional exercise training on balance and gait performance in cerebral palsy: a randomized controlled trial

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Abstract

Background: This study aimed to examine the combined effect of orthotic intervention and conventional therapeutic exercise training on balance and gait performance in children with cerebral palsy. This study was a randomized control trial. Forty children with dyskinetic cerebral palsy of both genders with ages ranged from 12 to 16 years were included. Participants in the control and study groups received a conventional therapeutic exercise training program for two 2 h ours per session. The treatment program was conducted three sessions per week, for twelve 12 successive weeks. Children in the study group additionally wore TheraTogs orthotic undergarment with the strapping system. Pediatric Balance Scale score and postural stability indices (overall, anteroposterior , and mediolateral) evaluated by the Biodex Balance System were assessed (in both groups) at baseline and after 12 weeks of treatment. The changes of step length, gait cycle time, cadence, and velocity were also measured by an electronic walkway.

Results: Children in the study group showed significant improvements in the scores of all the measured variables post-treatment compared to the control group ($P < 0.05$). The P -values for overall, anteroposterior and mediolateral postural stability indices were 0.011, 0.014, and 0.021, respectively. The P -values for Pediatric Balance Scale score, step length, gait cycle time, cadence, and velocity were 0.001, 0.023, 0.041, 0.011, and 0.013 respectively.

Conclusions: Conventional therapeutic exercise training combined with orthotic intervention were more effective in improving balance and gait performance in children with dyskinetic cerebral palsy.

Trial registration: The ClinicalTrial.gov PRS (NCT04990193).

Registered 4 August 2021 - Retrospectively registered.

Keywords: Cerebral Palsy, Orthoses, Strapping, Trunk Control, Balance

Introduction

Dyskinetic type of cerebral palsy typically results from extrapyramidal and basal ganglia damage. The most common dyskinetic movement disorders are choreoathetosis and dystonia [1]. Their clinical features include fluctuation of muscle tone, involuntary and in-coordinated movement, and posture instability. These features have significant negative impacts on the children's quality of life and performance of daily activities [2]. Choreoathetosis is characterized by hyperkinetic movement. Chorea is involuntary, fast, dysrhythmic, and frequently interrupted movements, while movement associated with athetosis is slower, snake-like, writhy, and constantly varied [3].

Poor postural control often features children with dyskinetic cerebral palsy. They frequently show axial

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body instability and limited range of motion in many joints resulting in atypical posture alignmnet in sitting, standing, and walking. This abnormal posture has enforced them to use a substitutional posture or slow down their movement speed to execute their intended voluntary action which inturn negatively influences their balance and gait performance [4–6].

Management strategy for children with dyskinesia requires both medical and rehabilitative treatment [1]. The therapeutic modalities used for their rehabilitation need more evidence to be certain of their efficacy [7–10]. Moreover, further researches are necessary to explore new conservative therapeutic protocols and techniques that should contribute to addressing postural instability and improve poor mobility of these children. They are also needed to improve their functional activities and facilitate their societal participation [11].

TheraTogs orthotics undergarment and the strapping system are made from a soft, lightweight, breathable material. It has been manufactured to supply an amiable, external force to modify and adjust the posture [12]. TheraTogs and strapping system has been recommended to enhance body awareness, improve postural stability, facilitate balance performance, and increase movement efficiency [13, 14]. It is also used to modulate postural deformities and promote appropriate functional activities [15, 16]. The objective of this study was to examine the effectiveness of TheraTogs soft orthotic undergarment and strapping system accompanied with conventional exercise training on balance and gait performance in children with dyskinetic cerebral palsy.

Methods

Study design

The research design of this study was a randomized control trial. It was approved by the Ethics Review Committee of the Ethics Review Committee of the Faculty of Applied Medical Sciences - Umm Al Qura University. This trial was registered in the ClinicalTrial.gov PRS (NCT04990193). Children's parents signed a consent for permitting the engagement of their children in this study. The study was proceeded according to the Declaration of Helsinki of 1975, as revised in 2013. The study was conducted in the Department of Physical Therapy - Umm Al Qura University. The involved children were recruited from kingdom of Saudi Arabia - western region. The organization responsible for the integrity, conduct and financial support of this study was the Deanship of Scientific Research at Umm Al Qura University - Grand Code (19-MED-1-01-0004).

Participants

Children of a confirmed diagnosis of dyskinetic cerebral palsy of choreoathetosis type were selected to participate in this study. The diagnosis was confirmed by magnetic resonance images obtained from medical records or personal physicians. These children (of both genders) were between 12 and 16 years old. Their height and weight were more than 100 cm and 20 kg, respectively, to be eligible for the evaluation process on the Biodex stability system.

Children were able to comprehend and follow orders. Children with level I and II Gross Motor Functional Classification System (GMFCS) were recruited to participate in the study [17]. They were able to walk 10 m openly without any orthoses. So that they were able to perform the gait evaluation procedures. Participating children were not subjected to any other physical therapy programs throughout the study period except the assigned treatment protocol.

The children were excluded from this study if they had fixed spinal deformities interfering with their spinal and limb functional mobility. Children were also excluded if their skin were sensitive or inflamed to any materials used. Children who had seizures, perceptual disorders, visual problems, and auditory deficits did not participate as well.

Sample size and randomization

A sample size of 40 participants was calculated for this study based on a preliminary power analysis (power = 0.8, $\alpha = 0.05$, effect size = 0.5, groups = 2 and evaluation times = 2) [10–13]. The total number of participants was raised to 56 for anticipation of withdrawals. The participants were divided equally into two groups: control and study groups.

The randomization process was performed by an independent person who was blinded to the study procedures. It was performed simply by adding a specific identification number for each participating child. SPSS program (version 25) was used to randomly assign children to both groups.

Assessments

Assessments of the children with dyskinesia were conducted by blinded evaluators who didn't participate in the application of intervention and were also blinded from the randomization process. The evaluation was carried out to assess the following outcome measures: (1) Overall, anteroposterior and mediolateral stability indices (%) of Postural Stability Test from standing position at the static mode of platform tilt, (2) Pediatric Balance Scale score, and (3) gait parameters including step length (cm), gait cycle time (s), cadence (steps/min) and velocity (m/s). The evaluation process was conducted at both baseline and immediately after 12 weeks of intervention.

Biodex Balance System SD (BBS; Biodex Inc., Shirley, NY) measured stability indices (%) of postural stability test from standing position at the static mode of platform tilt with high reliability and validity [18]. The postural stability indices were measured to evaluate the children's capabilities to control their balance in different directions. The higher the indices values (%) were recorded, the less stability the children had, and the children had balance control difficulties.

The Pediatric Balance Scale is a valid and reliable test to assess and re-assess balance deficits in children with mild and moderate motor disabilities. The test includes fourteen tasks that evaluate balance abilities and motor performance in children. 0–4 is the rating score for each item, where 0 is the lowest score and 56 is the highest possible score for all tasks that indicate the best balance and motor performance ever [19].

An electronic walkway (GaitRite , CIR Systems Inc., New Jersey, USA) connected to a portable computer was used to measure the gait parameters (step length, gait cycle time, cadence, and velocity). The length of the GaitRite walking mat was about 5 m. The electronic walkway GaitRite is a reliable and valid tool for analyzing spatial and temporal gait parameters in children with cerebral palsy and Gross Motor Function Classification System—level I or II [20]. Children were requested to walk barefoot along the walkway. Each participant was asked to start walking 3 m far from the walking mat to reach his/her natural walking pattern before the actual measurement. Three trials were performed and the average measurment of them was calculated.

Interventions

Children in both groups (control and study) received the conventional therapeutic exercise training protocol, which was designed, to improve trunk steadiness during standing and walking. The exercise training protocol for both groups is fully outlined in Appendix 1

The conventional therapeutic exercise training protocol for every child was three sessions per week for 12 consecutive weeks. The interventions were performed by two experienced physical therapists. Every treatment session was conducted for 2 h with a 15-min rest between the two training hours.

The children in the study group received the conventional exercise protocol given to the control group. Moreover, they wore TheraTogs orthotic undergarment with the strapping system 8 h every day for 12 consecutive weeks.

A TheraTogs orthotic undergarment and its strapping system developed by Cusick, 1997 is composed of a sleeveless Tank-Top (vest) and two shorts (Hipster), each with two thighs and limb cuffs [12]. All parts are fabricated from nylon and spandex with a foam layer and a variety of elasticized straps. They are designed to be worn directly on the skin as undergarments that allow unobstructed toileting. A TheraTogs system provides the wearer a vertical compression and stiffness to support posture, and reinforce stability.

Each child had his/her own TheraTogs orthotic undergarment and strapping materials. It was not allowed for any child to share his/her orthosis with others to avoid any infectious disease transfer. In this study, the participating children wore the TheraTogs and strapping system under their regular dresses, so it was not annoying or disturbing.

A pre-training period, before starting the treatment program, was given to all participating children for preparing them to get used and endure the wearing of the TheraTogs orthotic undergarment and strapping system. The pre-training period lasted for 14 days. During which the wearing period gradually increased from 1 h at the beginning of the course until reached 8 h by the fourteenth day. The rate of wearing period increment was 1 h every 2 days. This pre-training period was completed 1 week before starting the treatment program. If any participating child failed to follow this regimen, the training was repeated again until the child reached the 8 h of daily wearing the TheraTogs system. This pre-training course was completed one week before starting the treatment program.

Throughout this pre-training period, the therapist who is responsible for the strapping protocol trained one of the child's family members on (1) how to fit the TheraTogs orthosis to his/her child, and (2) how to apply the prescribed strapping technique for the involved body parts. By the end of this training, the therapist made sure of the skills of this member in the application of the TheraTogs strapping protocol before the actual beginning of the treatment program.

It was not allowed to start the treatment program with TheraTogs and strapping until making sure of the family member's skill and proficiency in providing the prescribed TheraTogs protocol. Any member who was not successful in this preparatory course was retrained again. The therapist daily followed up the process of wearing TheraTogs and strapping by telephone with this member and made sure that the process was completed successfully. This daily communication continued throughout the treatment period (12 weeks).

The fitting and strapping techniques of the TheraTogs system for all participating children in the study group are fully outlined in Appendix 2.

Statistical analysis

The statistical analysis for all recorded scores pre-and post-treatment was reported as mean ± standard deviation (SD). The Shapiro-Wilk test and the Levine's test were used to test the variables' normal distribution and variances homogeneity, respectively. The data of this study were homogeneous and normally distributed. The comparison between both groups, pre-and immediately post-treatment, was carried out by using unpaired *t* test. Recorded data were analyzed by using SPSS computer program version 25.00. *P* values less than 0.05 were accepted to represent a statistical significance.

Results

A total of 40 children out of 56 recruited children with dyskinetic cerebral palsy were met the inclusion criteria and participated in different study processes. The study flow chart is illustrated in Fig. 1. The baseline demographic characteristics of the participants are outlined in Table 1.

The findings of this study, as elucidated in Table 2, indicated significant differences between both groups post-treatment in the overall, anterolateral, and mediolateral stability indices (%) of postural stability test, and the total score of the pediatric balance scale. These significant differences were in favor of the study group.

Table 2 also showed that there were significant differences between both groups post-treatment when comparing the mean values of gait parameters, step length (cm), gait cycle time (s), cadence (steps/min), and velocity (m/s) in favor of the study group.

Discussion

The findings of this study showed significant differences in all measured variables post-treatment in favor of the study group than the control group. These differences reflected the effectiveness of the conventional exercise training and TheraTogs orthotic undergarment with its strapping system on augmenting trunk stability.

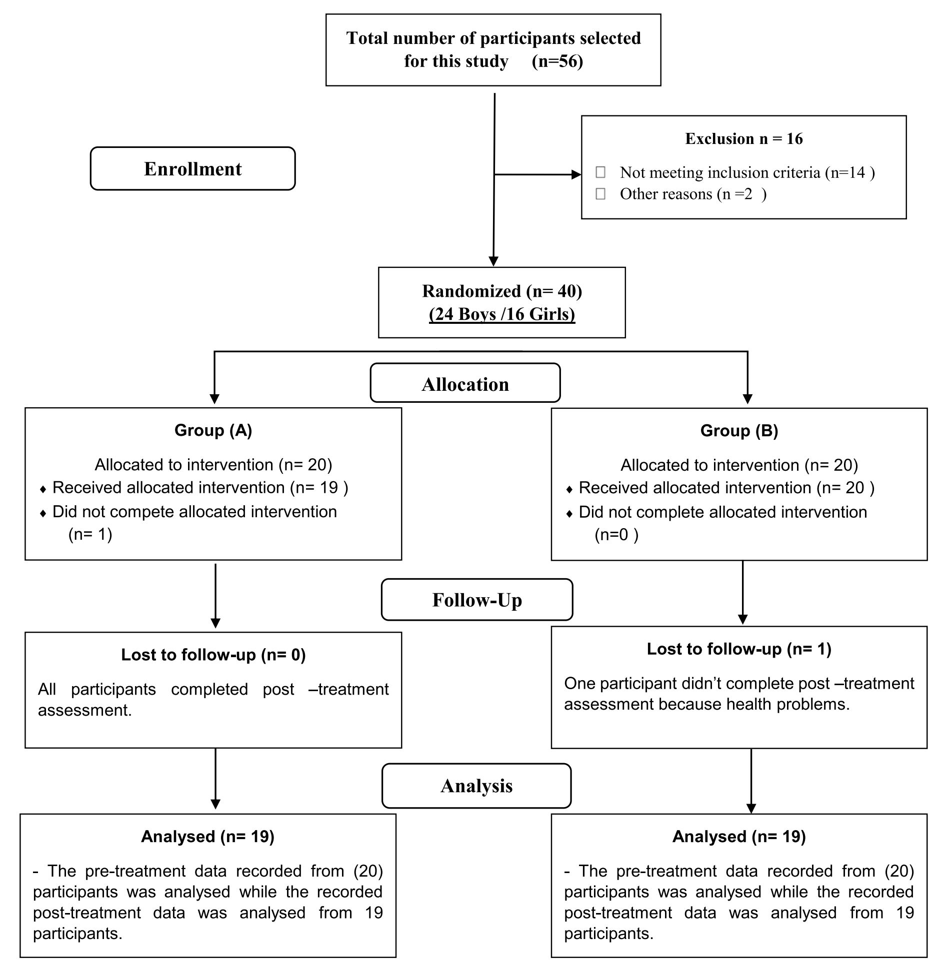

Fig. 1 Flow diagram of the study

Table 1 The demographic characteristics of the participants

Characteristics	Control group ($n = 20$)	Study group ($n = 20$)	*P* value
Age (years)	14.7 ±1.4	14.5 ± 1.3	0.472
Height (cm)	145 ± 9.38	147 ± 8.57	0.526
Sex (boy/girl)	(13/7)	(11/9)	0.351
GMFCS level			
I	8	6	0.763
II	12	14	

GMFCS Gross Motor Function Classification System

Unpaired *t* tests was used for the comparison between basic features between the two groups

Consequently, improving balance and gait performance in children with dyskinetic cerebral palsy.

Dyskinesia has commonly resulted from extrapyramidal and basal ganglia damage. The basal ganglia acts as an entrance for sensory processing. So damaged basal ganglia may lead to supplying the cerebral cortex with atypical sensory experiences; therefore, executing a disorganized and uncoordinated movement [5, 21],

TheraTogs orthotic undergarment provide a firm but comfortable compression sensation similar to that normally felt with the hugging effect. The soft texture of the TheraTogs orthotic undergarment provided the sensory receptors of the trunk region with continuous soft and calming sensory inputs. These effects might help the wearers of this type of soft orthoses in improving sensory awareness, and promoting sensorimotor integration [13, 14, 16, 22].

Therefore, wearing TheraTogs orthotic undergarment for the children included in the study group might assist them in normalizing the sensory experiences that nourish the cerebral cortex. The normal sensorimotor experiences are crucial for the execution of controlled movements, and for the process of motor learning of any motor skill [23].

The sensory experiences that were provided by TheraTogs might have an important role in improving overall stability indices which helped in controlling the swaying movement of the trunk and increasing the trunk stability. The improvement of anteroposterior and mediolateral stability indices might have a significant impact on controlling the disturbed movements associated with dyskinesia, augmenting trunk steadiness, and improving balance perfoemance and gait performance in these children [24, 25].

The application of lateral vertical compression to both sides of the trunk, as reported in many studies, increases the proprioceptive inputs and weight loading on the strapped side [13, 14, 16, 22, 26]. Therefore, the TheraTogs external strapping technique provided the children, in the study group, with a vertical stiffness to their upper body, trunk, and pelvis which in turn increased their core stability. It also assisted them to reduce lateral trunk lurch and to maintain their body in a stable posture alignment with the least energy cost. Consequently, the children felt secure and steady that enable them to improve their balance and gait performance.

Woollacott and Shumway-Cook., 2005 stated that the monitoring of the head, arm, as well as trunk segments, is a crucial component of controlling stability and mobility [27]. The adaptability of the spine and postural fixation (head on shoulder, shoulder on trunk, trunk on pelvis, and pelvis on lower furthest points) are essential factors to maintain a stable stance posture [25, 28].

It has been demonstrated that the involuntary hyperactive movements in children with dyskinetic cerebral palsy are featured by greater signal-dependent noise of the motor system [29, 30]. This noise in motor commands leads to excess motor command's intensity [31]. This means that if the children with dyskinesia wish to

Table 2 Comparison between the two groups (control and study), for the mean values of all measured variables, at baseline and immediately after 12 weeks of intervention

Variables	Control group (Mean ± SD)	Study group (Mean ± SD)	*P* value
Overall SI (%)			
Pre	4.76 ± 0.48	4.54 ± 0.18	0.785 [b]
Post	3.14 ± 0.54	2.35 ± 0.35	0.014 [a]
Antero-posterior SI (%)			
Pre	3.65 ± 0.32	3.53 ± 0.26	0.428 [b]
Post	2.76 ± 0.41	2.19 ± 0.35	0.018 [a]
Medio-lateral SI (%)			
Pre	3.38 ± 0.51	3.45 ± 0.43	0.832 [b]
Post	2.87 ± 0.27	2.43 ± 0.31	0.021 [a]
Pediatric balance scale score			
Pre	20.17 ± 0.29	19.83 ± 0.36	0.538 [b]
Post	26.35 ± 0.54	33.61 ± 0.42	0.001 [a]
Step length (cm)			
Pre	33.70 ± 7.84	33.26 ± 8.42	0.647 [b]
Post	40.82 ± 8.27	44.69 ± 9.13	0.011 [a]
Gait cycle time (s)			
Pre	1.72 ± 0.24	1.69 ± 0.28	0.723 [b]
Post	1.43 ± 0.31	1.21 ± 0.21	0.025 [a]
Cadence (steps/min)			
Pre	73 ± 5.41	72 ± 7.26	0.492 [b]
Post	82 ± 6.35	91 ± 6.38	0.001 [a]
Gait velocity (m/s)			
Pre	0.41 ± 0.04	0.39 ± 0.08	0.815 [b]
Post	0.56 ± 1.07	0.68 ± 0.14	0.001 [a]

SD standard deviation, *Pre* pre-treatment, *Post* post-treatment, *SI* stability index

[b] Non-significant difference between both groups ($P > 0.05$)

[a] Significant difference between both groups ($P < 0.05$)

Unpaired *t* tests was used for the comparison between both groups accomplish normal accurate movement performance, they need to decline the increased electric signals of the motor system and slow down their movements to overcome the increased motor variabilities [32].

The continuous soft and calming sensory inputs caused by TheraTogs might (1) reduce the increased signal-dependent noise, (2) decrease the motor command's magnitude, (3) inhibit undesired muscle patterns, (4) modify the delay in the onset of muscle contraction, (5) improve movement speed, and (6) promote reactive postural balance control [13, 14, 22, 26, 32].

Therefore, the improvement of the trunk stability obtained by the participating children, in the study group, due to the application of TheraTogs and external strapping was beneficial in promoting the abilities to control their balance. It also assisted them to execute their intended voluntary movement with more stability. This improvement in postural balance control helped in the better results of gait parameters findings post-treatment in this group.

El-Shamy and Abd El kafy 2021, demonstrated that TheraTogs orthotic undergarment only without external strapping has a considerable effect in improving gait parameters in children with mixed type of cerebral palsy (dyskinesia with spasticity). The age range for children included in their study was 8 to 12 years [33].

Abd El kafy et al., Siracusa et al., and Brehm et al., showed that TheraTogs orthotics undergarment and strapping system are effective in reducing trunk malalignment, improving postural stability, facilitating functional joint alignment, and enhancing walking efficiency in children with cerebral palsy [15, 26, 34]. However, Almeida et al., reported that the effectiveness of TheraTogs and its strapping system to improve postural alignment and walking performance in children with cerebral palsy needs more investigations [22].

No harmful effect was recorded regarding wearing TheraTogs with external strapping. This proposes that this soft type of orthoses can be a light-weight, convenient, well-tolerated, and worthwhile conservative treatment to improve stability and gait performance in children with dyskinetic cerebral palsy.

This study has some limitations that need to be considered: (1) given the nature of the therapeutic interventions in this study, it was not possible for the treating therapists and the children in this study to be blinded, (2) the level of tension of the elastic strapping elements was not accurately detected, (3) the level of motor function of the participating children were I and II, according to the Gross Motor Function Classification System, which limits the results of this study to only the mild form of dyskinetic cerebral palsy. These results could not be generalized to other severity levels, (4) the children in the study group need follow-up several months post-training to be certain of the long-lasting benefits of TheraTogs and its stapping system on balance and gait performance.

Future work will be needed to investigate the effect of other treatment periods of wearing TheraTogs and external strapping to determine the most appropriate dose-response of this intervention. Further studies are also recommended to examine the effectiveness of this intervention on balance and gait performance in other types of cerebral palsy with varied ages and for a large sample of children with cerebral palsy to make generalizations for the results of this study.

Conclusions

The rehabilitation intervention composed of the conventional therapeutic exercise training in addition to TheraTogs orthotic undergarment and its strapping system was more effective in optimizing trunk stability, promoting balance capability and improving gait performance in children with dyskinetic cerebral palsy than conventional exercise training alone.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s43161-022-00071-1.

Additional file 1: Appendix 1. Exercise training protocol

Additional file 2: Appendix 2. TheraTogs fitting and strapping technique

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Authors' contributions

All authors conceived and designed the study, conducted the data collection, analyzed and interpreted the data in addition to reviewing the final results. They are responsible for the findings, and have critically reviewed and approved the final draft of the article. The authors 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. Parents of all participants signed written informed consents before starting the study.

Competing interests
The authors declare that they have no competing interests.

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Appendix I:

The exercise training protocol

1- Supine lying position to standing exercise (supine lying to side sitting to sitting to standing) (with hand support then gradually without hand support).
2- Prone lying position to standing exercise (Prone lying to quadruped to kneeling to half kneeling to standing) (with hand support then gradually without hand support).
3- Sitting position on chair to standing exercise (with hand support then gradually without hand support).
4- Kneel standing exercise.
5- Standing alone exercise with gradually increasing the time of standing.
6- Stride standing exercise with gradually increasing the time of standing.
7- Step standing exercise. (One limb rested on ground and other limb rested on wooden step (stable surface) with gradual change to (uneven surface as on small ball or small balance board)
8- Standing exercise on the balance board.
9- Equilibrium reaction training exercises from standing position.
10- Protective reaction training exercises from standing position.
11- Walking exercise alone between parallel bars forward and backward slowly with bilateral hand support then gradually decrease hand support.
12- Walking exercise between parallel bars on stepper with bilateral hand support then gradually decrease hand support.
13- Walking exercise between parallel bars over balance board with bilateral hand support then gradually decrease hand support.

14- Walking exercise in stepper outside parallel bars without hand support.

15- Side walking exercise outside parallel bars without hand support.

16- Back-word walking exercise outside parallel bars without hand support.

17- Walking alone exercise in altered surface conditions, such as on (firm, sand, carpets, ramps, grass, and gravel).

18- Zigzag walking exercise.

19- Walking up low inclined ramp then walking down.

20- Climbing up and down stairs exercise with bilateral hand support then gradually decrease hand support.

Appendix II:

TheraTogs fitting and strapping technique

The fitting and strapping techniques of TheraTogs system for all participating children in group (B) were as follow:

<u>The aim of wearing TheraTogs orthotic undergarment and applying strapping system for children included in this study was</u> to reduce uncontrolled swaying movement of the trunk, improve axial stability and increase trunk support through: (1) fitting the top tank parts which provided a firm but comfortable compression similar to that felt with the hugging effect, and (2) providing the strapping technique throughout the application of lateral vertical compression to both sides of the trunk to reduce lateral trunk lurch and increases proprioceptive and weight loading on the strapped side.

<u>(1) Firstly Tank-Top and Hipster fitting:</u>

Normally, the proper fitting of these two parts for children should favor them with continuous extro and proprioceptive awareness and firm but comfortable compression similar to that felt with the hugging effect. This effect provided children with vertical stiffness to their (upper body, trunk, and pelvis), reinforced their core stability, helped them in establishing proper postural alignment, and gave them the feeling of safety and stability. The vest and shorts were fitted well to the children.

The following considerations were taken when providing this fitting technique; (1) the children were convenient without feeling tightness, , circulatory constrictions, or itching (2) the garments were fitted well so that it effectively grip the wearer's skin without slipping, and (3) there were no loose material, noticeable spaces , or wrinkles in the garment's materials .

(2) Secondly the strapping technique application:

The strapping technique application included the following procedures: (1) firstly, the children were in standing position with or without assistance with both feet slightly a parted ; (2) two wide large split straps with appropriate length applied laterally on both trunk sides (one on each trunk side) to connect lateral ribs to the pelvis; (3) the top two divisions of each split strap were attached and staked to the tank-top (vest) from the front and back sides ; (4) the bridge of the strap was located over the lateral sides of the trunk and pelvis ;(5) the lower two splits of the straps were pulled down for applying vertical lateral trunk compression and finally (6) the lower two divisions were fixed and attached to the thigh cuff of the hipster in the front and back sides.