
NEW Clinical Trial Studies

Offer Evidence of TheraTogs Effectiveness



Effect of the dynamic orthotic garment on postural control, and endurance in children with spastic diplegic cerebral palsy: a randomized controlled trial

Emara, Hatem A et al. "Effect of the Dynamic Orthotic Garment on Postural Control, and Endurance in Children with Spastic Diplegic Cerebral Palsy: A Randomized Controlled Trial." *Journal of multidisciplinary healthcare* vol. 17 419-428. 30 Jan. 2024, doi:10.2147/JMDH.S438474

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10838099/>

Abstract background: This study investigated the effect of dynamic orthotic garments (Thera togs) on foot pressure distribution, postural control, and endurance in children with spastic diplegic CP.

Study design/methods: This is a single-blind randomized controlled clinical trial involving 34 (8-10 years) with spastic diplegic CP. The control group received conventional physical therapy (CPT), whereas the study group received CPT in addition to wearing TheraTogs. We recorded foot pressure distribution, trunk control measurement scale, trunk position sense, Pediatric Berg Balance Scale (PBS), and six-minute walking distance (6MWD).

Results: Both groups showed improvement. The study group had significant improvement in foot pressure distribution (p-value 0.003, 0.001, <0.001 for forefoot, midfoot, and rearfoot mean pressures respectively, and 0.005, <0.001, and 0.005 for forefoot, midfoot, and rearfoot peak pressures respectively), Pediatric balance scale, The trunk control measurement scale, and Trunk position sense (p-value < 0.001) and six-minute walking distance (p-value 0.029). Our data suggest that adding TheraTogs to conventional physiotherapy improves foot pressure, postural control, and endurance in children with spastic diplegic cerebral palsy.

Conclusion: Both TheraTogs and conventional physical therapy corrected foot pressure distribution, trunk control, improved balance, and increased 6MWD in children with spastic diplegic CP but the improvement was more significant in TheraTogs group.

Clinical trial registration: [NCT05271149](https://www.clinicaltrials.gov/ct2/show/study/NCT05271149).

Keywords: balance score; children with disability; foot pressure; orthotic devices; theratogs.

The impact of conservative soft orthotic intervention with strapping on thoracic kyphotic posture and spinal mobility in children with cerebral palsy: a randomized control trial

El-Kafy, Ehab Mohamed Abd, and Shamekh Mohamed El-Shamy. "The impact of conservative soft orthotic intervention with strapping on thoracic kyphotic posture and spinal mobility in children with cerebral palsy: a randomized control trial." *Bulletin of Faculty of Physical Therapy* 27.1 (2022): 1-8.

<https://bfpt.springeropen.com/track/pdf/10.1186/s43161-021-00068-2.pdf>

Abstract Background: This study mainly aimed to evaluate the influences of TheraTogs orthotic undergarment with its strap-ping system on dorsal kyphotic posture and spinal mobility in children with spastic diplegic cerebral palsy. The study also investigated the impact of the modulation of thoracic kyphosis on balance and risk of falls in these children.

Study design: This study was a randomized control trial. Participants: Forty children with diplegic cerebral palsy, aged from 8 to 10 years were met the inclusion criteria and participated in this study. Only 38 children completed the study.

Methods: The children in the control group received 2 h of conventional exercise protocol aiming for modulating thoracic kyphotic posture. The treatment program was conducted 3 times/week, for 12 successive weeks. Children in the study group wore TheraTogs orthoses with the strapping system for 8 h every day in combination with the conventional exercise program.

Outcome measures: For both groups, the primary outcome measures (thoracic kyphotic angle, and thoracic flexion and extension range of motion), and the secondary outcomes (the overall stability index of fall risk test, and the pediatric balance scale score) were recorded at baseline and after completion of the treatment. T test was used to compare the changes within-and between-groups in all measured variables, at baseline and immediately after 12 weeks of treatment.

Results: Children in the study group showed significant improvements in the scores of all primary and secondary measures post-treatment compared to the control group ($P < 0.05$). Conclusion: Conservative treatment composed of TheraTogs orthotic system with conventional exercise treatment is effective in modulating thoracic kyphosis and improving dorsal range of motion in children with spastic diplegic cerebral palsy. This improvement has a positive influence on postural balance performance and reduces the risk of fall in these children.

Trial registration: The ClinicalTrial.gov PRS (NCT05063175). 30 September 2021—retrospectively registered, <https://clinicaltrials.gov/ct2/show/NCT05063175>.

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

El-Shamy, Shamekh Mohamed, and Ehab Mohamed Abd El-Kafy. "Combined effect of orthotic intervention and conventional exercise training on balance and gait performance in cerebral palsy: a randomized controlled trial." *Bulletin of Faculty of Physical Therapy* 27.1 (2022): 1-7.

<https://bfpt.springeropen.com/track/pdf/10.1186/s43161-022-00071-1.pdf>

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).

<https://clinicaltrials.gov/ct2/show/NCT04990193?term=NCT04990193&draw=2&rank=1>.

Efficacy of axial TheraTogs on gait pattern in children with dyskinetic cerebral palsy: a randomized controlled trial

El-Shamy, Shamekh Mohamed, and Ehab Mohamed Abd El Kafy. "Efficacy of axial TheraTogs on gait pattern in children with dyskinetic cerebral palsy: a randomized controlled trial." *Bulletin of Faculty of Physical Therapy* 26.1 (2021): 1-7.

<https://bfpt.springeropen.com/track/pdf/10.1186/s43161-021-00030-2.pdf>

Abstract / Background: TheraTogs promotes proprioceptive sense of a child with cerebral palsy and improves abnormal muscle tone, posture alignment, balance, and gait. Therefore, the aim of this study was to investigate the efficacy of TheraTogs orthotic undergarment on gait pattern in children with dyskinetic cerebral palsy. Thirty children with dyskinetic cerebral palsy 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. Gait parameters were measured at baseline and after 3 months of intervention using Pro-Reflex motion analysis.

Results: Children in both groups showed significant improvements in the gait parameters ($P < 0.05$), with significantly greater improvements in the experimental group than in the control group.

Conclusions: The use of TheraTogs may have a positive effect to improve gait pattern in children with dyskinetic cerebral palsy.

Trial registration: This trial was registered in the ClinicalTrial.gov PRS ([NCT03037697](https://clinicaltrials.gov/ct2/show/NCT03037697)).
<https://clinicaltrials.gov/ct2/show/NCT03037697?term=NCT03037697&draw=2&rank=1>.

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

Kafy, El, Ehab Mohamed Abd, and Shamekh Mohamed El-Shamy. "Efficacy of TheraTogs orthotic undergarment on modulation of spinal geometry in children with diplegic cerebral palsy." *Bulletin of Faculty of Physical Therapy* 26.1 (2021): 1-8.

<https://bfpt.springeropen.com/track/pdf/10.1186/s43161-021-00047-7.pdf>

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) PRS (NCT04271618).
<https://clinicaltrials.gov/ct2/show/NCT04271618?term=NCT04271618&draw=2&rank=1>.