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ORIGINAL ARTICLE

The effects of vest type dynamic elastomeric fabric orthosis on sitting balance and gross manual dexterity in children with cerebral palsy: a single-blinded randomised controlled study*

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ABSTRACT

Purpose: To evaluate the effects of vest type dynamic elastomeric fabric orthosis on posture and balance during sitting and gross manual dexterity and to compare the efficacy of daily wearing time of 2 h versus 6 h.

Method: Twenty-four children with cerebral palsy (CP) aged 3–9 years with GMFCS levels III and IV were randomised to either of three groups: (i) a control group who received only conventional exercise therapy, (ii) dynamic elastomeric fabric orthosis 2 h group who wore the orthosis for 2 h during therapy and dynamic elastomeric fabric orthosis 6 h group who wore the orthosis for 4 h in addition to the 2 h of wear along with therapy during hospital inpatient stay for 2 weeks. Children continued to use dynamic elastomeric fabric orthosis during the post-discharge period. The primary outcome measure was the Sitting Assessment Scale. The secondary outcome measurements were the sitting dimension of Gross Motor Function Measure, Box and Block Test and Parent Satisfaction Survey. Assessments were made before treatment, at post-treatment, at 1-month post-treatment, and at 3-months post-treatment. Sitting Assessment Scale and Box and Block Test were also assessed when immediately after wearing the orthosis. This trial is registered with Clinicaltrials.gov, under number NCT03191552.

Results: All groups showed similar improvements except the control group which showed less improvement in Sitting Assessment Scale scores compared to the dynamic elastomeric fabric orthosis groups. Dynamic elastomeric fabric orthosis groups showed greater improvements compared to the control group in the Sitting Assessment Scale but not in the sitting dimension of Gross Motor Function Measure and Box and Block Test at post-treatment, at 1-month post-treatment and at 3-months post-treatment. When the dynamic elastomeric fabric orthosis groups (2 h versus 6 h) were compared, there were no significant differences in any of the assessments. The Sitting Assessment Scale and Box and Block Test scores also improved immediately after the patients put on the orthosis. At 1-month post-treatment, parents of children in the control group reported less satisfaction than parents of the children in dynamic elastomeric fabric orthosis groups.

Conclusions: Dynamic elastomeric fabric orthosis vest has an immediate effect on the sitting balance and gross manual dexterity. It also provides improvements in posture and balance during sitting. Wearing dynamic elastomeric fabric orthosis vest for 2 h during therapy is as much effective as wearing it for 6 h in children with CP in addition to therapy to improve sitting balance.

IMPLICATIONS FOR REHABILITATION

- Dynamic elastomeric fabric orthosis vest provides improvements in sitting balance when used in addition to conventional therapy in children with cerebral palsy.
- Wearing dynamic elastomeric fabric orthosis for 2 h and wearing dynamic elastomeric fabric orthosis vest for 6 h resulted in similar clinical outcomes.
- Dynamic elastomeric fabric orthosis vest has an immediate effect on sitting balance and gross manual dexterity in children with cerebral palsy.

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Cerebral palsy; dynamic elastomeric fabric orthosis; orthosis; sitting balance; suit therapy

Introduction

Cerebral palsy (CP) is a disorder of development of movement and posture due to non-progressive lesion in fetal or infant brain [1]. Children with CP exhibit deterioration in postural control due to impaired sensorimotor coordination in which inappropriate muscle force and impaired sensory processing play a role [2–4]. The trunk plays a crucial role in postural control and it is also essential to provide a stable base of support during execution of

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*The study results were presented as oral presentation at the 5th Medical Rehabilitation Congress, Istanbul, Turkey and 12th Mediterranean Congress of Physical Medicine and Rehabilitation, Malta. The study was highly ranked by the abstract evaluation committee of 12th World Congress of the International Society of Physical and Rehabilitation Medicine (ISPRM 2018) and accepted as oral presentation. Also, a short workshop on the topic by authors was given.

Supplemental data for this article can be accessed here.

Figure 1. Dynamic elastomeric fabric orthosis vest.

upper and lower limb movements [5]. Despite the fact that the trunk plays a crucial role in postural control and extremity functions, research and treatments in CP have focused on extremities rather than trunk control. Both evaluation and treatment of trunk impairment have not been addressed in adequate specificity in previously published studies compared to extremities [5–8].

Suit therapies involve the use of garments, which are a type of dynamic orthosis. They are usually made of lycra or a similar elastomeric fabric and custom made for each child. Dynamic elastomeric fabric orthoses, a kind of these orthoses, constituting a type of the said orthoses, provide extra proprioceptive information which enhances body awareness [9]. It has been suggested that a more correct proprioceptive input result in more proper alignment [10–12]. Dynamic elastomeric fabric orthosis vest is a type of lycra based orthotic garment composed of a front part which is comprised of double-or triple-layer lycra fabric attached to velcro sensitive neoprene back panel (Figure 1). It is proposed that these orthotic garments provide stabilisation of the trunk, shoulder, and pelvic girdle and thus improve proximal stability and upper extremity function [9, 13]. The developers of this kind of orthotic suits claim that children with sensory deficits and poor muscle strength-including children with neuromotor developmental disorders and hypotonia-can benefit from the use of dynamic elastomeric fabric orthosis [9,14]. The adverse effects pertaining to the use of these orthoses are difficulty in donning/doffing, toileting problems such as constipation or urinary leakage, decrease in respiratory function, heat, and skin discomfort [13–17]. Due to such unwanted effects, it can be assumed that a prolonged wear time of the orthosis may lower compliance. However, the optimal wear regime for dynamic elastomeric fabric orthosis has not been established so far.

Suit therapies are alternative and complementary treatment methods which are increasingly utilised in paediatric rehabilitation settings. Although their use has become popular, scientific evidence supporting their efficacy is lacking. The existing studies evaluating the effects of orthoses for children with CP lack a well-specified research question, sufficient detail of the methodology, adequate outcome assessments and patient selection criteria, and description of the intervention and intention to use. Moreover, the subject matter of the evaluation is not clear [18]. A recent systematic review of interventions for children with CP categorised suit therapy as "yellow" intervention, indicating "needs to be measured" [19]. Recent systematic reviews on the effectiveness of suit therapies on impairments and functional limitations in children with CP concluded that further studies including samples with appropriate sizes presenting power or sample size calculations; more homogeneous groups concerning age, sex, type, and distribution of CP and Gross Motor Function Classification System level; valid and reliable measures assessing all domains of the International Classification of Functioning, Disability and Health (ICF); longitudinal studies to assess the long-term impact of suit therapy; data assessing kinetic and kinematic parameters of postural control; cost-effectiveness analysis; and assessment of patient and family satisfaction concerning the devices and investigating the intensity and duration with an appropriate design are needed. Therefore, there is a need for studies with a high level of evidence identifying the sufficient and appropriate intensity and duration of suit wearing [20–22]. Given these results, we aimed to assess the immediate and long-term effects of dynamic elastomeric fabric orthosis vest on sitting balance and gross manual dexterity compared to conventional exercise therapy in children with CP in a properly designed randomised controlled study. The secondary aim of this study is to evaluate parent satisfaction and to compare the efficacy of daily wearing time of 2 h versus 6 h.

Methods

Participants

Eligible children with CP who were admitted to Pediatric Rehabilitation outpatient clinic of the Physical Therapy and Rehabilitation Department of Marmara University, Istanbul, Turkey were enrolled to the study based on the inclusion criteria. Children with diplegic or tetraplegic spastic CP aged 3–9 years having impaired trunk control were recruited into the study. The inclusion criteria were: (1) being classified at Gross Motor Function Classification System level III–IV; (2) being classified at Manual Ability Classification System level III–IV; (3) being able to understand and execute instructions for evaluation; and (4) parental consent for the use of the dynamic elastomeric fabric orthosis vest. The exclusion criteria were: (1) having a serious respiratory restriction; (2) having refractory cyanosis or circulatory disorder; (3) having reflux more than 3 times a week; (4) having previously undergone dynamic elastomeric fabric orthosis treatment programme; (5) having uncontrolled epilepsy; (6) having a severe visual/or hearing impairment; (7) having undergone botulinum toxin injection within the last 3 months or an orthopaedic surgery within 1 year; (8) having severe scoliosis (Cobb angle $>40^{\circ}$); (9) having intrathecal baclofen pump; and (10) having undergone selective dorsal rhizotomy. The trial is registered with ClinicalTrials.gov, under number NCT03191552. The study was conducted after obtaining approval from the institutional Human Research Ethics Committee in accordance with the Declaration of Helsinki (approval number: 09.2013.0351). Informed consent was obtained from all legal guardians of the participating children. Reporting was conducted in accordance with Consolidated Standards of Reporting Trials (CONSORT) and recommendations for pilot studies [23].

Study design

The study was designed as a prospective, single-blinded, randomised, and controlled trial. Children with CP were randomised to either of three groups: dynamic elastomeric fabric orthosis 2 h, dynamic elastomeric fabric orthosis 6 h and a control group which the assessors were blinded to. The enrolment of the participants was carried out by an independent researcher who was not involved in the study enrolled participants and assigned them to groups

using the block randomisation procedure. Block randomisation procedure was used to assign blocks of three participants to one of three study arms using sealed opaque envelopes containing a group allocation number obtained from a computer-generated random number table. The physiotherapist has opened the envelopes and started the interventions based on group allocation.

Sample size

The sample size estimation was performed using the GPower V.3.1.7 (University of Kiel, Kiel, Germany). It was found that eight individuals for each group must had been recruited to have 80% power with 5% type 1 error level to detect a minimum clinically significant difference of 1 units of the Sitting Assessment Scale score, when the average expected value in the first group was 16.47 (with a standard deviation of 1.96) and the average expected value in the second group was 13.20 (with a standard deviation of 3.32) based on the previous research conducted by Şimşek et al. evaluated the effects of kinesiology taping on trunk control [2].

Intervention

All children were hospitalised for a period of 2 weeks in order to ensure appropriate orthosis wear time and equality of intervention. They received conventional exercise therapy for 2 h on a daily basis during such 2-week period including range of motion, tone regulation, trunk control, and upper and lower extremity strengthening exercises as well as exercises to improve fine and gross motor skills, upper extremity activities like grabbing–releasing and sitting activities and balance reactions related to sitting during the hospital inpatient stay [2]. The control group only received conventional exercise therapy. Dynamic elastomeric fabric orthosis 2 h group received conventional exercise therapy by wearing the garment for 2 h. Dynamic elastomeric fabric orthosis 6 h group wore the dynamic elastomeric fabric orthosis vest 4 h longer (i.e., in addition to the 2 h wear time) during therapy. After the treatment for two weeks, dynamic elastomeric fabric orthosis groups continued wearing the orthosis at home during the follow-up period and all children continued their regular therapies at specialised outpatient clinics of rehabilitation for CP for one hour per day (for a total of two days per week). The wear time of the garment during the follow-up period was checked through weekly phone calls. No other changes in physiotherapy or orthotic management or the application of a new treatment method were permitted during the follow-up phase.

Outcome measures

The primary outcomes of interest were the evaluation of posture and balance during sitting, hence the Sitting Assessment Scale was set as the primary outcome measure while the sitting dimension of Gross Motor Function Measure, Box and Block Test, and the Parent Satisfaction Survey were applied as the secondary outcome measures.

Assessments were made before treatment, at post-treatment (at the end of inpatient hospital stay for 2 weeks), at 1-month post-treatment and 3-months post-treatment. The Sitting Assessment Scale and the Box and Block Test were also applied immediately after the patients put on the orthosis. Children were assessed without wearing dynamic elastomeric fabric orthosis or any other orthosis during evaluations other than in the immediate effect assessment. During the assessment of the immediate effect, children wore the dynamic elastomeric fabric orthosis under their clothing in order to hide the orthosis from the evaluator.

The Sitting Assessment Scale was used to evaluate posture and balance during sitting while sitting dimension of Gross Motor Function Measure was applied for assessing sitting as a Gross Motor Function. The Box and Block Test was used to evaluate gross manual dexterity. A standard chair as described in Sitting Assessment Scale Manual was used for the assessments [24].

Sitting Assessment Scale

The Sitting Assessment Scale was developed for the observational assessment of posture and balance during sitting after seating interventions. The scale consists of five items including head control, trunk control, foot control, arm function and hand function which are assessed as follows: 1 = none; 2 = poor; 3 = fair; and 4 = good). The minimum and maximum possible scores range between 5 and 20, respectively. The Sitting Assessment Scale has a high intra (Intraclass correlation coefficient (ICC) 0.87–1.0) and inter-rater reliability (ICC 0.87–1.0) [25,26].

Gross Motor Function Measure-B, sitting dimension

The Gross Motor Function Measure indicates the gross motor functional status and shows change in the functional status of children aged between 15 months and 13 years following interventions. It is composed of 88 items which are categorised into five dimensions including lying and rolling (17), sitting (20), crawling and kneeling (14), standing (13), and walking, running, and jumping (24). It assesses the degree of achievement of Gross Motor Functions rather than their quality. Each item is scored according to special instructions on Gross Motor Function Measure Manuel with a 4-point Likert scale including 0 = does not initiate, 1 = initiates, 2 = partially completes, and 3 = completes. Should the testing of an item proves to be impossible, it should be marked as not tested (NT) [27,28]. The reliability of the Gross Motor Function Measure has been identified as excellent (ICC =0.99 for total score; ICC =0.98 for sitting dimension) [27].

In this study sitting dimension of Gross Motor Function Measure was applied to evaluate the degree of achievement of sitting as a Gross Motor Function. Evaluations were made with the instructions as described under Gross Motor Function Measure User's Manual [28].

Box and Block Test

The Box and Block Test consisting of a box divided into two compartments through a partition and blocks with standardised dimensions applied to assess unilateral gross manual dexterity. The subject is instructed to move the boxes one by one from one compartment of the box to the other in 60 s. The score is the number of boxes transferred from one compartment to other in 60 s. The subject should sit on a standard-height chair and face the box. He/she should practice for a 15 s trial period before commencement of the test. If two blocks are carried at the same time, such move should be scored as one. Additionally, if the block falls on the floor after being carried across, such action should be counted nonetheless [29,30].

Parent satisfaction survey

A non-standardised 5-point Likert type scale [31] was applied to assess satisfaction concerning the wear of orthosis and

satisfaction with the general treatment (Supplementary Table S1). Parents completed the survey at post-treatment, 1-month post-treatment, and 3-months post-treatment. The items numbered 3, 5, and 7 include questions about the treatment efficacy while the other items consist of questions about the ease and utilisation of the orthosis. Therefore; in order to compare all groups, only items 3, 5, and 7 were applied while all items were applied to compare the dynamic elastomeric fabric orthosis groups.

Statistical analysis

IBM SPSS Statistics for Windows, version 20.0 (Armonk, NY) was used to perform the analysis. Statistical significance was accepted as $p < 0.05$. The histogram and normality plots and Shapiro–Wilk normality test were applied for the data distribution analysis.

Descriptive statistics were used to determine mean and 95% confidence interval (CI) of normally distributed quantitative data and number (percentage) for the categorical variables. The groups were compared in respect of demographic characteristics by using multiple chi-square tests for categorical variables and using analysis of variance (ANOVA) for continuous variables. Inter-group analyses were performed using one-way ANOVA if data followed a normal distribution. Otherwise, Kruskal–Wallis test was performed. Mann–Whitney U test or t-test was performed to test the significance of pairwise differences using *post-hoc* tests (Bonferroni correction or *post-hoc* Tukey) to adjust for multiple comparisons. For *post-hoc* tests, a p values of less than 0.017 (0.05/3) was determined as the level of statistical significance.

Depending on the distribution analysis, Wilcoxon and dependent t-tests were utilised to detect within group analyses. To assume changes over time with treatment Friedman and repeated measures analysis of variance were conducted.

Mann–Whitney U and independent sample t-tests were applied to compare the dynamic elastomeric fabric orthosis 2 h and 6 h groups.

Results

Thirty-six children with CP who had impaired trunk control were screened for eligibility. Among them, 26 children met the inclusion criteria. One of them lost follow up before the assessment at 1-month post-treatment and one of them withdrew due to surgery for progressive hip dysplasia between the follow-up points of 1-month and 3- months post-treatment. All the other 24 children attended and successfully completed the interventions. Figure 2 shows the CONSORT diagram of the enrolment to study. The demographic and clinical features of the groups were identified similar (Table 1). No adverse events occurred in either of the intervention or the control group.

Inter-group analysis

In statistical terms, the Sitting Assessment Scale scores were significantly lower in the control group than other groups at post-treatment, at 1-month post-treatment and 3-months post-treatment. No statistically significant differences were identified between the groups in terms of Gross Motor Function Measure sitting dimension or the Box and Block Test (Table 2).

Upon comparison of the dynamic elastomeric fabric orthosis 2 h and dynamic elastomeric fabric orthosis 6 h groups, no statistically significant differences between the groups for any of the assessments at any of the follow-up time points (Table 2).

The dynamic elastomeric fabric orthosis groups had significantly higher scores than the control group in the Parent Satisfaction Survey at 1-month post-treatment (Table 3). At 1-month post-treatment, 75% of parents of children in the dynamic elastomeric fabric orthosis groups reported that their child's sitting balance and confidence had improved while 75% of parents of children in the control group agreed that their children showed a slight improvement. There were no differences between the groups in terms of the Parent Satisfaction Survey results at the 3-months post-treatment (Table 3).

There was no statistically significant difference between the dynamic elastomeric fabric orthosis 2 h and dynamic elastomeric fabric orthosis 6 h groups in terms of the Parent Satisfaction Survey scores at post-treatment, 1-month post-treatment, and 3-months post-treatment.

Intra-group analysis

There were statistically significant differences in Sitting Assessment Scale, sitting dimension of Gross Motor Function Measure and Box and Block Test scores for all groups at all the post-treatment follow-up points compared to the baseline. Furthermore, Sitting Assessment Scale, sitting dimension of Gross Motor Function Measure and Box and Block Test scores showed statistical significant changes over time in all groups (Table 2). The Sitting Assessment Scale and Box and Block Test scores increased immediately after putting the orthosis on (Table 4).

Discussion

In this study, the immediate and long-term effects of a specific type (vest) of a dynamic elastomeric fabric orthosis on a selected group of children with CP (bilateral CP at Gross Motor Function Classification System level III–IV) to achieve a specific goal (sitting balance and upper extremity function) were assessed. Inter-group comparisons indicated that the use of the dynamic elastomeric fabric orthosis vest is only associated with an effect on the Sitting Assessment Scale and not on the sitting dimension of Gross Motor Function Measure or the Box and Block Test. Wearing the orthosis for 2 h and 6 h yielded similar outcomes. The Sitting Assessment Scale and Box and Block Test scores also improved immediately after wearing the orthosis. Parental satisfaction was greater in dynamic elastomeric fabric orthosis groups at 1-month post-treatment while no differences were detected in parental satisfaction levels between groups at 3-months post-treatment.

The sitting dimension of Gross Motor Function Measure and the Sitting Assessment Scale scores showed improvements in all groups. All groups demonstrated similar improvements except the control group which showed less improvement in the Sitting Assessment Scale score than the dynamic elastomeric fabric orthosis groups. Alagesan and Shetty [32] established the existence of a significant increase in sitting dimension of Gross Motor Function Measure scores of children with diplegic CP after completing a modified suit therapy for 2 h per day for a period of 3 weeks compared to controls. However, the said study did not evaluate the long-term effects. Bar-Haim et al. [33] compared the efficacy of the Adeli suit and neurodevelopmental treatment in children with diplegic and quadriplegic CP at Gross Motor Function Classification System Levels II and IV [33]. Similar to the findings of this study, improvements in sitting dimension of Gross Motor Function Measure-66 scores and their retention after 9 months post-treatment were not significantly different between the two treatments following the completion of the 4-week treatment

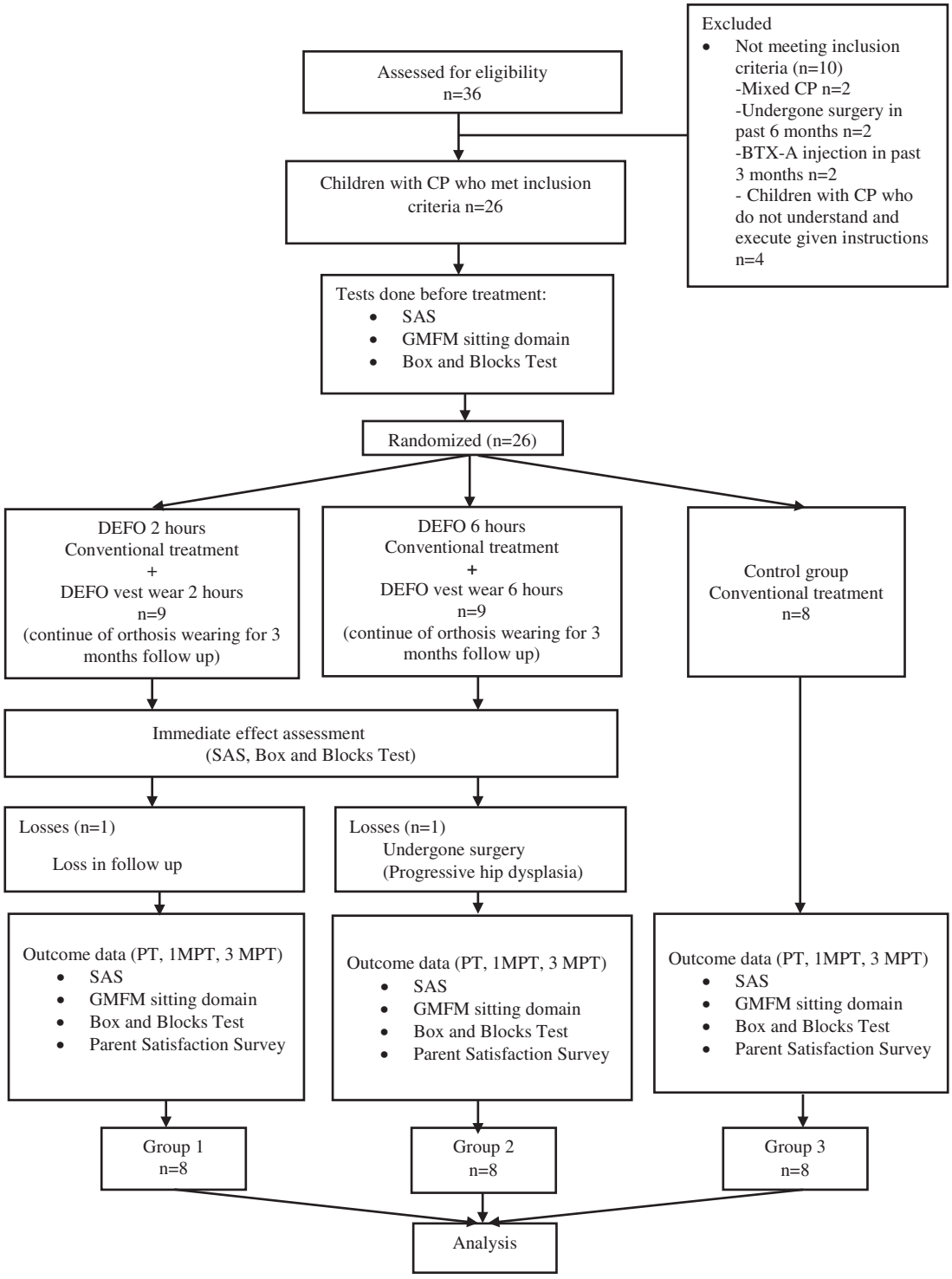

Figure 2. CONSORT diagram of the study. CP: cerebral palsy; SAS: Sitting Assessment Scale; GMFM: Gross Motor Function Measure; DEFO: Dynamic elastomeric fabric orthosis; BT: before treatment; PT: post-treatment; MPT: month post-treatment.

(2 h daily, 5 days per week). Flanagan et al. [31] investigated the effects of the short-term intensive orthotic garment use and identified stable gains in gross motor skills in the follow-up points of 2 months and 4 months post-treatment. Due to the differences among therapeutic suits and the time regimens in which they were implemented, the existing evidence is not conclusive concerning the optimal intensity of wear in order to guarantee their efficacy [32].

In this study, significant group differences were detected in terms of the Sitting Assessment Scale scores but not in the sitting dimension of Gross Motor Function Measure. These findings are consistent with the outcome reported by Şimşek et al. [2] who studied the effects of kinesiotaping on trunk control in children classified at lower functional levels on the Gross Motor Function Classification System, Levels III, IV, and V, and reported a significant change in the Sitting Assessment Scale scores but no change in the sitting dimension of Gross Motor Function Measure scores. This can be explained in several ways. The Sitting Assessment Scale evaluates postural changes during sitting while the Gross Motor Function Measure primarily assesses achievement of Gross

Table 1. Baseline characteristics of groups[a].

	DEFO 2 h	DEFO 6 h	Control
Age (mean ± SD, months)	64.29 ± 18.09	60.5 ± 19.57	55.63 ± 18.11
Gender (*n* (%)			
Male	2 (25)	1 (12.5)	2 (25)
Female	6 (75)	7 (87.5)	6 (75)
CP type			
Diplegic	1 (12.5)	0	1 (12.5)
Tetraplegic	7 (87.5)	8 (100)	7 (87.5)
GMFCS			
Level 3	2 (25)	2 (25)	1 (12.5)
Level 4	6 (75)	6 (75)	7 (87.5)

[a]Values are presented as mean ± SD for continuous variables, frequency (%) for categorical variables. CP: cerebral palsy; DEFO: dynamic elastomeric fabric orthosis; GMFCS: Gross Motor Function Classification System.

Motor Functions. Thus, the Sitting Assessment Scale measures at impairment and activity level while the Gross Motor Function Measure and Box and Block more at activity level. Therefore, the Gross Motor Function Measure might have been insensitive to detect short-term improvements between groups [34]. Sitting Assessment Scale is originally developed to be applied in studies of individuals with CP, while box and block test while box and block test was not developed specifically for CP [35]. If it is considered that all groups received conventional exercise therapy, exercise therapy might be the probable cause of similar improvements observed in all groups. To assess the isolated effect of the dynamic elastomeric fabric orthosis vest, a group should have only received the orthosis, but it would be unethical to apply a complementary treatment without a proven one. Our primary aim was to improve trunk balance; therefore, the primary outcome of the study was the Sitting Assessment Scale. The sample size calculations are performed based on the primary outcome of the study. The study is insufficiently powered to detect differences in sitting dimension of Gross Motor Function Measure and Box and block test.

Postural stability and manual dexterity are related to each other [36]. Improved proximal stability achieved through better trunk control may lead to improvements in the upper extremity function [36,37]. It was demonstrated that a more appropriate seating position causes a better upper extremity function in children with CP [38]. In light thereof, we have also investigated the effect of orthoses in manual dexterity. Although the Box and Block Test scores have significantly improved in all groups, contrary to previous findings, none of the groups demonstrated superiority over each other in terms of Box and Block Test scores. The use of dynamic elastomeric fabric orthosis vest resulted in an improvement in the Sitting Assessment Scale scores but not in the Box and Block Test scores. Similar to the findings of this study, a case report by Angilley [39] investigating the effects of short bodice on gross motor and upper extremity functions demonstrated no change in fine motor skills domain of Bruininks-Oseretsky test of motor proficiency.

All groups showed improvements over time in all outcome assessments rendering the interpretation of the study results difficult. One can ask whether the improvements are the result of interventions or the child's development. This is a well-known phenomenon during child development also in children with CP. However, the parallel randomised controlled study design helps to overcome this challenge since randomisation allows comparison between groups (comparison of change over time in patients in one group with the other).

Posture and balance during sitting and gross manual dexterity improved immediately after wearing the orthosis. Similar to the results of this study, previous studies demonstrated the immediate effects of dynamic elastomeric fabric orthoses. Gracies et al. [40] determined that a lycra arm splint had an immediate effect on normal blinded subjects. Hylton and Allen [14], the developers of stabilising input pressure orthosis being a type of dynamic elastomeric fabric orthosis, have reported that they observed immediate improvements through the wear of dynamic elastomeric fabric orthosis including better posture and balance during sitting, standing and lying prone and improved body wrighting and weight displacement on the therapy ball. In another study conducted by Blair et al. [9], in order to investigate the effects of UPsuit on postural stability, the quality of upper limb movement video records of children were evaluated through a non-standardised rating method developed by the investigators. In accordance with the results of this study, it was determined that the difference between the quality of upper extremity movement with orthosis wear had almost twice the quality of upper extremity movement immediately after the removal of the orthosis. Cheng [41] also reported that right after wearing the dynamic pressure garment (being a kind of dynamic elastomeric fabric orthosis), four-year-old children with hypotonic CP showed improved upper limb activity and upright sitting. Elliott et al. [42] also demonstrated that the range of motion in pronation and supination and in shoulder flexion while reaching during the hand to mouth task improved immediately after the application of the lycra arm splint [42]. In another study, jerkiness of upper extremity movement in children with CP increased immediately after splint removal [43]. Immediate effects represent isolated effects of dynamic elastomeric fabric orthosis. Due to ethical considerations isolated long-term effect of the dynamic elastomeric fabric orthosis vest could not be measured. Given the immediate effects of these orthoses, such kind of orthoses should be used in rehabilitation programmes in order to practice targeted movement or posture many times while wearing the orthosis to improve motor learning and to facilitate neuroplasticity. In this way, with the repeated use of the orthosis in therapy, even though trunk control seems to be improved only through the use of orthosis, it can be generalised over time to situations without the orthosis wear [42]. All groups showed significant changes over time supporting the previous hypothesis. This study demonstrated an immediate increase in the Sitting Assessment Scale and the Box and Block Test scores, but long-term results indicated significant differences between groups in terms of the Sitting Assessment Scale scores but not in the Box and Block Test. This can be explained by the fact that the Box and Block Test is not sensitive enough to detect differences between groups in carry-over improvements. Elliott et al. [42] evaluated the immediate and carryover effects of lycra arm splints in children with CP *via*

Table 2. Inter and intragroup comparisons.

	DEFO 2 h	DEFO 6 h	Control	*p* value[b]
SAS total score				
BT	12.13 (9.87–14.37)	13 (11.05–14.94)	13.6 (11.95–15.29)	0.455
PT	17 (14.11–19.38)*	18 (16.58–19.41)*	14.5 (12.61–16.88)[x]*	**0.027**
1MPT	17.5 (15.6–19.39)*	18.63 (17.08–20.16)*	15.13 (13.48–16.76)[y]*	**0.008**
3MPT	18 (16.28–19.21)*	20 (18.38–20.36)*	16 (13.68–17.56)[z]*	**0.004**
p value[a]	**0.0001**	**0.0001**	**0.001**	
GMFM sitting dimension				
BT	30.38 (18.29–42.45)	29.88 (20.7–39.04)	29.38 (22.76–35.98)	0.985
PT	40 (25.03–48.71)*	40.5 (27.58–46.41)*	36 (27.57–40.42)*	0.837
1MPT	43.25 (33.01–53.48)*	40.88 (31.11–50.63)*	37.25 (37.66–38.5)*	0.570
3MPT	45 (37.44–52.55)*	45.38 (39.08–51.66)*	39.25 (30.63–47.86)*	0.334
p value[a]	**0.001**	**0.0001**	**0.0001**	
BBT				
BT	9.38 (5.88–12.86)	11 (7.1–14.9)	11.63 (8.13–15.11)	0.573
PT	14 (7.92–20.07)*	12.63 (8.5–16.74)*	14.75 (9.96–19.53)*	0.778
1MPT	14.75 (9.1–20.4)*	14 (9.44–18.55)*	15.5 (10.3–20.69)*	0.889
3MPT	15.63 (8.74–22.5)*	14.88 (11.6–18.14)*	15.75 (10.73–20.76)*	0.956
p value[a]	**0.003**	**0.0001**	**0.002**	

Data were expressed as mean (95% confidence interval) or median (95% confidence interval).
Control group received only conventional exercise therapy, DEFO 2 h group wore DEFO 2 h during therapy and DEFO 6 h group wore DEFO 4 h in addition to 2 h of wear during therapy.
SAS: Sitting Assessment Scale; DEFO: dynamic elastomeric fabric orthosis; BT: before treatment; PT: post-treatment; MPT: month post-treatment; GMFM: Gross Motor Function Measure; BBT: Box and Block Test
p value[a]: Intragroup comparisons by Friedman test or repeated analysis of variance.
p value[b]: Intergroup comparisons by ANOVA or Kruskal–Wallis.
*$p < 0.05$ by the Wilcoxon signed-rank test or dependent t-test for intragroup changes compared to baseline.
[x]$p = 0.011$ by Mann–Whitney u test to test the significance of pairwise differences using Bonferroni correction to adjust multiple comparisons.
[y]$p = 0.007$ by *post-hoc* Tukey for pairwise *post-hoc* test for multiple comparisons.
[z]$p = 0.002$ by Mann–Whitney u test to test the significance of pairwise differences using Bonferroni correction to adjust multiple comparisons.

Table 3. Comparisons of parent satisfaction survey results between groups.

	DEFO 2 h	DEFO 6 h	Control	*p* value[a]
Parent satisfaction survey				
PT	12 (10.15–12.13)	11 (10.22–11.77)	9 (7.53–10.96)	0.07
1MPT	12 (10.5–12.33)	12 (10.86–12.13)	9 (6.6–10.39)*	**0.001**
3MPT	12 (10.7–12.15)	11 (10.22–11.77)	10 (6.24–11.75)	0.14

Data were expressed as median (95% confidence interval).
BT: before treatment; PT: post-treatment; MPT: month post-treatment; DEFO: dynamic elastomeric fabric orthosis
Control group received only conventional exercise therapy, DEFO 2 h group wore DEFO 2 h during therapy and DEFO 6 h group wore DEFO 4 h in addition to 2 h of wear during therapy.
p value[a]: Intergroup comparisons by Kruskal–Wallis.
*$p = 0.002$ by Mann–Whitney *U* test to test the significance of pairwise differences using Bonferroni correction to adjust multiple comparisons.

Table 4. Immediate effects of dynamic elastomeric fabric orthosis vest ($n = 16$).

	SAS	BBT
BT	12 (11.24–13.88)	10.5 (7.86–12.5)
İmmediately after wearing the orthosis	16 (13.7–16.41)	11.5 (8.91–14.08)
p value[a]	**0.002**	**0.001**

Data were expressed as median (95% confidence interval).
SAS: Sitting Assessment Scale; BBT: Box and Block Test; BT: before treatment
p value[a]: *p* values by Wilcoxon signed-rank test.

3D motion analysis system and detected a quantifiable improvement in supination which may be of great importance for daily functioning. The researchers concluded that the existing assessments other than the motion analysis have failed to show discrete improvements. Further studies with kinematic analysis are required to clarify differences of carryover improvements in upper extremity function between groups.

Parental satisfaction and compliance are important issues in suit therapy programmes. No adverse effect was observed during the follow-up stage of the present study and all groups demonstrated a high level of satisfaction concerning the treatment. At 1-month post-treatment, parental satisfaction survey scores in the control group were lower than the dynamic elastomeric fabric orthosis groups. However, although unexpectedly, parental satisfaction in the dynamic elastomeric fabric orthosis groups did not persist over time. Since all groups received therapy and showed improvements, parents may have become equally satisfied with the improvements. The difference between the groups in the family satisfaction survey resulted from parents' answers to the question whether the "Child's confidence was improved" under questionnaire. In previous studies, similar to this result, increased confidence thus increased attempt to start a task was noted through the use of dynamic elastomeric fabric orthosis [9,14,17,41]. In a study conducted by Rennie et al. [16], full body suit was used to assess the effect of orthosis on gait, and the parents of the children participating to the study reported that the orthosis was too difficult to down on and off and thus they had experienced toileting problems. Additionally, the respective parents reported that their children did not enjoy wearing the garment and they did not consider using the orthosis in the future [13,16]. Similar to the findings of the aforementioned study, Blair et al. [9] also noted that children were not happy wearing the suit and their families decided to discontinue the use of the orthosis. In another study, difficulty in applying the lycra based glove and urinary incontinence were reported [17].

Wear time of lycra based compression orthosis has not been standardised. As per the previous literature, wear time varies from 2 to12 h per day and duration period last between 2 and 12 weeks [15]. When the orthosis was worn for 6 h per day, the compliance was found to be low [13,16]. It is noteworthy that there were no differences in any of the assessments between the dynamic elastomeric fabric orthosis 2 h and dynamic elastomeric fabric orthosis 6 h groups. When low compliance with orthosis due to adverse effects is considered, 2 h of wear time could be enough especially when compliance problems occur. Previous studies have evaluated only the effects of the use of suits or their use in combination with therapy. Our aim was to compare the isolated and combined effects of therapy and dynamic elastomeric fabric

orthosis wearing. The lack of any difference between the results of the dynamic elastomeric fabric orthosis 2 h and dynamic elastomeric fabric orthosis 6 h group can be explained through the fact that wearing dynamic elastomeric fabric orthosis aside from therapy does not provide any additional effects.

The studies investigating the effects of the aforementioned type of orthosis mainly consist of case reports and case series [13,14,16,17,39,41,44]. They also have a limited number of subjects and include heterogeneous study populations such as CP and Duchenne Muscular Dystrophy [9,14,16–18,41–43]. Children varying between 10 months and 18years of age, with various types of CP at various Gross Motor Function Classification System levels have been recruited into said studies. Moreover, different types of orthoses (full body suit, vest, pants, etc.) were used but the patients were evaluated based on the same outcome measures in the hope that the same improvements will occur [13,14,17]. Furthermore, some of the referenced studies were funded by orthotic device companies and most of them lack validated and standardised assessment tools [16,17]. Results of previous studies are mainly based on improvement observations and clinical experience comments [45,46]. In this study – in contrast to the previous studies – a homogenous sample of children with CP was recruited to the study and only vest type orthosis was used to target trunk control and objective and standardised assessment methods were applied. All the aforementioned features of the study, as well as the relatively long follow up period, close supervision of orthosis wear during the hospital stay and blinding of outcome assessors can be viewed as strengths of the study. To the best of our knowledge, the present study is the first single-blinded randomised controlled study to verify the effect of dynamic elastomeric fabric orthosis vest on sitting balance, gross manual dexterity and parent satisfaction in children with CP.

Study limitations

This study has some limitations to be considered. First, kinematic assessment of posture and upper extremity cannot be performed. Second, outcome measures used in the study only assess body structure, function and activity, and lacks assessment of participation.

Conclusion

This study has demonstrated that dynamic elastomeric fabric orthosis vest is effective in improving sitting balance when used during therapy and 2 h of wear is as effective as 6 h of wear. Also, dynamic elastomeric fabric orthosis vest has an immediate effect on posture and balance during sitting and upper extremity function. To draw a final conclusion on the effects of dynamic elastomeric fabric orthosis vest, further studies including (1) large numbers of children with CP at different functional levels and ages in order to establish impact of this orthosis type in children with CP at different functional levels and ages *via* subgroup analysis (2) kinematic assessment of posture and upper extremity and (3) assessment of activity and participation in addition to body structure and function must be conducted.

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Clinical trial registration number

The trial is registered with ClinicalTrials.gov, number NCT03191552.

Disclosure statement

No potential conflict of interest was reported by the authors.

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