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**The Effect of Vest Type Dynamic Elastomeric Fabric Orthosis (DEFO) on Sitting Balance and Gross Manual Dexterity in Children With Bilateral Cerebral Palsy: A Feasibility and Randomized, Single-blinded, Pilot Study (NCT03191552)**

**(Unique Protocol ID:09.2013.0351)**

## **STUDY PROTOCOL**

### **Participants**

Eligible children with CP who were admitted to Pediatric Rehabilitation outpatient clinic at a tertiary university hospital were enrolled to study according to inclusion criteria. Children with mild- moderate, diplegic or tetraplegic spastic CP aged 3 to 7 years and who had impaired trunk control were recruited to the study. Some of the children were on a wait list for treatments such as botulinum toxin injection, surgery etc. The inclusion criteria were: (1) being classified at Gross Motor Function Classification System (GMFCS) level III-IV; (2) being classified at Manual Ability Classification System (MACS) level III-IV; (3) being able to understand and execute given instructions for evaluations; (4) parental acceptance of using the lycra based compression garment. The exclusion criteria were: (1) serious respiratory restriction (2) having refractory cyanosis or circulatory disorder; (3) having undergone lycra compression orthosis treatment programme previously; (4) having undergone botulinum toxin injection within last 3 months or orthopedic surgery within 1 year; (5) severe scoliosis (Cobb angle (CA)  $>40^\circ$ ); (6) uncontrolled epilepsy; (7) having intrathecal baclofen pump; (8) having undergone selective dorsal rhizotomy; (9) having reflux more than 3 times a week. The study was conducted after approval from the the institutional Human Research Ethics Committee in accordance with the Declaration of Helsinki. Informed consent was obtained from all legal guardians of the children. Reporting was conducted in accordance with CONSORT14 and recommendations for pilot studies <sup>16</sup>.

### **Study design**

The study was designed as prospective, single-blinded, randomized, controlled trial. Children with CP were randomized to either of three groups: SPIO 2 hours, SPIO 6 hours and control group (EKS) which the assessors were blinded to (EG, TO). To ensure group concealment, randomization was done using sealed opaque envelopes which were sequentially numbered in

advance, including the information about which group the child would have been allocated to. The physiotherapist opened the envelopes and started the interventions according to group allocation.

### **Sample size**

It was found out that 8 individuals for each group must have been recruited to have 80% power with 5% type 1 error level to detect a minimum clinically significant difference of 1 units of 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 evaluating the effects of kinesiology taping on trunk control <sup>2</sup>.

### **Intervention**

All children were hospitalized for 2 weeks and received conventional exercise therapy including range of motion, strengthening, trunk control and strengthening exercises and exercises to improve fine and gross motor skills during hospital inpatient stay throughout 2 weeks 2 hours a day (SG). Control group received conventional exercise therapy only. SPIO 2 hours group received conventional exercise therapy with the garment on for 2 hours. SPIO 6 hours group wore the SPIO 4 hours more in addition to 2 hours during therapy. After the treatment for two weeks, during the follow-up period SPIO groups continued wearing the orthosis at home and all the children continued their regular therapies for one hour a day, two days a week. After hospitalization, wear time of garment during follow-up was checked by weekly phone calls. No other changes in physiotherapy or orthotic management or no addition of a new treatment method were permitted during follow-up.

### **Outcome measures**

The primary outcomes of interest were feasibility and evaluating posture and balance during sitting, therefore SAS was set as the primary outcome measure while secondary outcome measures were Gross Motor Function Measure (GMFM), Box and Block Test (BBT), Parent Satisfaction Survey.

Assessments were conducted before treatment (BT) (TO), at posttreatment (PT), 1 month posttreatment (1 MPT) and 3 months posttreatment (3 MPT) (EG). SAS and BBT were also tested immediately after the orthosis was worn (EG). Children were assessed without the suit on and without any other orthosis except for the assessment of the immediate effect. During the assessment of the immediate effect children wore SPIO under their clothings to hide orthosis from the evaluator.

### **Sitting Assessment Scale (SAS)**

Sitting Assessment Scale (SAS) was used to evaluate posture and balance during sitting while sitting dimension of Gross Motor Function Measure (GMFM) were used for assessing sitting as a gross motor function. Box and Block Test was used to evaluate gross manual dexterity. Sitting Assessment Scale was developed for observational assessment of posture and balance during sitting after seating interventions. The scale consists of 5 items including head control, trunk control, foot control, arm function and hand function which are assessed as follows: 1= none; 2= poor; 3= fair; 4= good). The minimum and maximum possible scores are 5 to 20 respectively. SAS has high intra (ICC 0,87-1,0) and inter rater reliability (ICC 0,87-1,0)<sup>17,18</sup>.

### **Gross Motor Function Measure-B, sitting dimension**

Gross Motor Function Measure shows gross motor functional status and changes in functional status of children ages between 15 months and 13 years after interventions. It is composed of 88 items which are categorized into 5 dimensions including lying and rolling (17); sitting (20); crawling and kneeling (14); standing (13); and walking, running, and jumping (24). It

assesses degree of achievement of gross motor functions rather than quality of them. Each item is scored according to special instructions on GMFM Manuel with a 4-point Likert scale including 0 = does not initiate, 1 = initiates, 2 = partially completes, 3 = completes. If it is not possible to test an item, it should be noted as not tested (NT)<sup>19,20</sup>. The reliability of GMFM has been found to be excellent (ICC= 0.99 for total score; ICC= 0.98 for sitting dimension)<sup>19</sup>.

In this study sitting dimension of GMFM was used to evaluate degree of achievement of sitting as a gross motor function. Evaluations were done according to GMFM User's Manuel<sup>20</sup>.

### **Box and Block Test**

Box and Block Test which consists of a box divided into two compartments by a partition and blocks with standardized dimensions is used to assess unilateral gross manual dexterity. The object is instructed to transport boxes one by one from one compartment of the box to other in 60 seconds. The score is the number of boxes transferred from one compartment to other in 60 seconds. The object should sit on a chair with a standard height and face the box. He/she should practice for a 15 second trial period before testing. If two blocks are carried at the same time, it is counted as one. And also if the block falls on the floor after it has been carried across, it is still counted<sup>21,22</sup>.

### **Parent Satisfaction Survey**

A non-standardized 5-point Likert type scale was invented by the investigators to assess compliance and satisfaction with wearing orthosis. Parents were completed the questionnaire PT, 1 MPT and 3 MPT. The items numbered 3, 5 and 7 were questioning about treatment efficiency while the other items were questioning the ease and utilization of the use of orthosis. That's why to compare all groups only 3, 5, and 7. items were used when all of them were completed for the comparisons of SPIO groups.

