

**Pilot Study: Application of KINISIFORO (K-SET Method) medical device on children with cerebral palsy with limited physical abilities for Gait improvement and basic daily activities.**

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**Key Words:**

AFO: Ankle-foot orthosis

BWS: Body-weight support

CP: Cerebral Palsy

Gait Rehabilitation

K-SET Method: Kinisiforo System of Elliptical Training Method

**Objective**

To investigate the impact of **KINISIFORO (K-SET Method), a medical device**, on children with cerebral palsy with limited physical abilities for gait improvement and basic daily activities.

**Design**

Comparison of 57 children with cerebral palsy with limited physical abilities. Comparison of individuals pre and post the application of exercise on Kinisiforo (K-SET Method).

**Setting**

57 Children visit NicoMed Rehabilitation Center in Limassol City and Paphos city.

Comparison of Participants before using kinisiforo and after using kinisiforo for 3 months.

1. Children with cerebral palsy able to walk with assistance (walking frame, brace or orthotics) group (number = 27).
2. Children with cerebral palsy are not able to walk at all. group (n=24).
3. 6 Children with cerebral palsy were excluded from the study (n=6).

Total number of participants 51

All individuals visit daily the rehabilitation center for exercise on Kinisiforo for 5 times a week for 12 weeks.

### **Interventions**

Kinisiforo (K-SET Method) gait training with body weight support (BWS)

### **K-SET Method composed by:**

- Warm up (stretching for upper and lower extremities and torso muscle) 20 minutes;
- Main part Training on Kinisiforo 30 minutes;
- Balance and coordination exercise on Kinisiforo 20 minutes;
- Gait training on the ground 20 minutes;

### **Main Outcome Measures**

1. Gait kinematics and Body Symmetry;
2. Endurance;
3. Muscle Strength;
4. Spasticity test (Modified Ashworth Scale for children with cerebral palsy);
5. Flexibility and Range of motion;
6. Balance and coordination;
7. The FIM has been used for Skill and daily activities improvement.

Reports of gait velocity for children with CP vary greatly, depending on factors such as muscle hypertonicity, muscle strengthening, range of movement. Velocity for a group of children with CP in the beginning of training with KINISIFORO was reported at  $.29 \pm .27 \text{ m/s}$ ,<sup>15</sup> where velocity of  $.58 \pm .38 \text{ m/s}$  was reported for a diverse group of children with CP that are not exercise with Kinisiforo. In contrast, velocity for healthy children has been reported at approximately  $1.49 \text{ m/s}$ .<sup>16</sup> It has also been shown that the metabolic costs of walking are considerably higher for children with CP that are not exercise on

Kinisiforo, with gait requiring between 50% to 67% more metabolic energy expenditure than for children with CP that exercise on Kinisiforo walking at the same velocity. The characteristic slow, asymmetric, and inefficient pattern of walking for children with CP often limits the ability for daily living activities. previous roles within the home and the community.

There is no consensus regarding the optimal treatment to reestablish normative gait for children with CP. A variety of techniques are applied in clinics, from traditional techniques to newer technologies. Many clinicians throughout the world use the Bobath concept, also known as neurodevelopmental treatment. Unfortunately, few treatments have strong evidence to support or refute their use in gait rehabilitation for children with CP.

There is a growing body of evidence on the centers that using **Kinisiforo elliptical** gait training with body-weight support (BWS) may be an effective method of improving gait quality, velocity, and trunk stability for children with CP. The application of Kinisiforo training involving BWS in subjects with neurologic impairment and it was first proposed from Hadjionisiforou Onisiforo, a kinisiologist from Cyprus with a revolutionary counter weight method with early clinical applications in children with Cerebral palsy. Since those initial studies, small clinical trials have been performed to establish the feasibility and safety of the intervention.

There is also increasing evidence that using Kinisiforo is superior to conventional training approaches for gait training for children with CP. Several advantages of gait training on the kinisiforo with BWS have been highlighted in these early studies. The intervention allows the manipulation of postural instability and balance through weight-bearing progression while facilitating elliptical motion. It also makes gait training possible with children's who cannot safely be guarded during over ground gait training, and the intervention can be initiated earlier than conventional methods. Kinisiforo elliptical gait training with BWS has been shown to reduce the cardiovascular demands on children with CP and has the advantage of eliminating the fear of falling.

It has been shown that in gait training for children with CP is associated with future gait independence and that task-specific interventions that are applied early and intensively may be the most effective.

Reports are showing initiation of kinisiforo at early age, greatly from 2 - 5 years, as the timing and training of the overground component of gait were not well addressed. There appears to be a general consensus that early intervention is optimal to encourage motor improvements for children with CP.

To our knowledge, this study is the first to report kinisiforo training before over ground gait has been attempted.

Therefore, the purpose of this study was to investigate the impact of kinisiforo method on children with CP as early as possible. Children with CP at age between 8-18 that they try many different traditional methods and they still are not able to walk without assistance.

The research hypothesis was that children with CP who are gait trained in younger ages using Kinisiforo before the initiation of overground walking with assistance, will have improved gait kinematics, gait symmetry, gait velocity, and gait endurance greater compared with a group of children with CP who received traditional gait training in older age and couldn't walk at all.

## **Results**

Data from 3-dimensional gait analysis and 6-minute walk test (6MWT) supported improved gait for children with CP who practiced gait on Kinisiforo before walking over ground.

Gait analysis showed increased knee flexion during swing and absence of knee hyperextension in stance for the group of children before exercise on Kinisiforo. In addition, more normal ankle kinematics at initial contact and terminal stance were observed. Improved gait symmetry to all children after using Kinisiforo was confirmed by measures of single support time, hip flexion at initial contact, maximum knee flexion, and maximum knee extension during stance. The children after using Kinisiforo also walked further and faster in the 6MWT than before. In addition to that also children with CP they show significant changes in balance in standing position and movement coordination.

## **Conclusions**

Application of Kinisiforo elliptical gait training with BWS before overground gait training may be more effective in establishing symmetric and efficient gait in children with CP than traditional gait training methods in rehabilitation.

## **Study Design**

The NICOMED Rehabilitation center and the Center of Orthopedic and orthosis with the cooperation with the Association for the rehabilitation for people with disabilities in Cyprus are approved this study.

Children with CP were entered without regard to race or sex and were not excluded based on funding status. Each child, or his/her designated representative, signed a consent form before the initiation of the study. The study

was comparison of the same group before and after using kinisiforo elliptical gait training in order to investigate the benefits of the device in children with cerebral palsy.

### **Study Sample**

Children were recruited for exercising on Kinisiforo to a satellite unit of NICOMED Rehabilitation Centers in Limassol and Paphos City. (The equipment necessary to implement the training was located on this satellite unit.)

All children who met the inclusion criteria on this unit between September 2018 and December 2018 were approached concerning participation in the study. A total of 57 children with cerebral palsy were approached, 6 of whom were ultimately disqualified (1 for cerebellar lesion and mental retardation, 2 for Epilepsy issue, 1 for size issues, 1 very limited range of motion in knee extension, 1 had semi -subluxation to right hip. Seven physiotherapist and kinesiologist were enrolled and completed the study protocol.

The inclusion and exclusion criteria for this pilot study are outlined in [table 1](#). [Table 2](#) includes the descriptive details of the participants, including age, frequency of the session per week, and FIM instrument scores. The FIM has been used extensively with subjects with severe hypertonicity and limited range of movement on rehabilitation units [44](#), [45](#) and was used to validate the similarities and difference between before and after training on Kinisiforo. [Table 3](#) describes the type of Children with CP and the side and location of the lesion, along with medical comorbidities of the participants.

**Table 1.** Inclusion and Exclusion Criteria for Study Participants

Inclusion Criteria	Exclusion Criteria
• Boys or girls 6 –18y of age	• Epilepsy
• <6wk after first time ischemic or hemorrhagic stroke	• Significant cognitive impairment (<2 on comm/soc cog section of FIM)
• Able to sit independently at least 3min	• Severe cardiac problems (ie, CHF, uncontrolled hypertension)
• Able to stand with or without assistance	• Over Weight
• Able to give consent or have available authorized surrogate for consent	

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> <li>No significant therapeutic gait practice before start of study (&gt;2 on locomotion section of FIM)</li> </ul>	<ul style="list-style-type: none"> <li>Presence of comorbidities or health conditions that would affect gait training</li> </ul>
<ul style="list-style-type: none"> <li>2–8wk of inpatient rehabilitation LOS at Baylor Institute for Rehabilitation</li> </ul>	<ul style="list-style-type: none"> <li>Severe heart or pulmonary disease</li> </ul>

Abbreviations: CHF, congestive heart failure; comm/soc cog, communication and social cognition;

**Table 2.** Participant Demographic and Initial Clinical Characteristics

Characteristics	Kinisiforo (n=51)		P
	Min–Max		
Age (y)	6 – 18	.949	
	19.3±5.6	12–28	.608
Initial comm/soc cog FIM <sup>†</sup>			
Initial gait FIM <sup>‡</sup>	0.71±0.49	0–1	.375
Discharge gait FIM	5.29±1.11	4–7	.086
Total gait training (min) <sup>§</sup>	437±102	270–540	.306

Abbreviations: Max, maximum; Min, minimum; SD, standard deviation.

<sup>†</sup>For communication and social cognition sections (comprehension, expression, social interaction, problem solving, memory), maximum possible points is 35.

<sup>‡</sup>For gait item only (no stairs), maximum possible points is 7.

<sup>§</sup>Total number of minutes spent on gait training during inpatient rehabilitation stay.

## Interventions

### Children after using Kinisiforo

Thirty minutes of each subject's daily scheduled one-hour therapy program was allocated for gait training and implemented by a physical therapist trained in the research protocol. An additional 30 minutes of daily physical therapy was allocated for other nongait activities, such as bed mobility, transfers, strengthening, and balance training. All physical therapists involved in the study were trained in the protocol and documented participants' daily compliance with the protocol. In addition, the entire rehabilitation team was educated concerning the experimental study protocol to ensure compliance when participants were not working with therapy staff. All participants received an identical lower-extremity orthosis to improve ankle and foot stability during exercise and over ground gait training. The orthosis of choice was a custom-fabricated polypropylene ankle-foot orthosis (AFO) with a double-adjustable ankle joint. This type of joint provided maximum adjustability to control forces during loading and stance while maintaining movement at the ankle, allowing for close replication of normative gait mechanics.

The first gait training session for these participants was on Kinisiforo. No over ground gait training was done before gait training on Kinisiforo. The initial BWS amount was set at 30%, and the speed of Kinisiforo was set at 1.12km/h (0.7mph). These initial training parameters were chosen based on the literature<sup>22, 23</sup> as well as clinical experience. The goal in subsequent sessions (ie, days) was to reduce the amount of BWS by 5%. Efforts were also made to progressively increase the speed of Kinisiforo in .16-km/h (0.1-mph) increments after a participant could tolerate 2 consecutive bouts of at least 3 minutes minimum at the same speed. Speed and BWS were adjusted based on participant response to the progression, primarily the amount of assistance required to advance the more involved lower extremity. Participants could take rest breaks as needed during Kinisiforo training, with a goal of 3 minutes minimum for each gait effort or bout. Kinisiforo training was discontinued when participants were able to walk 10 continuous minutes at a speed of 2.4km/h (1.5mph) without a rest and without BWS (vest on for safety), upper-extremity support, or assistance for weight shift or lower-extremity control.

(Subject 34 reached 2.4km/h on the treadmill the day before discharge from rehabilitation.)

During the training sessions, 2 trained staff members assisted each participant to facilitate normal loading, stance, and swing components for the lower extremities and to facilitate normal weight shift at the pelvis. Participants were forced to hold onto kinisiforo railing once the target speed was reached during each training session. Liberal use of verbal cues was used during the training to facilitate the

best gait pattern possible. To ensure participant safety, vital signs, including heart rate, blood pressure, and oxygen saturation were monitored before and after the training. Treatment was discontinued or deferred if abnormal vital signs were detected, and the participant's physician was notified. All participants were instructed that they could terminate the treatment at any time during training.

- Overground gait was initiated when a participant was for at least 15 minutes on Kinisiforo with no more than 10% BWS and with minimal assistance or less at a speed of 1.3km/h (0.8mph) or greater. A single-point cane was used when over ground gait was initiated. No harness or other support apparatus was used during over ground gait training. Once a participant start a session began with Warm up (stretching for upper and lower extremities and torso muscle) 20 minutes, Main part Training on Kinisiforo 30 minutes, Balance and coordination exercise on Kinisiforo 20 minutes, Gait training on the ground 20 minutes.

. [Table 4](#) details the Kinisiforo training parameters.

**Table 4.** Kinisiforo Training Parameters

Subject	Days After CVA*	Days on Kinisiforo†	Max Kinisiforo Speed‡	Max Kinisiforo Minutes§	Total Kinisiforo Minutes	Progression to Overground Gait¶
01	27	9	1.2	5	49	5
02	17	16	1.1	5	106	12
03	6	18	1.5	10	121	10
04	6	16	1.4	10	135	6
05	14	12	1.3	8	101	7
06	6	16	1.3	7	88	11
1.						
Mean $\pm$ SD						
$12.4 \pm 7.8$ $13.9 \pm 3.5$ $1.3 \pm 0.2$ $7.9 \pm 2.3$ $101.4 \pm 27.5$ $8.7 \pm 2.7$						

\*Number of days after CVA that Kinisiforo training started.

†Total days on which Kinisiforo training occurred.

§Longest time walking on treadmill in 1 bout.

Subject	Days After CVA*	Days on Kinisiforo†	Max Speed‡	Max Kinisiforo Minutes§	Total Kinisiforo Minutes	Progression to Overground Gait¶
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¶Total time on treadmill during inpatient rehabilitation.

†Days on treadmill before beginning over ground gait.

All Children continued use of the AFO through their rehabilitation treatments. At the time of the 3-month reassessment, all had discontinued use of the AFO, either by direction of a physical therapist or by personal choice. Likewise, all children no longer used the single-point cane.

### Data Collection

Data collection was performed for all children. Three-dimensional (3D) gait analysis was recorded using a 12-camera Vicon Motion Capture System, and Vicon Bodybuilder software was used to process the data. Reflective markers were placed bilaterally over the anterior superior iliac spine, the posterior superior iliac spine, the lateral and medial knee epicondyles, the lateral and medial ankle malleoli, the head of the third metatarsal, and the posterior portion of the heel level with the third metatarsal head marker. Markers were also attached laterally to the midthigh in line with the greater trochanter and lateral knee epicondyle markers and on the lower leg in line with the lateral knee epicondyle and lateral malleoli markers. Once markers were positioned, data were collected as participants walked over a level 12-m walkway without an AFO or assistive device or physical assistance from the physical therapist for a total of 10 trials. No practice was done before testing began for any of the participants. The total number of individual gait cycles was averaged together. Measurements included cadence, single- and double-limb support time, step length, and joint angles in the sagittal plane at the hip, knee, and ankle. Testing, including child preparation, took approximately 45 minutes. Children were given the opportunity to rest at any time throughout the testing. Two of the coauthors conducted the testing.

In this study the six-minute walk test (6MWT) has been used successfully to measure gait endurance and velocity of the children. For the test, a trained physical therapist asked participants to walk indoors on a level surface as far as possible in a 6-minute time. Participants were instructed to walk at a pace they felt they could sustain for 6 minutes but were also instructed that they could rest

if needed. They were not given any verbal encouragement during the test. They could use AFOs and assistive devices for the test if they routinely used them in the community.

A stopwatch was used to time the test, and distance was measured with a measuring wheel. Gait velocity was calculated from the distance measurement.

Given the small sample size, the research design, and the ordinal scale FIM data, nonparametric statistics were used for group comparisons. Data were analyzed using the Mann-Whitney U test. An independent t test was used to calculate the symmetry data. Results were considered significant for a P value of less than .05. JMP by SAS<sup>b</sup> was used for the statistical analysis.

## Results

### Demographic Data

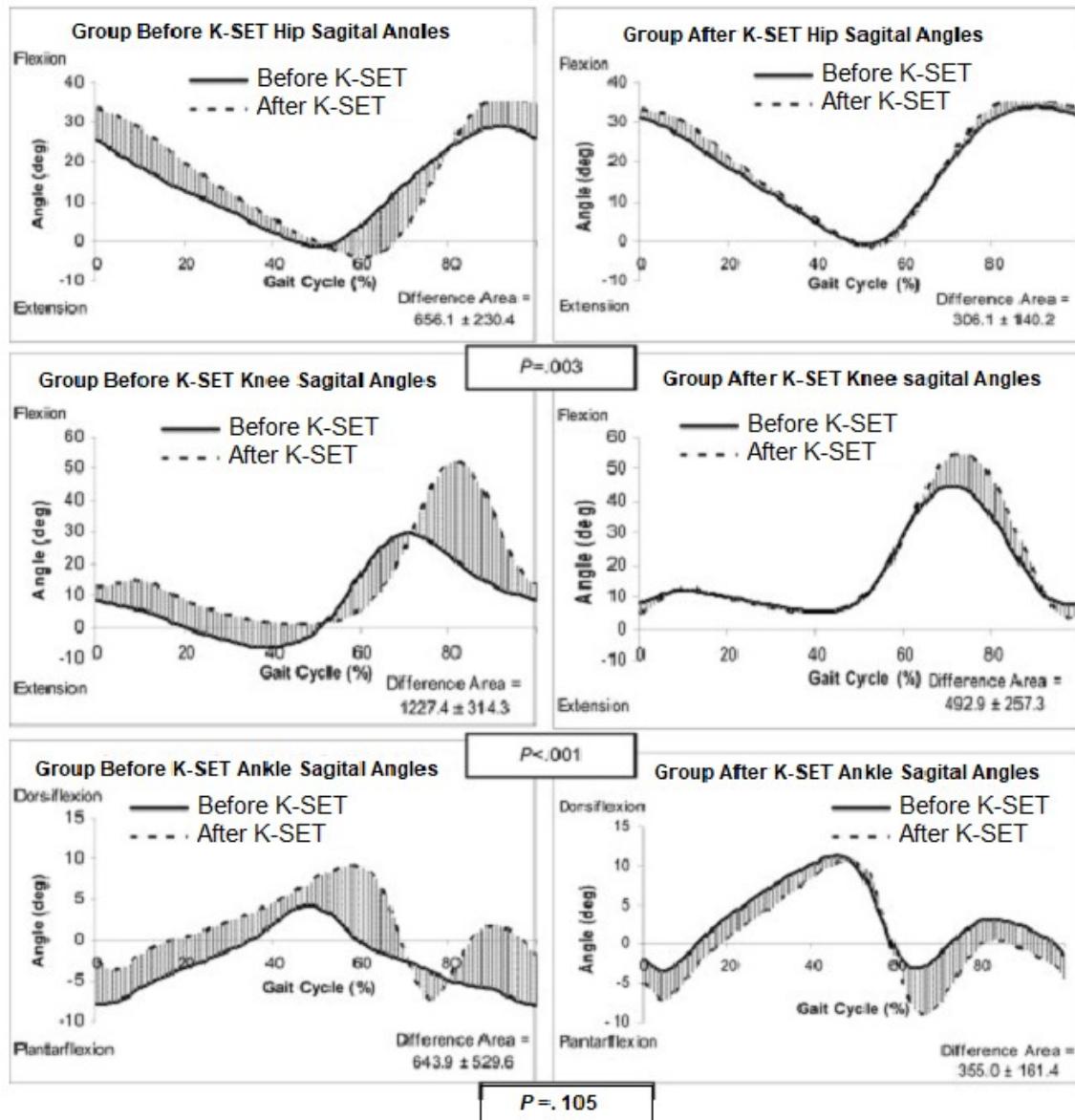
There were significant statistical differences between pre and post Kinisiforo treatment.

### Kinematic Data

Specific kinematic parameters that are typically altered in gait for children with CP and have been previously reported in the literature, were examined (table 5). Hip flexion at initial contact was greater after Kinisiforo training, although not significantly different. Maximum knee flexion was significantly greater during swing phase, as was maximum knee extension during stance. In addition, the ankle at initial contact was closer to neutral after Kinisiforo training. Last, there was increased maximum ankle dorsiflexion at terminal stance after Kinisiforo training.

**Table 5.** 3D Gait Analysis Data\*

Parameters	Kinisiforo (n=7)	P
Hip flexion at initial contact	31.4±7.6	.371
Maximum knee flexion	46.0±11.5	.030
Maximum knee extension in stance	4.4±4.6	.022
Ankle dorsiflexion at initial contact	-0.6±5.3	.041
Maximum ankle dorsiflexion in stance	11.5±2.4	.011



## Symmetry Data

The P values indicate superior symmetry after Kinisiforo training at the hip and knee but not at the ankle.

Single-limb support times were significantly different, meaning the participants after using Kinisiforo training had more symmetric stance times between limbs. Hip flexion at initial contact was significant changed, however, maximum hip flexion was not significant. The maximum knee flexion difference during swing between groups did reach statistical significance, as did maximum knee extension during stance. Last, there was no difference between limbs for maximum ankle dorsiflexion at terminal stance.

**Table 6. Gait Symmetry**

Parameters	Kinisiforo (n=7)	P
Single support*	2.8±4.2	.030
Hip flexion at initial contact†	2.5±1.8	.007
Maximum hip flexion†	3.5±2.4	.125
Maximum knee flexion†	10.2±12.5	.030
Maximum knee extension in stance†	3.1±2.0	.007
Maximum ankle dorsiflexion in stance†	2.1±1.2	.064

NOTE. Values are mean ± SD.

\*Percentage difference of stance time between limbs during gait cycle.

†Difference between affected and unaffected limbs in degrees of motion.

### Endurance Data

The results of the endurance testing are outlined in [table 7](#). Differences in the 6MWT proved to be significant by using Kinisiforo, as they walk further and faster than before.

Table 7. Endurance Data (6MWT)

Parameters	Kinisiforo (n=7)	P
Velocity (m/s)	1.1±0.3	.021
Distance (m)	382.9±107.7	.030

NOTE. Values are mean ± SD.

### Discussion

Children who initiated gait training on Kinisiforo with partial BWS before the initiation of overground gait had better gait kinematics, symmetry, velocity, and endurance than before.

The 3D data collected in this pilot study supported the hypothesis that the gait of children with CP, by using Kinisiforo was closer to a normative gait than before. Mean hip flexion at initial contact on the limbs was closer to the normative value

of 30°<sup>48</sup>. Likewise, the mean maximum knee flexion of 46° observed in the group was closer to the normative average value of 60°<sup>49</sup> during initial swing in healthy gait, allowing easier swing limb advancement. Finally, the mean maximum dorsiflexion observed at terminal stance in the group (11.5°) was closer to the normative value of 10°, allowing for improved trailing limbs position and longer step length after Kinisiforo.

Gait for children with CP is notable for its asymmetry. Data collected in this pilot study confirmed that gait was more symmetric after Kinisiforo treatment sessions. This was validated in the analysis of single support time, hip flexion at initial contact, and maximum knee flexion and extension.

Findings for gait endurance also supported the early Kinisiforo intervention. The velocity of the participants was significantly faster. Velocity after Kinisiforo training was  $1.1 \pm 0.3$ m/s. Gait velocity during a 6MWT has been observed  $73 \pm 36$ m/s. The velocity in the current study was closer to normative values.

The children also walked significantly farther than before in the 6MWT, 382.9m versus 249.7m, respectively.

We believe that these encouraging outcomes with respect to gait symmetry, kinematics, velocity, and endurance in the treadmill group can be attributed to the nature and timing of the Kinisiforo training intervention, as well as to the introduction and integration of the over ground gait component. This study is the first to report improved gait kinematics after Kinisiforo training with BWS in children with CP.

We believe the Kinisiforo environment provided optimum learning conditions at a critical time in the recovery of participants. Recent research in neuroscience has provided new insight into neural plasticity and neural recovery, with evidence of functional reorganization of the motor cortex resulting from behavioral experience. Some of the essential components of training that must be addressed for learning including task complexity, task intensity, and task specificity. Kinisiforo training with partial BWS maximizes many of these key variables, and its application with children with CP.

The Kinisiforo environment provided the opportunity to practice gait efforts with more normative kinematic and temporal features than what is common in clinical practice. With evidence, gait returns to an automatic, or subcortical activity establishing effective gait patterns.

As with other studies, efforts were made to progressively reduce the amount of BWS as gait skill improved. Exactly what role BWS played in the gait recovery of children was not clear. The use of BWS in training facilitates the replication of normative loading responses and weight shifting by the therapists and thus eases the physical burden of the intervention for both subject and therapist. The extent to which the unweighting actually facilitated stepping, as others have postulated, was not determined in this study. Also, not evaluated in this pilot

study was the role of the lower-extremities bracing. As noted, each of the children using Kinisiforo were trained with the same AFO, which was designed to closely replicate normative gait kinematics.

The intervention was completed during 1:30-minute treatment sessions on a typical rehabilitation unit. The protocol of Kinisiforo was designed with controlled training parameters to decrease the effort for both participants and therapists. There were no adverse effects for any children on Kinisiforo.

The decision to progress to over ground gait as defined in the protocol was based primarily on clinical experience but appeared to be an appropriate starting point. Gait training with upper-extremity support on Kinisiforo appeared to make the transition to over ground walking using a single-tip cane a successful experience.

### **Study Limitations**

This was a small pilot study with very encouraging results. Despite a nonrandomized design, there were no statistical differences between the groups. There was no attempt to control for therapeutic activities after discharge from rehabilitation. As is common after discharge from rehabilitation, all participants in the group received continued physical therapy. It was not possible to blind the therapists or testers to group allocation. However, the kinematic testing was all computerized and therefore was not subject to tester bias. The therapists involved in treatment of the participants did not perform the 6MWT with anyone for whom they were the primary therapist.

### **Conclusions**

Gait in children with CP is often slow, asymmetric, and inefficient, affecting the child's ability to resume meaningful roles in society. The results of this study support utilization of Kinisiforo training with BWS before over ground gait training. Given the apparent difficulty in changing an established gait pattern, the potential to restore gait without the typical asymmetries would represent significant progress in the rehabilitation of children with CP.

Further research is needed to replicate these findings in a larger cohort of participants. In addition, the optimum training parameters for this acute application of Kinisiforo training with BWS will have to be established. It is not known, for example, if the current progression to over ground gait is ideal or if a better model exists. Likewise, it has yet to be determined if additional training would further enhance outcomes. The role of bracing will also need to be evaluated to determine the impact on the kinematic variables.

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