Research Paper

Designing a Gait Enhancer and Determining its Effect on Standing Ability and Gait Speed of Children With Cerebral Palsy Spastic Diplegia

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Cerebral palsy, Gait training, Standing ability, Gait speed

ABSTRACT

Objective This study aimed to design a "gait enhancer" and investigate its effect on standing ability and gait speed of children with cerebral palsy spastic diplegia.

Materials & Methods A new gate trainer was designed based on Theo Johnson mechanism. Johnson's two separate movement chains were placed on either side of the gate trainer body and attached to the lower limbs by a foot plate. To investigate the effect of the designed device, a single-item experimental study with baseline design, treatment and maintenance (ABA) was performed on four children with available spastic diplegia cerebral palsy. These children received routine occupational therapy sessions.

Results The designed "gait enhancer" increased standing ability and gait speed scores in all subjects. Non-overlapping measures also indicated the improvement in both variables. Measured by Cohen's d, the effect size for standing ability were 1.95, 2.29, 1.83, and 2.3 for the child No. 1, 2, 3, and 4, respectively. Regarding walking speed, the effect size for these children, No. 1 to 4, were 1.13, 3.37, 2.15, and 2.21, respectively. Cohen's d values were greater than 0.8, indicating the considerable effect of the intervention. Hedges' g was also calculated due to the small sample size, which was greater than 0.8 for all subjects in standing ability and gait speed.

Conclusion Following the use of Gait Enhancer along with conventional occupational therapy, we observed an increase in the ability to stand and walk at children with cerebral palsy. Findings showed that the change in standing ability and walking speed occurred more during the period of using the designed device than other stages, which could be a consequence of using Gait Enhancer along with routine occupational therapy sessions at this stage of the study. However, it should be noted that this study was only a single case study and to prove the effectiveness of this tool in children with cerebral palsy, it is necessary to conduct clinical trial studies.

Extended Abstract

Introduction

Cerebral palsy, with a prevalence of 2-2.5 in 1000 live births [1], is the most common physical disability in childhood. This problem in the developing brain leads to a group of non-progressive disorders. Deficiency in the proper functioning of the muscular system impairs the control of selective movements and muscle tone [2]. The limitations caused by cerebral palsy are often associated with impaired gait speed and endurance and limitations on crossing obstacles [3]. Children with cerebral palsy are less active than their peers [4]. Lack of proper

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mobility and high dependence postpones their growth and social interactions [5, 6]. For these children and their families, improving the walking ability is the ultimate goal of rehabilitation [7] because walking plays an undeniable role in daily living activities and improving bone density and cardiopulmonary function [8].

Various studies on children with cerebral palsy have indicated a clear relationship between the severity of cerebral palsy and walking ability [9]. The severity of cerebral palsy is divided into 5 levels based on the Gross Motor Function Classification System (GMFCS) [10, 11]. Many children with cerebral palsy, especially spastic diplegia, have serious problems due to poor control of the trunk, abnormal muscle tone, and lack of coordination in the lower limbs [12]. According to the GMFCS, children at level III need to use a hand-held mobility device such as a cane to walk [13]. Half of the parents of these children admitted that the use of these devices had a good effect on their child's mobility [14]. In a study on adults with cerebral palsy, it was found that 35% of these people, despite the use of assistive devices, experienced a decrease in walking ability. In 9% of cases, this ability was completely lost over time [13]. Decreased endurance and muscle strength seem to be the main reason for this problem [15]. Gait trainers and support walkers are the most used tools by this group, and this issue has been addressed in the International Classification of Functioning, Disability, and Health [16]. However, these devices are often not used to train walking but increase the child's activity and participation [17]. Therefore, existing gait trainers are not used as tools to improve gait [17]. Although the role of gate trainers in increasing children's ability to travel further distances has been confirmed in some studies, more research is needed to investigate the overall impact of these tools [18]. Therefore, proper tools should be designed that can improve the gait of children with cerebral palsy.

Materials and Methods

The device designed in this study, "gait enhancer" was made according to Theo Jansen's mechanism. The schematic view of this mechanism is shown in Figure 1. It is known among robot designers for its adjustable design, optimal energy consumption, and fast walking pattern [19]. The device was made of a 3-mm steel sheet and aluminum bars (Figure 2). In this study, an experimental single-subject approach with an ABA design was used. This type of research is powerful for clinical decision-making [20]. Because of the novelty of the study and the uncertainty of the appropriate effect of the designed tool, 4 children with spastic diplegia were selected from rehabilitation centers affiliated to Iran Medical Council in Tehran in 2018. The inclusion criteria for them were as follows: having cerebral palsy spastic diplegia, being 6-10 years old, walking independently with a walker, understanding and following simple verbal instructions based on the SPARCLE Questionnaire [21], being at level III based on GMFCS for cerebral palsy, having family consent to participate in the study, and lacking orthopedic surgery or Botox injections in the past year. The exclusion criteria were as follows: Having uncontrolled seizures, having dislocation or partial dislocation of the hip joint, and suffering from shortness of more than 2 cm in one of the lower limbs. The mean age of the participants was 7 years and 9 months, and they were all boys.

The baseline period was 4 weeks and the intervention and follow-up periods were 8 weeks. All participants had 3 routine occupational therapy sessions per week during the study. During the intervention period, besides routine occupational therapy, they practiced with the "gait enhancer" for 30 minutes 3 times per week. In most studies related to children's gait training tools, 30-40 minutes of walking with the device have been applied [8]. The gross motor function and gait speed in children were assessed with the gross motor function measure-66 (GMFM-66) and 10-m walk test, respectively. All assessments were performed without placing the child in the device. The GMFM-66 has five dimensions of lying and rolling, sitting, crawling and kneeling, standing and walking, running, and jumping [22]. In this study, only the standing dimension was investigated. The assessments were performed by a senior occupational therapist, who was blind to the study process. The 10-m walk test is a valid test for children with cerebral palsy [23]. This test is a suitable tool for measuring the results of treatment after therapeutic intervention [24]. The person is asked to travel 10 m with or without an assistive device and at a maximum selected speed [25].

Results

The results of single-case studies are reported and analyzed mostly in the form of graphs [26]. In this study, for each variable, graph analysis and calculation of non-overlapping indices (PND, PAND, NAP, PEM, IRD, Phi, Tau-U) were performed. The intervention effect was calculated by using Cohen's d and Hedges' g:

$$Cohen's\ d = (M2 - M1) / SDpooled$$

Standing ability

The assessment of children's ability to stand based on the GMFM-66 is shown in Figure 3. Based on the visual analy-

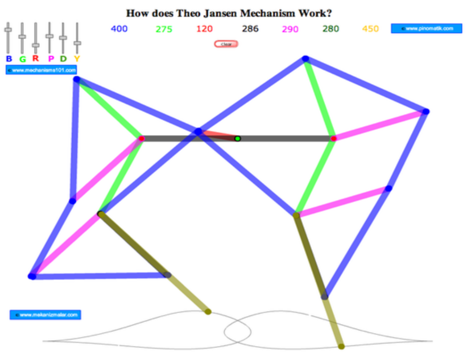

Figure 1. Schematic diagram of the Theo Jansen linkage mechanism

sis of the change process, the scores related to the standing ability in the intervention phase had an upward trend in all four children compared to the baseline scores. The standing ability of child No.1 increased by 20.5% in the intervention phase and 2.6% in the follow-up phase. In child No.2, the increase was 25% in the intervention phase and 2.7% in the follow-up phase. In child No.3, the increase was 17.9% in the intervention phase and 2.6% in the follow-up phase. In child No.4, the increase was 20.5% in the intervention phase and 7.7% in the follow-up phase.

To accurately examine the observed changes and conduct a pairwise comparison of the results between baseline and intervention phases, non-overlapping parameters were calculated. The results are given in Table 1. Comparing the baseline and intervention phases, these values were slightly lower in the third child than in the other children, but in the other three children, the obtained values indicate a further increase in scores in the intervention phase. These differences were significant. The effect size of the intervention using Cohen's d and Hedges' g are presented in Table 2.

Walking ability

The results of the 10-m walk test are shown in Figure 4 for all four children. The visual analysis of the graphs shows

Figure 2. The designed "gait enhancer" device

the downward trend of the scores in the intervention phase. The downward trend was stopped in the follow-up phase. In Child No.1, the test duration was reduced from 11 to 8.9 s after the intervention, but after removing the intervention effect, this time was extended by 0.5 s. In child No.2, there was a decrease of 3.6 s in the test duration following the intervention and remained constant in the follow-up phase. In child No.3 and No.4, the test times were reduced by 6 and 3.7 s, respectively, in the intervention phase. In the follow-up phase for child No.3, there was a reduction in duration by 1 s, but for child No.4, the travel time increased by 0.2 s. Therefore, in all children, gait speed increased significantly after the intervention, but in the follow-up phase, only the third child showed a slight increase in gait speed. For the pairwise comparison of the phases, non-overlapping indices were calculated (Table 3). The obtained values indicate an increase in gait speed in all children. The increase was lower in the fourth child than in other children. Non-overlapping measures indicated a significant reduction in the time recorded for traveling the test distance for all children. The effect size of the intervention using Cohen's d and Hedges' g are reported in Table 4. The results showed a significant difference in the intervention phase compared to baseline and follow-up phases. Therefore, the use of the designed device along with conventional occupational therapy was effective in increasing the gait speed of children.

Table 1. Non-overlapping measures related to the standing ability scores between baseline and intervention phases

Child	PND (%)	PAND	NAP	PEM (%)	IRD (%)	Phi	TAUnovlap	Tau-U
1	100	1	1	100	100	1	1	0.92
2	100	1	1	100	100	1	1	0.92
3	83	0.87	0.96	100	67	0.67	0.92	0.83
4	100	1	1	100	100	1	1	0.92

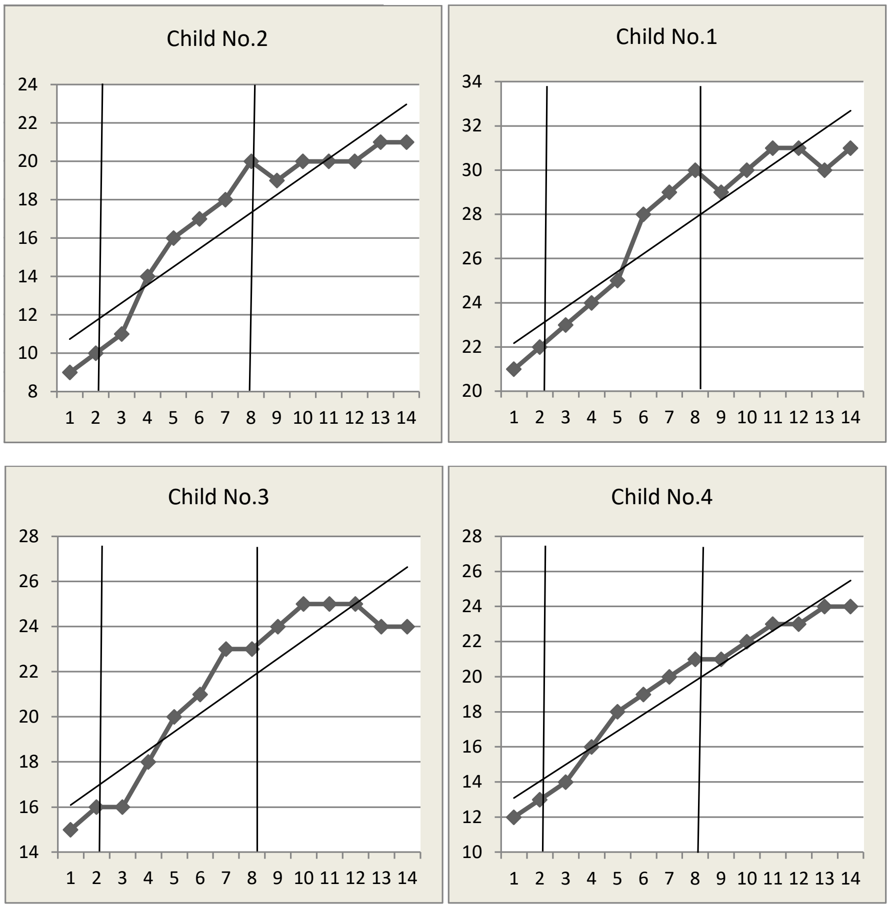

Figure 3. The standing ability scores of children with spastic diplegia based on the Gross Motor Function Measure-66

Discussion and Conclusion

The results showed the effectiveness of using the designed device in improving the standing ability of four children with spastic diplegia. This result is consistent with other study results [27, 28]. Schindl et al. investigated the effect of gait training on a treadmill in improving cerebral palsy children's standing ability. Their results showed that, although this type of intervention increased the standing ability, the rate of progress was much higher in children who could walk with weight support than in children without this ability [29]. The children in our study were all able to walk with assistive devices; hence, their results are consistent with our results. Provost et al. obtained similar results to Schindl et al. following gait training in children with cerebral palsy [30]. Because of the continuous weight-bearing exercise on the lower limbs using the gait trainer and the apparent effect of this type of exercise on increasing muscle strength and standing on the legs, an increase in the ability to stand in these children was expected [31]. By concentrating on the walking, the standing duration on two legs decreases, while its duration on one leg increases. This finding can also justify the improved standing ability in children [22]. In children No.3 and No.4, the standing duration was significantly prolonged after the intervention.

In this study, gait speed was measured using a 10-m walk test, and the results showed the desired effect of gait training with the "gait enhancer" device along with occupational

Table 2. The effect size of the intervention in improving the standing ability

Effect Size	Child 1	Child 2	Child 3	Child 4
Cohen's d	1.95	2.29	1.83	2.3
Hedges' g	1.7	1.99	1.59	2

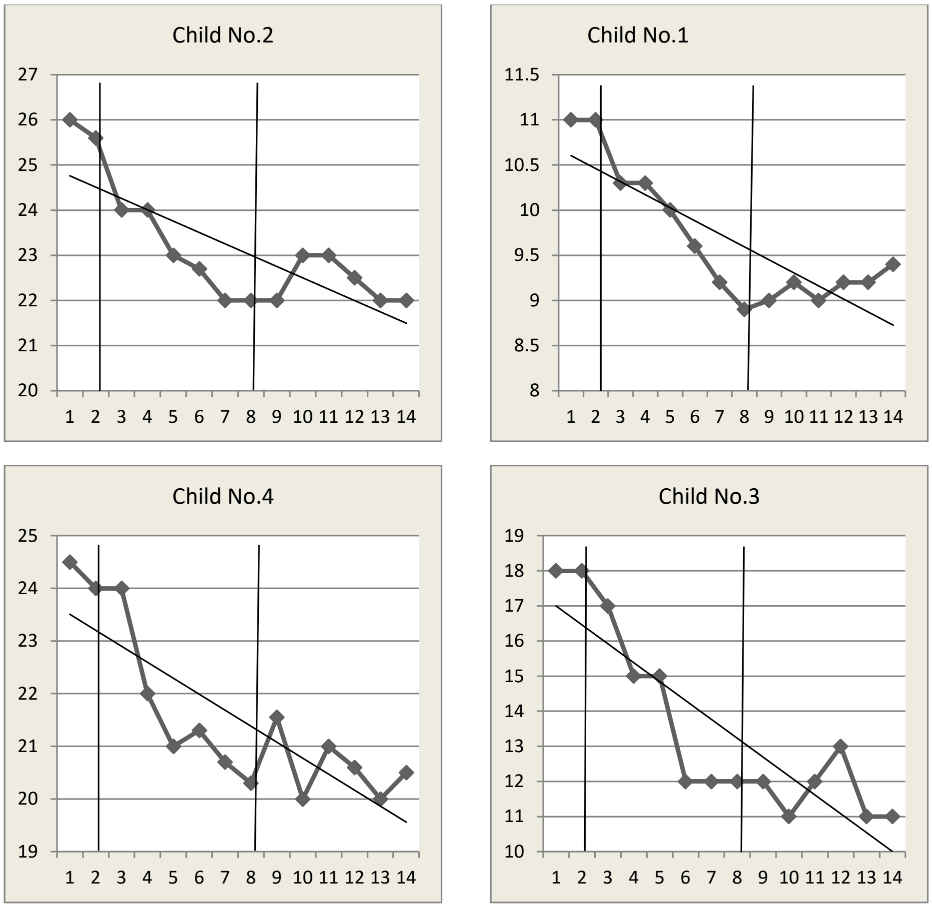

Figure 4. The recorded time (s) for children with spastic diplegia in the 10-m walk test

therapy. Many studies have examined gait speed with the 10-m walk test. The results of some of these studies are consistent with the results of the present study [32-34]. This similarity may be because of the reduced time it took to stand on two legs following gait training with the designed device. These assistive tools reduce the standing duration on both feet while walking by increasing the swing time in the lower limbs and, hence, increase gait speed [35, 36]. Dodd et al. also reported improvement in gait speed after the intervention [8]. Willoughby et al. in a clinical trial, compared two ways of walking on the ground and a treadmill. Their results showed no significant differences between the two groups. Therefore, both methods increased gait speed to the same extent [37]. Fatorehchy et al. in a pilot study, examined the effect of aquatic therapy in children with cerebral palsy. The results showed improved gait balance and walking capacity in children [38]. In another study, they found an improvement in gait endurance after using gait enhancer in children with cerebral palsy [39]. Therefore, increased balance and endurance of walking can be a reason for increased gait speed in these children.

Table 3. Non-overlapping measures related to the walking ability scores between baseline and intervention phases

Child	PND (%)	PAND	NAP	PEM (%)	IRD (%)	Phi	TAUnovlap	Tau-U
1	100	1	1	100	100	1	1	1
2	100	1	1	100	100	1	1	0.92
3	100	1	1	100	100	1	1	1
4	83	0.87	0.96	100	67	0.67	0.92	0.83

Table 4. The effect size of the intervention in improving the walking ability

Effect Size	Child 1	Child 2	Child 3	Child 4
Cohen's d	1.13	3.37	2.15	2.21
Hedges' g	0.98	2.93	1.87	1.92

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Although the gross motor function level of the children in the study was the same, they showed a large difference in gait performance. Therefore, only children at level III of GMFCS had to be selected for the study, and they prolonged the research process. Children have different body dimensions. This device has limited settings for a child. Another limitation of this research was the need for financial resources. In the process of designing and manufacturing the device, repeated actions were required. Moreover, difficulty in purchasing equipment and manufacturing different parts made the research process longer than initially expected. Because of the effectiveness of the designed device, it is recommended that a study be performed to increase the symmetry of lower-extremity motor function in children with hemiplegia. The use of this device in children under 6 years of age is recommended for better therapeutic results.

Using the designed gait enhancer and common occupational therapy can improve the standing ability and gait speed of children with spastic diplegia. The gait enhancer is a valuable device for gait training in these children, with no adverse effects. The difference in results between the four participating children was due to differences in lower-limb muscle strength and muscle tone. This study's results cannot be generalized to all children with cerebral palsy; hence, more research is needed.

Ethical Considerations

Compliance with ethical guidelines

This study obtained its ethical approval from the Research Ethics Committee of the University of Social Welfare and Rehabilitation Sciences (Code: IR.USWR.REC.1396.286).

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Authors' contributions

Designing of Gait Enhancer: Saeid Fatorehchy and Seyed Mehdi Hosseini; Date analysis: Samaneh Hosseinzadeh; Editing: Saeid Fatorehchy; Revision and Supervision: Hojjat Allah Haghgoo and Seyed Mehdi Hosseini.

Conflict of interest

The authors declared no conflict of interest.

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