DOI: 10.22122/jrrs.v15i6.3482 Published by Vesnu Publications

Designing a Clinical Trial to Determine the Effect of Conventional Physiotherapy Plus Ankle KinesioTaping® on Walking and Balance in Children with Spastic Diplegia Cerebral Palsy: A Protocol for a Double-Blind Randomized Clinical Trial

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Original Article

Abstract

Introduction: This study is a protocol of a double-blind randomized clinical trial with the aim of determining the effect of ankle KinesioTape® in addition to the routine physiotherapy approach on walking and balance of children with cerebral palsy (CP) suffering from spastic diplegia.

Materials and Methods: The present clinical trial was performed on 20 children who were randomly divided into the two groups of control and intervention. 4 weeks of routine physiotherapy program was carried out for all the participants in both groups. In the intervention group, the KinesioTape® was applied to the ankles of the patients for 4 weeks in addition to the routine treatment. After completing this course, a 6-week follow-up phase was conducted for both groups, in which both groups received routine physiotherapy treatment. The treatment program was repeated twice a week. The outcome measures included modified Timed Up and Go (TUG) test, Gross Motor Function Measure (GMFM), and Pediatric Balance Scale (PBS). The normal distribution of the data was determined using the Shapiro-Wilks test. Paired-sample t-test and Wilcoxon nonparametric test were employed to analyze the data and check for changes before and after the treatment in each group. Additionally, the repeated measures analysis of variance (ANOVA) was used to compare between the two groups ($P < 0.05$).

Conclusion: KinesioTape® improves voluntary movement, coordination and balance, and functional independence in children with CP. According to the comprehensive search of literature, it seems that no study to date has examined the effect of ankle equinus corrective KinesioTaping® on walking and balance in children with spastic diplegia. The results of the study can be used to examine the effectiveness of the addition of ankle Kinesio Taping® to physiotherapy on the function and balance of these children.

Keywords: Cerebral palsy; Walking; Kinesio tape; Posture balance

Citation: Ziaei B, Nassadj G. **Designing a Clinical Trial to Determine the Effect of Conventional Physiotherapy Plus Ankle KinesioTaping® on Walking and Balance in Children with Spastic Diplegia Cerebral Palsy: A Protocol for a Double-Blind Randomized Clinical Trial.** J Res Rehabil Sci 2019; 15(6): 305-10.

Received: 18.12.2019 Accepted: 23.01.2020 Published: 04.02.2020

Introduction

Cerebral palsy (CP) is a non-progressive growing brain lesion that occurs before, during, or after birth (1) and has a prevalence of 1.4 to 2.4 per 1000 live births (2). One of the most common clinical types of CP is spastic diplegia (3) in which the sensory-motor disorder in the lower extremity is more than the upper extremity and also, there is a significant weakness in the trunk muscle of these patients (4). A major disorder in children with CP is the inability to coordinate the activation of the postural muscles in the proper sequence, especially during functional activities (5), which leads to functional limitations (6).

Spasm is a complex movement disorder caused by dysfunction of the central nervous system (CNS) that leads to changes in all locomotor systems and affects the large functional motor abilities of children with spastic CP (7,8). Spasm causes many movement disorders such as reduced range of motion (ROM), feeling of stiffness, difficulty moving, muscle shortening, and equinus (9). Equinus, the most

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common foot complication in children with CP, is caused by a muscle disorder in which the plantar flexor muscles of the ankle are 5 to 6 times stronger than the dorsiflexors (10).

Walking is one of the most complex functions that it is very difficult to predict when it will start in children with CP (11). Static and dynamic balance is required to stand and walk, which is impaired in children with CP, including spastic diplegia (12). Poor static balance causes limitations in movement and, consequently, a decrease in the ability to perceive the environment and communicate (2,12-15). Dynamic imbalance makes it difficult to perform daily functions (16). Common complications of dynamic balance disorder include frequent falls due to the inability to control postural fluctuations (17). Balance assessment is rarely performed in the clinic (18).

Kinesio Taping (KT) is a relatively new technique used in rehabilitation programs (19) and was first proposed by Dr. KenzoKase in 1996 (20). Kinesiotape can increase proprioception, reduce muscle spasm, strengthen weak muscles, correct joint orientation and, consequently, improve voluntary movements, coordination and balance, and functional independence in children with CP (20,21).

One of the main problems of children with spastic CP is walking disorder and imbalance, and the ankle equinus is one of the most important causes of gait disorders in these children. On the other hand, little research has been conducted on the effect of long-term use of Kinesiotape on the ankles of these children (21-23). Additionally, based on the investigations, no study has been performed so far on the effect of Kinesiotaping on ankle equinus and gait and balance in children with diplegia. Therefore, this study is performed with the aim to evaluate the effect of corrective Kinesiotaping on improving gait pattern and static and dynamic balance in children with CP with spastic diplegia.

Materials and Methods

This was a double blind (child and analyzer) randomized clinical trial which was approved with the code IR.AJUMS.REC.1397.820 by the ethics committee of Ahvaz Jundishapur University of Medical Sciences (AJUMS), Ahvaz, Iran. The study protocol was also registered and approved on the Iranian Registry of Clinical Trials (IRCT) system with the code IRCT20181211041931N1.

20 children with spastic diplegia CP who referred to the physiotherapy clinic of AJUMS since May 2019 participated in this project. Calling the children to the study was performed by a pediatric neurologist and their treatment was also free of charge. Prior to the implementation of the plan, information about the objectives, study steps, test time, and possible risks was explained to the parents of the children and the informed consent form was completed by the participants.

Sampling was carried out in a simple non-probability method and samples were selected from among the children who meet the conditions for admission to the study. The clinical trial inclusion criteria included age less than 9 years (22), ability to stand and walk independently or with assistive devices (24), diagnosis of spastic diplegia by the physician (22), and ability to understand verbal instructions for tests (21,24,25). History of surgery or botulinum toxin injection during the six months prior to treatment (21,24,25), sensitivity to Kinesiotape (by performing allergy testing) (21), lack of parental compliance with the treatment plan provided to the child (21), tumor lesions CNS injury following any trauma, and history of any lower limb correction surgery were also considered as the exclusion criteria. Random evaluation and assignment of the subjects to treatment groups was carried out by the physiotherapist, and to avoid bias, the number of files recorded was reviewed by another physiotherapist.

The children were randomly assigned to one of the control (conventional physiotherapy treatment) or intervention (conventional physiotherapy treatment + ankle Kinesiotape) groups.

At the beginning of treatment, the participants' demographic information, including age, height, and weight, was recorded to calculate their body mass index (BMI). The child's standing and walking performance level was measured based on version 88 of the Gross Motor Function Measure (GMFM) (3), the Timed Up and Go (TUG) test (26), and the Pediatric Balance Scale (PBS) (25). At the end of four weeks of treatment in each of the study groups, the tests were repeated and the results were recorded. Six weeks after the end of the treatment sessions, the relevant evaluations were repeated. Children in both groups received regular physical therapy treatment during the six weeks.

GMFM: This scale has been designed to assess changes in gross motor function over time or after treatment in children with CP. There are two versions of the test, 66-GMFM (27) and 88-GMFM (3). The GMFM scale consists of 88 items in five subgroups: "sleeping and rolling, sitting, crawling, and kneeling, standing, walking, and running, and jumping" (3), with "standing, walking, running, and jumping" examined in the present clinical trial. The validity and reliability of this test in Iran has been confirmed by Salehi et al. (28).

TUG test: This scale has been designed to assess children's functional movements and balance (30) and is such that the child sits on a chair (the height of which is such that the child's knees and pelvis are in 90 degrees and his soles are on the ground). The child is told to stand up from the chair, walk 3 meters, and come back and sit on the chair again. The time it takes for the child to stand up and sit down is recorded (31).

PBS: This balance scale consists of 14 items to assess motor skills out of the person's base of support (BOS). The PBS items are used to assess the child's ability to maintain and change position while the BOS decreases (25) and are graded from zero to four; with a higher score indicating more balance (3). The scale examines static and dynamic balance, of which 8 items are related to dynamic balance (maximum score 32) and 6 items are related to static balance (maximum score 24) (25). The validity and reliability of the test in Iran have been reviewed and confirmed by Kalantari et al. (32).

Interventions: The number of treatment sessions for the child was twice a week, with each session lasting 1 hour. Common physiotherapy treatments included stretching of the gastrosoleus and adductor muscles of the hip joint, strengthening the anterior tibialis muscles of both legs by functional electrical stimulation (FES), balance exercises, and posture and gait training (22).

Electrotherapy was performed with a stimulator device (NEURADYN 710L, Novin Company, Iran). The current used was FES current with a wavelength of 180 microseconds and a frequency of 60 Hz. In most studies that used FES for children with CP, a frequency of 20-40 Hz and a wavelength of 350-250 microseconds were used (30,33,34), but in the present clinical trial, with a decrease in wavelength and increase in the frequency, the unpleasant effect of the current was reduced (35). This current was applied to the anterior tibialis muscles of both legs for 20 minutes (31) each session. The electrode placement method was as the active electrode was placed under the fibula head and the passive electrode was placed on the anterior tibialis muscle motor point (30).

The Kinesiotape in these children was utilized to correct the ankle equinus and was applied once a week and remained six days a week, and the last day was removed from the child's skin by the parents (22,36). Before attaching the Kinesiotape, the sensitivity test was performed by attaching a Kinesiotape measuring 5 x 3 cm to the inside area of the knee, and after two days, that part was examined for any skin allergies. The Kinesiotape attaching was in such a way that first the ankle was maintained to the maximum dorsiflexion and the adhesive was attached from the back of the foot (base of the toes) with 25 to 50% of stretch to below the knee. Another Kinesiotape was then attached to the middle of the sole (between the calcaneus and the head of the metatarsals) and brought diagonally to the front area of the ankle, ending with more stretch on the outside area of the foot (Figure 1). Three transverse Kinesiotapes were attached so that the first was on the head of the metatarsals, the second on the ankle joint, and the third on the head of the fibula (23).

Figure 1. How to attach the ankle corrective Kinesiotapes

Randomization: The first referring child was randomly placed in one of the treatment groups by tossing a coin (heads: intervention group and tails: control group) and then the children were divided into the groups according to the even or odd case number.

Blinding strategy: The participants knew that they would receive full physiotherapy treatment, but were not aware that there were two treatment groups and that there was a difference between the treatment groups. For this purpose, treatment sessions were arranged in such a way that the children who referred for treatment in one day were placed all in one group (intervention or control). The child's parents were reassured that there would be no negligence in treating their child. The data was encrypted by the main researcher and the analyzer was not aware of the design protocol when analyzing the data.

The normal distribution of the data was examined using the Shapiro-Wilk test. If the data had a normal distribution, the paired t-test and otherwise, Wilcoxon test were used to analyze the

data and examine changes before and after treatment in each group. Additionally, repeated measures analysis of variance (ANOVA) test was applied for the inter-group comparisons. Finally, the data were analyzed in SPSS software (version 22, IBM Corporation, Armonk, NY, USA). $P < 0.05$ was considered as the data significance level. Moreover, the test power was obtained using G*Power software version 3.1.5 (version 3.1.5, University of Düsseldorf, Düsseldorf, Germany) and the drop in participants during the project was reported via the CONSORT chart.

Based on a similar study by de Costa et al. (25) and given the TUG test score, as well as considering the 95% confidence level and 99% test power, the sample size for the present clinical trial was estimated to be 10 people in each group.

Discussion

CP includes a group of progressive sensory, motor, and postural disorders caused by non-progressive damage to the developing brain (less than 2 years old) (1). Damage to the CNS may lead to secondary injuries such as spasms, decreased muscle tone, or skeletal abnormalities in children with CP, which impair balance (37). Kinesiotape is a non-invasive, cost-effective, relatively new, and accessible method for treating some of the lesions and function of these children (38). The use of Kinesiotapes affects the skin receptors of the locomotor system and can increase proprioception, reduce muscle spasm, strengthen weak muscles and, consequently, improve the function of children with CP (20,21).

The present clinical trial was designed to determine the effect of ankle Kinesiotape on standing, walking, and balance in children with spastic diplegia and its purpose, in addition to examining the effect of Kinesiotape on the improvement of gait and balance in these children, was also to determine the duration of Kinesiotape effect.

Limitations

None.

Recommendations

None.

Conclusion

None.

Acknowledgments

The present study was taken from an MSc thesis of physiotherapy with code PHT-9740, ethics code IR.AJUMS.REC.1397.820, and IRCT code IRCT20181211041931N1, approved by AJUMS. The authors would like to appreciate the supervisor, consultant, and all those who contributed to this project.

Authors' Contribution

Bahare Ziaei: Study design and ideation, attracting financial resources for the study, study support, executive, and scientific services, providing study equipment and samples, data collection, analysis and interpretation of results, manuscript preparation, specialized evaluation of the manuscript in terms of scientific concepts, approval of the final manuscript to be submitted to the journal office, responsibility of maintaining the integrity of the study process from the beginning to the publication, and responding to the referees' comments; Gholamhosein Nassadj: Study design and ideation, attracting financial resources for the study, study support, executive, and scientific services, providing study equipment and samples, analysis and interpretation of results, manuscript preparation, specialized evaluation of the manuscript in terms of scientific concepts, approval of the final manuscript to be submitted to the journal office, responsibility of maintaining the integrity of the study process from the beginning to the publication, and responding to the referees' comments.

Funding

This study was part of the information of an MSc dissertation on physiotherapy with code PHT-9740, ethics code IR.AJUMS.REC.1397.820, and IRCT code IRCT20181211041931N1, which was prepared with the financial support of AJUMS. This university did not comment on data collection, analysis, and reporting, manuscript preparation, and final approval of the article for publication.

Conflict of Interest

The authors declare no conflict of interest. Dr. Gholamhosein Nassadj attracted the budget for basic studies related to this article from AJUMS and has been working as an assistant professor of physiotherapy at this university since 2012. Bahare Ziaei has been a graduate student of physiotherapy at the School of Rehabilitation, AJUMS since 2017.

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