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Effect of New Inventive Happy Strap in Children with Down Syndrome

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Abstract: Children with Down syndrome begin to develop orthopedic problems including inefficient gait pattern for walking early in childhood. To reduce the sequences of these orthopedic problems few treatment modalities such as serial immobilization casting, corrective splints and surgery were used. However, these modalities may delay the progression of neuro-motor development in a child. Alternatively, treatment model such as new inventive strap "Happy Strap" which correct deformities, increase stability and allowed child to walk and movement may be considered. The aim of this project was to examine the effects of newly developed strap on stability and walking patterns in children with Down syndrome. In this Randomized controlled trials eight children aged 18 months to 4 years were randomized to an experimental (Happy strap) children or a control group. All 8 children were assessed without the strap, on and immediately after using the strap for experimental group and at 3 months for both groups using the Gross Motor Function Measure (GMFM) (standing, walking and running, jumping dimensions). The strap was applied for 24 hours a day every day for the 3-month intervention period. Results revealed that there is improvement of motor function for both groups but it was better in children who worn happy strap for 3 months. For experimental group the total mean of GMFM was improved from 172.45 ± 6 before applying the strap to194.32 ± 2 after. In conclusion: this study provides some preliminary evidence that happy strap may promote an improved motor function in young children with Down syndrome. However, larger sample size using more advanced measurement tools may reveal different findings.

Key wores: Down Syndrome · Strap · GMFM · Motor function

INTRODUCTION

Hypotonia, ligament laxity and motor alterations are characteristic for children with Down syndrome (DS). Motor disability is widespread among individuals with DS it includes balance, postural deficits and co- contraction of agonist and antagonist muscles [2-4]. Additionally, children with DS begin to develop orthopedic problems early in childhood and Caselli *et al*., reported that walking in children and adolescents with DS was characterized by a pattern with external rotation and abduction of the hips, increased knee flexion and valgus and external rotation of the tibia [5]. One problem is that, this is an inefficient gait pattern for walking. If this pattern is allowed to persist, problems will develop with both the knees and the feet, walking will become painful and endurance will be decreased. These problems tend to progressively worsen as the clinical picture advances, severely limiting the patients 'quality of life [6-9]. In order to decrease the severity of these problems and allow the individual to function much more efficiently, early detection and intervention of these physical consequences in a child with a Down syndrome is vital [10-13]. Limited information suggested that, the treatment modalities used in the correction of congenital abnormalities in the child with Down-syndrome are the same that would be used in the normal patient [14-17]. These include serial immobilization casting, corrective splints and surgery. However, it has been suggested that immobilization modalities that impede walking, such as plaster casts or restrictive splinting, should be avoided, since these can further delay the progression of neuro-motor development in a child that will already exhibit a significant delay in learning to walk. Alternative method of intervention may be considered which correct deformities, increase stability and allowed child to walk and movement is recommended. However, there are limited number of studies about physical intervention or/ and the use of strap or splint to prevent these deformities in children with DS. Additionally, a new inventive strap "Happy Strap" which has been designed

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by parents of child with DS as an aid for infants and children with hypotonia (low muscle tone) to assist the control of ligament laxity and joint flexibility in the hip joint. However, there is no previous research/ study to investigate the effect of "happy strap" in walking pattern and joints stability for children with DS. Thus, the aim of this project was to examine the effects of newly developed strap on stability and walking patterns in children with Down syndrome.

METHODS

Design: Randomized controlled trials

Participants: we intended to recruit twenty children with Down syndrome but at this stage eight children aged 18 months to 4 years were randomized to an experimental (Happy strap) or a control group (without happy strap). This study was approved by the Hashemite university review board and a parent of each participating children's' families provided a consent.

Intervention (3 Months): In experimental group, happy strap was modified to fit children size in order to be appropriate for each child. Prior to "happy strap" application children's mothers had received proper orientation about the use of happy strap. All intervention for these 4 children was carried out at children homes but GMFM tests were carried out at our rehabilitation lab.

Strapping Procedures: Happy strap was applied for 24 hours a day every day for the 3-month intervention period. The mothers removed the strap for daily necessary child activities such as bathing, dressing etc and once a week for one hour to allow active range of motion and to check skin integrity.

Outcome Measurements: All 8 children were assessed without " happy strap" on, immediately after using the happy strap for experimental group and at 3 months for both groups. At this stage 2 measurements were administered: The Gross Motor Function Measure (GMFM) (standing, walking, running, jumping dimensions) and Bruninks-Oseretsky Test of Motor Performance (BOTMP) (balance subtest). At this stage only data from the GMFM is analyzed but upon completed the entire study data from other measurement tools will be analyzed and correlated with each others. So, there is no sufficient data yet for proper statistical analysis.

Initial Results: No serious safety events were encountered or occurred during the study such as fractures, hip dislocations, or skin abrasions.

Table1 demonstrates that there is improvement of motor function for both groups but it was better in children who worn happy strap for 3 months. At this stage it was not possible to analyze hip stability due to the lack of valid accessible tools, following discussions with researchers and biomechanics scientists from various research centers, it was suggested that the best way of measuring the effects of happy strap on hip stability and gait analysis in children with DS is by using motion tools to analyze the immediate and long term effects of happy strap on hip stability and quality of movement.

Limitations of the Study: At this stage there is only one measurement outcome was analyzed (GMFM). The GMFM-66 is functional measures and may not detect changes in gait and quality of movement, which may be important areas to consider. Additionally, small sample size was used [only 8 children]. larger Larger sample size using more advanced measurement tools may reveal different findings.

Summary and Recommendation: This ongoing study is the first ever study to examine the effects of happy strap on motor function and hip stability in young children with Down syndrome. However, this study provides some preliminary evidence that happy strap may promote an improved motor function in young children with Down syndrome.

Table 1: GMFM scores for both happy strap group and control groups, [N= 8 children with DS]

Variable	Happy strap group before	Happy strap group after 3 months	Control group before	Control group after 3 months
	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)
GMFM total	172.45 (6)	194.32(2)	182.7(8)	184.6(6)
GMFM crawling and kneeling	34.7(3)	36.8(0.6)	33.9 (4)	34.2(4)
GMFM standing	25.7 (5)	29.3(3)	22.5 (7)	23.8 (2)
GMFM walking, running and jumping	18.4 (2)	21.6(08)	15.3(3)	16.5(1)

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