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EFFECT OF PEDIASUIT™ PROTOCOL ON GROSS MOTOR FUNCTION OF CHILDREN AND ADOLESCENTS WITH CEREBRAL PALSY

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ABSTRACT: Rehabilitation has been a fundamental pillar in the management of Cerebral Palsy, aiming to promote function, activity, and participation of individuals. Therapeutic suits or garments, associated with intensive protocols, have become popular in the rehabilitation of children with Cerebral Palsy. However, scientific evidence supporting their efficacy remains scarce. Therefore, the aims of this study were to investigate the effect of the PediaSuit™ protocol on the gross motor function of individuals with Cerebral Palsy, as well to assess safety of the intervention. Methods: This was a quasi-experimental, prospective, and longitudinal study with a single-group pre-post design, in which each participant served as their own control. Sixty-three children and adolescents with Cerebral Palsy, classified from Level I to V according to the Gross Motor Function Classification System and aged between 2 and 16 years, were recruited from various neurological rehabilitation centers. All participants were assessed using the Gross Motor Function Measure before and after participating in an intensive intervention based on the PediaSuit™ protocol. The intervention consisted of daily 4-hour sessions conducted over a 4-week period, totaling 80 hours

of therapy. Results: An improvement in gross motor function was observed after the intervention period with the PediaSuit method. Conclusions: The PediaSuit™ protocol demonstrated significant positive effects on gross motor function in all individuals participating in this study, regardless of cognitive variations, severity, and region. The findings suggest that PediaSuit™ is a promising intervention for improving motor function in children with CP, with potential for replication in different clinical settings due to the multicentric nature of the research, safety, and acceptability.

KEYWORDS: Cerebral palsy, suit therapy, PediaSuit™ Protocol.

Introduction

Cerebral palsy (CP) is a non-progressive movement and posture disorder resulting from a static lesion occurring in the pre-, peri-, or postnatal period, affecting the brain during its structural and functional maturation phase (Sadowska et al., 2020). Its etiology is influenced by a combination of environmental and genetic factors (Srivastava et al., 2022). Globally, the prevalence of children born with CP is 1.6 per 1000 live births in high-income countries, with significantly higher rates in low- and middle-income countries (McIntyre et al., 2022).

Clinically, CP often manifests through sensorimotor disorders, alterations in gross motor function, deficient postural mechanisms, and difficulty in gait acquisition (Srivastava et al., 2022). Associated characteristics include biomechanical alignment alterations, uncoordinated voluntary movements, stereotyped movements, fixed contractures, bone deformities, muscle we-

akness, and joint instability (Fang & Lerner, 2024).

CP is a chronic condition, and its prognosis depends on the degree of motor difficulty, the presence of musculoskeletal deformities, and the effectiveness of the rehabilitation process (Yuan et al., 2024). Rehabilitation has been a fundamental pillar in the management of CP, aiming to minimize impairments and promote function, activity, and participation of individuals. In recent decades, technological advancements have introduced new therapeutic approaches, including the use of therapeutic suits and dynamic orthoses (Guru et al., 2023).

These methods are based on the application of dynamic corrective forces, muscle strengthening, and provision of proprioceptive feedback, aiming to help brain reeducation (Semenova, 1997). The goal is to improve posture, movement, prevent deformities, and facilitate functional performance (Karadağ-Saygı & Giray, 2019).

Dynamic orthoses can modify joint alignment and enhance muscle strength and flexibility in children with CP. This can positively impact posture, balance, coordination, gross and fine motor skills, and gait (Semenova, 1997; Scheeren et al., 2012; Bailes et al., 2010). The mechanisms involve continuous compression and/or tension from the suit's elastic elements, which are customized for each child's needs (Semenova, 1997; Martins et al., 2015; Liptak, 2005).

The most recent model is the Dynamic Suit Orthosis (DSO) in a treatment protocol called "Suit Therapy." The literature describes two forms of intervention with the DSO: single use or as a part of an intensive training program (Flanagan et al.,

2009; Matthews et al., 2009; Degelaen et al., 2016).

Each method implements a different intensive treatment plan, which involves lengthy sessions, scheduled multiple times per week over the course of several weeks. Some of them also use body support elements, such as elastic cords and a metal cage (SPIDER system) to facilitate verticalization when the child is unable to stand upright alone (Glowinski & Blazejewski, 2020).

Suit therapies described in the literature include the Penguin Suit, AdeliSuit, TheraSuit, Full Body Suit, Dynamic Elastomeric Fabric Orthosis (DEFO), stabilization pressure input orthosis (SPIO), UpSuit, Second Skin, and PediaSuit™ (Semenova, 1997; Martins et al., 2015; Liptak, 2005; Degelaen et al., 2016).

Therapeutic suits or garments, whether associated with intensive protocols or not, have become popular in the rehabilitation of children with CP. However, scientific evidence supporting their efficacy remains scarce. Therefore, the aims of this study were to investigate the effect of the PediaSuit™ protocol on the gross motor function of children with cerebral palsy, as well as the efficacy and safety of the method.

Methods

This was a quasi-experimental, prospective, and longitudinal study with a single-group pre-post design. All participants underwent baseline assessments prior to the intervention and were re-evaluated immediately after completing the treatment protocol. No control group was included; thus, each participant served as their own control to measure changes in gross motor

function over time. The study was approved by the Research Ethics Committee of ----- (CAAE: 63749022.2.0000.5382) and conducted in accordance with the ethical principles outlined in the Declaration of Helsinki (2013). Parents or legal guardians of the participants received detailed information about the study procedures and provided written informed consent prior to enrollment.

Participant

The sample consisted of children and adolescents diagnosed with Cerebral Palsy (CP), recruited from various neurological rehabilitation clinics across Brazil. These centers were selected based on their clinical experience and the fact that their staff had completed training in the PediaSuit™ method and had at least five years of experience in neurofunctional rehabilitation. Additionally, all professionals involved in the study received specific training for the standardized application of the Gross Motor Function Measure (GMFM-88).

Inclusion criteria were: a confirmed diagnosis of CP; classification within Levels I to V of the Gross Motor Function Classification System (GMFCS); and provision of informed consent by legal guardians and participating centers. Exclusion criteria included: severe cardiac conditions preventing physical activity; degenerative joint disease; unhealed fractures; uncontrolled epileptic seizures; and anthropometric limitations that precluded appropriate use of the PediaSuit™.

Procedures

All participants were evaluated before and after the intervention. Data collection followed these steps:

1. Clinical and Neurological History:

A detailed clinical history was collected, including the child's neurological condition and GMFCS classification.

2. Medical History: Information regarding previous treatments, surgical procedures, use of orthoses, and current medications was documented.

3. Motor Function Assessment: The GMFM-88, a validated instrument for assessing gross motor function in children with CP, was applied. It comprises 88 items distributed across five dimensions: (i) lying and rolling; (ii) sitting; (iii) crawling and kneeling; (iv) standing; and (v) walking, running, and jumping. Scores are presented as percentages for each domain, along with a total combined score.

Following the initial assessment, we developed an intensive treatment plan using the PediaSuit™ protocol. This plan included daily 4-hour sessions conducted over a 4-week period, comprising a total of 80 hours of treatment. The sessions involved warm-up exercises, functional exercises, sensory integration exercises, and specific exercises using the PediaSuit™ and the therapeutic cage. The sessions were divided into 4 phases:

Phase 1 – Warm-up and Stretching

This phase began with brushing the upper and lower limbs, and trunk. Then, we did a therapeutic massage, joint mobilization, active and passive stretching of the main joints (wrist, elbow, shoulder, ankle, knee, and hip), as well as trunk rotation movements.

Phase 2 – Suit

In this phase, participants were fitted with a soft dynamic proprioceptive orthosis called the suit, with elastic cords attached to specific places on the suit to correct postural deviations. The suit adjusts the body position as close to normal as possible. Restoring correct posture plays a crucial role in normalizing muscle tone, sensory, and vestibular functions. Following that, activities such as weight bearing, mobility, agility, coordination, weight shifting, balance, transition, motor planning, and strengthening were done. The suit is used to train the child to acquire the ability to isolate the desired movements and strengthen the muscle groups that control them.

Phase 3 – Functional Exercises with the “Monkey Cage” Therapeutic Cage

This cage is used to assist with resistance and strength training for specific muscle groups. During this step, pulleys and weights are used and adjusted to give the desired resistance.

Phase 4 – “Spider Cage”

In the spider cage, the children wear a belt around their waist that is attached to the cage using bungee cords. The bungee cords are adjusted just enough to provide the child with the security and balance needed to practice activities independently. The cage also allows the child and therapist to work on activities that would normally require two or three therapists by acting as an extra set of hands. It is used to practice activities that promote postural stability and motor coordination. Daily activities were performed with the suit, including sitting, standing, walking, and climbing stairs. Breathing and relaxation techniques were used to conclude the session.

Equipment

PediaSuit™: An orthopedic suit consisting of a vest, shorts, knee pads, belts, and adapted shoes, all connected by a series of adjustable elastic bands.

Therapeutic Cage: A structure that allows strengthening, stretching, and coordination exercises with the help of pulleys, weights, and elastic bands.

Therapy Unit: A space equipped with support boards, parallel bars, therapeutic balls, activity mats, mirrors, and other rehabilitation equipment.

Statistical Analysis

Descriptive statistics, including means and standard deviations, were calculated for all continuous variables. The Shapiro–Wilk test was used to assess the normality of data distribution. Demographic characteristics were summarized using descriptive statistics.

To evaluate the effect of the PediaSuit™ intervention, participants ($n = 63$) were stratified into five subgroups according to their Gross Motor Function Classification System (GMFCS) levels (I to V), allowing for the assessment of treatment effects across varying levels of motor impairment. The primary outcome was the total score on the Gross Motor Function Measure-88 (GMFM-88), which was compared before and after the 4-week intervention period. Given the pre-post design in which participants served as their own controls, paired t-tests were used to compare GMFM-88 total scores when data met the assumption of normality. A significance level of $p < 0.05$ was adopted for all statistical comparisons.

The sample size calculation was based on a single-group pre-post design, with the

total score of the Gross Motor Function Measure-88 (GMFM-88) considered as the primary outcome. An expected mean difference of approximately 2 points, with an estimated standard deviation of 5 points, was assumed. A significance level of 5% ($\alpha = 0.05$), a statistical power of 90% ($1-\beta = 0.90$), and a two-tailed test were applied. Based on these parameters, the minimum required sample size was calculated to be 44 participants. Given that the study included 63 participants, the actual statistical power was recalculated and determined to be 98.9%, indicating a strong ability to detect meaningful differences under the proposed study design. All statistical analyses were conducted using JAMOV software (Version 1.6, 2021).

Results

Sample Characteristics

The sample consisted of 63 children with CP, recruited from various specialized neurological rehabilitation clinics.

Age

The ages ranged from 2 to 16 years, with an average of 8.2 ± 4.7 years, covering distinct stages of child development and allowing for a comprehensive analysis of the treatment's impact across different ages.

GMFCS Score	I	II	III	IV	V
Participants (n)	3	4	13	23	20
Age					
Mean	8.6	9	10.2	7.4	8.7
SD	6.02	7.0	6.08	4	5.2
Sex					
Male	1	2	7	15	10
Female	2	1	7	8	10
Topography					
Quadriplegic	0	0	0	16	19
Hemiplegic	2	2	8	0	0
Diplegic	1	2	5	7	1
Medication Use					
Yes	1	1	8	17	15
No	2	3	5	6	5

Abbreviations: GMFM-88, Gross Motor Function Measure-88; GMFCS, Gross Motor Function Classification System; SD, **standard deviation**.

Table 1 Participants' demographic characteristics

Gender

The sample included 35 boys (55.5%) and 28 girls (44.5%).

Presence of Cognitive Impairment

Clinical evaluation indicated that 38 children (60.3%) had some degree of cognitive impairment, while 25 (39.6%) did not showed significant cognitive impairments.

Severity in Relation to GMFCS

Participants were classified according to the GMFCS which categorizes the severity of cerebral palsy into five levels:

Level I: 3 children (4.7%) - Walk without limitations.

Level II: 4 children (6.3%) - Walk with limitations.

Level III: 13 children (20.6%) - Walk using a mobility device.

Level IV: 23 children (36.5%) - Self-mobility with limitations; may use wheelchairs.

Level V: 20 children (31.7%) - Transported in a manual wheelchair.

This distribution allowed for a detailed assessment of the treatment's impact on participants with varying levels of CP severity.

Medication Use

Among the study participants, 42 (66.2%) were regularly taking medication, with the sodium valproate or phenobarbital being the most used medications to control epileptic seizures. In addition, medications to control spasticity and other associated conditions were used, including the use of cannabidiol by one child. The remaining 21

(33.8%) were not taking continuous medication. The presence of medication was checked throughout the study to assess possible influences on treatment outcomes.

PediaSuit™ Protocol

The results showed a significant improvement ($p < 0.05$) in gross motor function in all groups after intensive treatment with the PediaSuit™ protocol (Table 2). In the GMFCS I group, the mean score increased from 67 ± 10.4 to 82 ± 12.7 , resulting in a percentage of improvement (final value - initial value / initial value * 100) of 22.30%. The GMFCS II group showed an increase from 65.8 ± 3.4 to 75.6 ± 3.8 , corresponding to an improvement of 14.87%. In the GMFCS III group, the score increased from 54 ± 16.6 to 62 ± 17.6 , with a percentage improvement of 14.81%. The GMFCS IV group showed an increase from 33.9 ± 14 to 43.4 ± 16 , corresponding to 28.02%. Finally, the GMFCS V group had an increase from 14.6 ± 11.6 to 20.6 ± 15.9 , resulting in a percentage improvement of approximately 41.10%.

These results indicate that these methods promoted significant improvements on the gross motor function of participants, regardless of the severity level of cerebral palsy.

Discussion

The sample represented a wide range of ages, CP severity levels, and associated conditions such as cognitive impairments and medication use. This diversity allowed a robust and detailed analysis of the effects of intensive treatment with the PediaSuit™ method. It is observed that 68.2% of participants fell into GMFCS levels IV and V,

GMFCS Score	I	II	III	IV	V
GMFM-88	67.1	65.8			
Baseline	10.4	3.4	54	33.9	14.6
SD	82	75.6	16	14	11.6
Pós Protocol			62	43.4	20.6
SD	12.7	3.8	17	16.4	15.9
<i>p</i> Value	0.020	0.030	0.001	0.020	0.002

Abbreviations: *GMFM-88*, Gross Motor Function Measure-88; *GMFCS*, Gross Motor Function Classification System; *SD*, **standard deviation**.

Table 2 GMFM-88 Scores Before and After the PediaSuit™ Protocol

showing a higher participation of individuals with severe conditions. These results confirmed the findings of Damiano et al. (2009), who describe the benefits of complementary interventions for children with CP levels IV and V. One reason for the greater representation of this population may be the need for more personalized and effective approaches to the management of various motor limitations. The literature suggests that intensive therapy, which involves prolonged and consistent use of therapeutic suits, promotes neuroplasticity, facilitating recovery and improving motor functions (Scheeren et al., 2012; Bailes et al., 2010). Moreover, families of these children tend to seek alternative methods due to frustration with the limited results of conventional therapies. This interest is also influenced by the greater availability of information about new therapies and the growing awareness of the potential for technological innovation in the field of rehabilitation.

Sample Characteristics

Another aspect observed was the presence or absence of cognitive impairment. It is known that cognition in children with CP can vary greatly, with some children

showing significant cognitive impairments while others do not have any impairment (Yuan et al., 2024). Assessing cognition in children with CP is a complex challenge, especially when the goal is to understand the ability to understand and perform simple motor tasks without applying specific cognitive tests. In our study, a clinical assessment of cognition was chosen for its practicality and applicability, focusing primarily on describing the participants' ability to follow commands and perform basic functional activities in a therapeutic setting. This approach is supported by the literature, which suggests that in contexts where motor function is the focus, assessing cognitive ability to follow basic instructions can be sufficient (Himmelman & Uvebrant, 2011). The inclusion of individuals with and without cognitive impairment allowed us to observe the effect of treatment with the PediaSuit™ in a diverse sample that was close to reality.

It is worth noting that this study showed a high level of acceptability among participants, with a dropout rate of 0%. The few adverse effects reported were irritability, discomfort with the suit, sleep disturbances, and fatigue in the first sessions, indicating the viability and safety of the treatment.

PediaSuit™ protocol

The protocol was applied intensively over four weeks and showed significant improvements in gross motor function at all GMFCS levels (I to V). This finding is consistent with previous reports that also documented notable improvements in gross motor function in a GMFCS III child (Oliveira et al., 2018) and five children with GMFCS levels I to IV (Mélo et al., 2017; Bailes et al., 2011) who underwent similar interventions with this suit. The effectiveness appears to be closely linked to the use of the therapeutic suit, which acts as an exoskeleton, helping to reorganize movement patterns and promote brain plasticity. This additional support is crucial, given that proprioception and motor control are often impaired in children with CP. The theory behind the use of therapeutic suits is based on the induction of strong proprioceptive stimuli, which can stimulate the formation of brain circuits compromised by neurological injury (Kim et al., 2016).

Bailes et al. (2011) reinforces this theory, demonstrating that the use of therapeutic suits, like the TheraSuit, which also uses elastic cords to provide proprioceptive feedback, can result in relevant improvements in the gross motor function of children with CP. In the same way, Scheeren et al. (2012) suggests that body alignment, joint compression, and muscle resistance during movement provided by the suit's elastic cords are crucial for motor rehabilitation.

Additionally, the work by Alagesan and Shetty (2011) compared the effects of the AdeliSuit with conventional physiotherapy, showing a more pronounced improvement in gross motor function in patients treated with this method. They attribute the benefits to the external stabilization of

the trunk provided by the garment, which allows more coordinated movements of the upper and lower limbs.

The association between enhanced sensory input, body alignment, and the resistance provided by the therapeutic suit seems to have played a crucial role in the effective improvement of gross motor function observed in all participants in this study. These factors were enhanced by the use of the Spider and Monkey cages recommended in the PediaSuit™ protocol.

Literature highlights the use of the Spider cage as an effective tool for improving motor function (Glowinski & Blazejewski, 2020). It allows for assisted and safe movements, improving participants' confidence when performing challenging motor tasks. Exercises performed here can strengthen muscles, improve coordination, assist with verticalization, and body balance using simple but very useful body support elements. Meanwhile, the Monkey cage adds an element of muscle strengthening by enabling weight training, which is essential for developing muscle strength and endurance (Scheeren et al., 2012).

Another crucial pillar of the PediaSuit™ treatment is that it is an intensive rehabilitation program. Conventional interventions, which typically involve less frequent and less intensive therapy sessions, may not provide sufficient stimuli to induce significant neuroplastic changes. In contrast, intensive intervention offers repetitive and sustained practice that can stimulate synaptic reorganization and strengthen neural circuits, leading to more evident and lasting functional improvements. Animal models of CP have shown that intensive intervention reduces brain inflammation, preserves myelination, and modulates the expression of proteins

involved in excitatory synaptic function in the brain (Sanches et al., 2024). Hilderley et al. (2024) suggested that early and intensive intervention based on motor skills learning can stimulate neuroplastic changes in both gray and white matter, leading to improvements in motor skills.

We must emphasize that all participants in this study, which included several clinical characteristics of CP, showed improvements in their gross motor function after the intervention. This approach combines the best elements of different techniques and methods, with a foundation based on exercise physiology and motor learning. It is important to note that the suit is just one part of this approach. The fact that it is an intensive 80-hour program conducted over four weeks, unlike traditional therapy which would deliver 80 hours over 30 weeks (an average of two hours per week), facilitates repetition, which is a key factor in motor learning of new tasks (Christy et al., 2012). However, it should be noted that the intensive program used in this study is not limited to repetition of exercises but involved structured activities that consider individual cycles. By strengthening muscles and improving function, the activities performed using the Spider and Monkey cages promoted general physical benefits. As children develop physically, they become more mobile and confident and begin to use these skills to a greater extent.

These consistent and clinically relevant improvements observed across all participants provide compelling preliminary evidence supporting the potential efficacy of the PediaSuit™ protocol.

A recent literature review emphasized the challenge of identifying methodologically sound studies involving Suit Therapy,

primarily due to the marked heterogeneity among individuals with CP. The wide variability in clinical presentations—ranging from differences in motor function and muscle tone to cognitive abilities and associated comorbidities—makes it difficult to establish and apply standardized research protocols (Wells et al., 2018; Belizón-Bravo et al., 2021; Almeida et al., 2017). However, it is important to recognize that there are no records of adverse effects or lack of positive impact. On the contrary, the associations between proprioceptive stimulation, workload, and training intensity are consistently described as beneficial. In the present study, for example, a significant improvement was observed in all participants, regardless of their cognitive abilities and the severity of their condition. This finding is consistent with the existing literature, suggesting that interventions demonstrate significant clinical benefits.

The main limitation of this study is the lack of a control group. This absence can be explained by the difficulty in finding families willing to commit to activities without the direct benefit of the intervention with PediaSuit™.

In summary, the available data from various rehabilitation centers in Brazil and abroad described here indicate significant positive effects resulting from the application of the PediaSuit™ protocol on the gross motor function of individuals with CP.

Conclusion

The PediaSuit™ protocol demonstrated significant positive effects on gross motor function in all individuals participating in this study, regardless of cognitive variations, severity, and region. The findings suggest

that PediaSuit™ is a promising intervention for improving motor function in children with CP, with potential for replication in different clinical settings due to the multi-centric nature of the research, safety, and acceptability.

Conflict of interest statement

On behalf of all authors, the corresponding author states that there is no conflict of interest.

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