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Investigation of Mollii Suit's effectiveness in children with cerebral palsy with different ambulance levels

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ABSTRACT

Aims: This study aimed to investigate the effects of the Mollii Suit method (MSM) on gross motor function, muscle tone, postural control and lower extremity selective motor control in children with cerebral palsy (CP) at different ambulance levels.

Methods: Children with CP were divided into two groups according to gross motor function classification system (GMFCS) levels. The first group consisted of 10 ambulatory children with spastic type CP from GMFCS levels I, II and III, and the second group consisted of 10 non-ambulatory children with spastic type CP from GMFCS levels IV and V. Both groups attended 6 weeks of routine physiotherapy sessions, 3 days a week, 60 minutes MSM. Gross motor function was assessed using the Gross Motor Function Measure-66 (GMFM-66); muscle tone was evaluated with the Modified Ashworth Scale (MAS); postural control was measured using the modified functional reach test (mFRT) and the Trunk Impairment Scale (TIS); and selective motor control was assessed with the selective control assessment of the lower extremity (SCALE). All evaluations were made at the beginning and end of the treatment (6 weeks later).

Results: A significant increase in total GMFM score was observed for all individuals after the intervention. In children with ambulatory CP, the TIS score showed a significant increase, whereas no significant change was observed in the other group. While the increase in mFRT score was not significant for both groups and the increase in SCALE score was significant for the non-ambulatory group. In the MAS score, there was no difference between the two groups.

Conclusion: This study has shown that MSM affects motor function, body control and selective motor control in children with CP. Based on these results, we think that the use of MSM in addition to rehabilitation in children with CP may be effective and hopeful.

Keywords: Cerebral palsy, Mollii Suit, spasticity, motor function, postural control, selectivity

INTRODUCTION

Cerebral palsy (CP) is the most common physical disability in childhood[1] and is currently defined as a permanent, nonprogressive disorder of movement, posture, and motor function resulting from a lesion or abnormality in the developing brain.[2] The epidemiological profile of CP has evolved over time. Although its prevalence has remained relatively stable for many years at approximately 2-3 cases per 1,000 live births,[3] notable advancements in early diagnosis, prevention, and treatment over the past decade have contributed to changes in incidence, prognosis, and treatment responsiveness.[1] CP results from damage to various regions of the brain, with the location and extent of the lesion influencing the severity, distribution, and type of motor impairments, such as muscle spasticity. In addition to motor dysfunction, individuals with CP frequently experience associated impairments, including sensory, cognitive, perceptual, and communication deficits, as well as secondary musculoskeletal complications and pain.[4]

Motor rehabilitation approaches for individuals with CP encompass a wide range of interventions, including conventional rehabilitation techniques (e.g., range of motion exercises, neurodevelopmental treatments, muscle strengthening and stretching, aerobic and biofeedback-based exercises, gait training, and the use of orthoses), intensive rehabilitation programs [such as constraint-induced movement therapy (CIMT) and hand-arm bimanual intensive therapy (HABIT)], physical and sports activities, as well as technology-assisted methods.[5] Among these, electrical stimulation is frequently employed and has been shown to contribute to the reduction of spasticity while enhancing functional capacity, muscle strength, and joint range of motion.[6] One specific technique that has gained increasing attention in recent years is transcutaneous electrical nerve stimulation (TENS). TENS functions by delivering electrical impulses to the nervous system, thereby modulating or altering neuronal activity. It is utilized in a variety of

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clinical domains, including neuromotor rehabilitation,[7] pain management,[8] the treatment of defecatory and urinary dysfunctions,[9,10] and cognitive modulation.[11] Furthermore, TENS can be integrated with other rehabilitation modalities to enhance the overall effectiveness of treatment strategies.[11]

The Mollii Suit method (MSM) (Exoneural Network AB, Danderyd, Sweden) is a wearable system that integrates TENS into a full-body garment equipped with strategically placed electrodes. These electrodes are designed to replicate the natural electrical signals of the nervous system, facilitating controlled muscle fiber contraction and relaxation. The primary aim of MSM is to reduce spasticity while enhancing flexibility and range of motion. The embedded electrodes provide targeted stimulation to specific muscle groups, allowing for precise and individualized therapeutic intervention. This selective stimulation approach enables accurate localization of affected areas, thereby supporting customized treatment plans tailored to the needs of each user. The suit is operated via a control unit that can be programmed according to individual therapeutic requirements, and these programs can be saved for repeated use, eliminating the necessity for continuous reprogramming.[12]

Developed to enhance motor function by reducing spasticity and pain, the Mollii Suit method is based on the principle of reciprocal inhibition, wherein stimulation of the antagonist muscle at low frequencies and intensities leads to the inhibition of the spastic muscle. Clinical studies conducted in pediatric populations have reported no discomfort or adverse effects associated with the use of this method.[13-18] In one study, children described the suit as making them feel like superheroes, contributing to a sense of well-being and motivation.[19] Parents also expressed optimism, noting that the method could serve as a promising alternative to conventional treatments.[16] In a pilot study conducted by Hedin et al.,[15] 16 individuals with CP of varying severity levels received 60-minute treatment sessions every other day for a period of six weeks. The results demonstrated a significant reduction in spasticity and an improvement in joint range of motion.

MSM has been utilized in the treatment of pain and spasticity in individuals with conditions such as CP, stroke, ataxia, and fibromyalgia. However, these studies have employed diverse methodologies, and the findings have demonstrated variability and inconsistencies across outcomes.[16-18,20] The majority of existing studies on the Mollii Suit have been conducted with limited samples or on homogeneous GMFCS groups. This limits the generalizability of its effectiveness in children with different motor function levels (GMFCS I-V). Furthermore, the Mollii Suit's operating principle is to modulate the neuromuscular system via low-frequency TENS. This mechanism may respond differently depending on GMFCS levels. Therefore, this study aimed to examine the effects of MSM on gross motor function, muscle tone, postural control, and selective motor control of the lower extremities in children with CP, according to ambulation status.

METHODS

This study was designed as an experimental clinical trial with two parallel arms. Ethical approval was obtained from the Gazi University Ethics Committee (Date: 13.06.2024, Decision No: 2024-989). The study was conducted in accordance with the principles outlined in the Declaration of Helsinki, and informed consent was obtained from all participants and their legal guardians.

The study was carried out between July 10, 2024, and November 30, 2024, at the Developmental Physiotherapy and Pediatric Rehabilitation Unit within the Department of Physiotherapy and Rehabilitation, Faculty of Health Sciences, Gazi University. Children diagnosed with spastic CP who were referred by a pediatric neurologist were assessed for eligibility. Only children whose parents provided both verbal and written informed consent were included in the study.

Inclusion criteria were: (1) voluntary participation, (2) diagnosis of spastic CP, and (3) age between 4 and 18 years. Exclusion criteria included: (1) receiving *Botulinum* toxin A treatment within the past 3 months, (2) undergoing any surgical intervention within the past 6 months, or (3) having an implanted invasive medical device (e.g., baclofen or insulin pumps).

The required sample size was determined using G*power software (version 3.1.9, Universität Düsseldorf, Düsseldorf, Germany).[21] Based on a power of 90%, a significance level of 0.05, and a minimally clinically important difference (MCID) of 1.6 on the Gross Motor Function Measure (GMFM), a sample size of 10 participants per group was calculated.[22,23] Accordingly, a total of 20 children with CP were included in the study, with 10 participants allocated to each group.

Measurements

All assessments were performed one day before and one day after the intervention by a pediatric physiotherapist with 10 years of experience in the field. During the initial evaluation, demographic data-including age, weight, height, and type of CP-were recorded. Motor function, muscle tone, trunk impairment and selective motor control were evaluated respectively. Motor function was classified using the Gross Motor Function Classification System (GMFCS) developed by Palisano et al.,[24] while motor performance was assessed using the Gross Motor Function Measure-66 (GMFM-66), a validated short form of the original scale.[25] The GMFM-66 evaluates motor activities across five domains: lying and rolling, sitting, crawling and kneeling, standing, and walking/running/jumping. Each item is scored on a 4-Point Ordinal Scale ranging from 0 (does not initiate the movement) to 3 (completes the movement independently).

Muscle tone was assessed using Modified Ashworth Scale (MAS), a widely used tool for evaluating spasticity. Bilateral assessments of the hamstring and gastrocnemius muscles were performed with the participant in a supine position, with the head in the midline and limbs in a relaxed position. Resistance encountered during passive movement of the antagonist muscles was graded on a scale from 0 to 4.[26,27]

Trunk stability during reaching was measured using the modified functional reach test (mFRT). This test assessed lateral reach from a seated position, with the distance measured from the tip of the third metacarpal while the participant reached laterally toward the wall.[28,29] Functional assessment of trunk control was further evaluated using the Trunk Impairment Scale (TIS), which includes three subscales; static sitting balance, dynamic sitting balance, and trunk coordination. The scale is scored on a total of 0-23 points, with higher scores indicating better trunk control.[30]

Selective motor control of the lower extremities was assessed using the selective control assessment of the lower extremity (SCALE). This reliable and valid instrument scores selective voluntary joint movements on a scale from 0 to 2, with higher scores indicating better motor control.[31]

Treatment Protocol

Children with CP included in the study were stratified into two groups based on the GMFCS levels. The first group consisted of ambulatory children classified as GMFCS levels I, II, or III, while the second group included non-ambulatory children classified as GMFCS levels IV and V.

All participants attended Neurodevelopmental Therapy (NDT) sessions twice a week throughout the six-week intervention period. To avoid fatigue, both groups attended 60-minute MSM sessions three times a week on days they were not attending NDT programs. The Mollii Suit is a neuromodulatory garment composed of a jacket and pants, incorporating a noninvasive, detachable control unit that delivers electrical impulses through 58 embedded electrodes. These electrodes are flexible, breathable, and strategically positioned over specific muscle groups to ensure direct contact with the user's skin.

The stimulation parameters were set as follows: pulse width of 25-175 microseconds, frequency of 20 Hz, voltage of 20 V, and a square wave pulse shape.[13,14,18] During each session, children were instructed to remain seated or lying down to minimize external interference and ensure the consistent efficacy of the intervention.

After completing a total of 18 sessions over six weeks, post-intervention assessments were conducted, and the treatment protocol was concluded.

Statistical Analysis

Data analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 28.0 (SPSS Inc., Chicago, IL, USA). The distribution of variables was assessed using both visual methods (histograms and probability plots) and analytical tests (Kolmogorov-Smirnov and Shapiro-Wilk tests). Continuous variables were presented as mean±standard deviation (SD), while categorical variables were expressed as frequencies and percentages.

For variables that met the assumptions of normality, between-group comparisons were conducted using the independent samples T test, and within-group comparisons were performed using the paired samples T test. For nonnormally distributed data, between-group comparisons were analyzed using the Mann-Whitney U test, and within-group differences were assessed using the Wilcoxon signed-rank test. A p-value of less than 0.05 was considered statistically significant.

RESULTS

The demographic and clinical characteristics of the participants are summarized in Table 1. The mean age of participants in group 1 was 6.70±0.51 years, while the median age in group 2 was 6 years. Female representation was 60% (n=6) in group 1 and 30% (n=3) in group 2. There were no statistically significant differences between the groups regarding baseline characteristics such as age, height, weight, and gender (p>0.05).

Table 1. Descriptive characteristics of the childrens (n=20)

	Group 1 (ambulatory) (n=10)	Group 2 (nonambulatory) (n=10)	p-value
Age (years)	6.70±0.51	6 (5-11)	0.631
Gender (female), n (%)	6 (60%)	3 (30%)	0.280
Gender (male), n (%)	4 (40%)	7 (70%)	0.380
Height (cm)	113.00±3.40	105.5 (100-146)	0.393
Weight (kg)	19.35±1.30	17 (14-36)	0.912
GMFCS level I-II-III	1-5-4	-	<0.001
GMFCS level IV-V	-	7-3	

Independent samples T test was used (p<0.05). GMFCS: Gross motor function classification system

In the ambulatory CP group, significant improvements were observed in both GMFM-T (p=0.026) and TIS scores (p=0.019), whereas the increases in mFRT, SCALE and MAS scores were not statistically significant (p>0.05). In the non-ambulatory CP group, GMFM-T (p=0.020) and SCALE (p=0.012) scores improved significantly, while changes in mFRT, TIS and MAS scores remained non-significant (p>0.05). Within-group comparisons are presented in Table 2.

Table 2. Within-group comparison before and after intervention

Group 1	Before intervention	After intervention	p-value
GMFM-T	77.63±4.86	82.29±4.55	0.026
SCALE	6.80±1.42	7.90±1.78	0.418
mFRT (cm)	23.95±1.77	25.70±1.86	0.437
TIS	26.80±3.83	35.90±4.48	0.019
MAS right gastrocnemius	2.5 (0-4)	2.5 (0-4)	0.655
MAS left gastrocnemius	2.5 (1-3)	2.5 (2-4)	0.180
MAS right hamstring	1 (0-3)	2 (0-2)	1.000
MAS left hamstring	1.5 (0-3)	1.5 (0-3)	0.739
Group 2	**Before intervention**	**After intervention**	**p-value**
GMFM-T	26.32±5.75	33.38±6.85	0.020
SCALE	3.20±0.90	5.30±1.46	0.012
mFRT (cm)	10.40±2.40	12.30±2.54	0.094
TIS	5.90±1.74	7.70±2.12	0.105
MAS right gastrocnemius	3 (1-4)	2.5 (1-4)	0.068
MAS left gastrocnemius	2.5 (0-4)	2 (0-4)	0.414
MAS right hamstring	3 (1-4)	2.5 (1-4)	0.102
MAS left hamstring	2 (0-4)	2 (0-4)	0.705

Paired samples T test and Wilcoxon rank test were used (p<0.05). GMFM-T: Gross motor function total score, SCALE: Selective control assessment of lower extremity, mFRT: Modified functional reach test, TIS: Trunk Impairment Scale, MAS: Modified Ashworth Scale

Between-group comparisons revealed no significant differences in the changes for GMFM-T, SCALE, or mFRT (p>0.05). However, the improvement in TIS scores was significantly greater in the ambulatory group compared to the non-ambulatory group (p=0.040). Between-group comparisons are shown in Table 3.

Table 3. Comparison of differences between groups

	Group 1 (ambulatory)	Group 2 (non-ambulatory)	p-value
GMFM-T	4.65±1.74	7.06±2.51	0.443
SCALE	1.10±1.29	2.10±0.67	0.505
mFRT	1.75±2.15	1.90±1.01	0.950
TIS	9.10±3.19	1.80±0.99	0.040

Independent sample T test was used (p<0.05). GMFM-T: Gross motor function total score, SCALE: Selective control assessment of lower extremity, mFRT: Modified functional reach test, TIS: Trunk Impairment Scale

DISCUSSION

This study represents the first investigation into the effects of the MSM on gross motor function, muscle tone, postural control, and lower extremity selective motor control in both ambulatory and non-ambulatory children with CP. No adverse effects or negative feedback were encountered during the evaluations and intervention. Our findings demonstrate that a six-week intervention with MSM led to significant improvements in gross motor function and trunk control among ambulatory children with CP, as well as enhanced lower extremity selective motor control in their non-ambulatory children. Based on these results, we suggest that incorporating a six-week MSM protocol into standard rehabilitation programs may effectively enhance motor function in children with CP regardless of ambulatory status. Furthermore, while six weeks of MSM appeared sufficient to promote trunk control development in ambulatory children, this duration may be inadequate for similar improvements in non-ambulatory children. Consequently, we recommend future research to explore the effects of prolonged MSM interventions on trunk control in non-ambulatory children with CP.

A significant improvement in gross motor function scores was observed in both groups following the application of the MSM for one hour, three times per week, over a six-week period. These findings align with previous research demonstrating positive outcomes with MSM applied thrice weekly for three weeks in children with spastic CP.[32] Similarly, Flodström et al.[18] reported increased GMFM scores in six children with CP who received MSM combined with activity for one hour every other day over a three-month period. Impaired sensory processing and integration are known contributors to motor dysfunction in CP.[33] TENS has been shown to preferentially activate large sensory fibers, primarily within the A-beta range, through cutaneous muscle stimulation, thereby enhancing sensorimotor cortex excitability.[34] This mechanism reduces deficits in somatosensory feedback, which may otherwise constrain motor performance.[34,35] Consequently, TENS normalizes sensory input by providing peripheral sensory stimulation, positively influencing sensorimotor integration and subsequently improving motor control and coordination.[36] Additionally, TENS may directly enhance muscle activity by stimulating motor nerves within targeted muscle groups via electrical currents,[37] thereby contributing to improved motor function.

Spasticity

Spasticity associated with CP is characterized by an increase in velocity-dependent tonic reflexes resulting from sensorimotor dysfunction caused by upper motor neuron lesions.[38] Previous studies investigating the effects of the MSM on spasticity have yielded inconsistent results. For instance, MSM applied three to four times weekly for four weeks in children with CP aged 4 to 17 years (GMFCS levels 1-4) demonstrated no significant changes in spasticity.[14] Similarly, Pennati et al.[13] reported no significant alteration in MAS scores following a single MSM session. Furthermore, a six-week MSM intervention involving 15 stroke patients and 12 children with CP also failed to elicit significant changes in spasticity measurements.[39] Consistent with these findings, the present study observed no statistically significant reduction in spasticity after administering MSM thrice weekly for six weeks in both ambulatory and non-ambulatory children with CP.

Despite the widespread use of TENS for spasticity management, the literature highlights a lack of consensus regarding optimal stimulation parameters necessary to effectively reduce spasticity.[38,40] In our study, assessments were conducted approximately 48 hours post-intervention, which may have limited detection of TENS's short-term effects on spasticity regulation. Given the absence of standardized timing for post-treatment evaluations, future research should focus on identifying optimal assessment intervals and include multiple evaluation points following successive treatment sessions.

Although our findings did not indicate significant changes in spasticity measured by MAS, it is important to note that MAS scores can reflect increased resistance due to changes in the elastic properties of muscle rather than purely neural contributions.[41] Clinically, spasticity treatment is recommended as part of a multidisciplinary approach targeting functional goals at the activity and participation levels.[42,43] While no significant reduction in resting spasticity was observed after a single MSM session in this study, repeated sessions over six weeks coincided with a notable decrease in spasticity during daily activities in approximately 60% of participants. These observations align with systematic review evidence supporting the efficacy of TENS applied during activity for spasticity management.[44] Therefore, the cumulative effect of repeated MSM sessions combined with active engagement may be critical to achieving meaningful reductions in spasticity, which may explain the absence of immediate effects following isolated treatments at rest.

Postural Control

Performance on the mFRT is closely associated with an individual's ability to effectively displace the center of gravity forward, as those with impaired balance or fear of falling often limit such displacement.[45] One of the primary postural deficits observed in children with CP is the inability to coordinate timely and sequential activation of postural muscles, particularly during functional activities.[46] Trunk control, including the capacity to execute selective trunk movements, is a critical component for maintaining postural stability and generating appropriate balance reactions.[47] However, spasticity and muscle weakness commonly seen in children with CP may contribute to diminished motor abilities, which typically require time and targeted interventions to improve.[48]

Although this study is the first to investigate the effects of wearable TENS on postural control, existing literature suggests that TENS combined with therapeutic exercise over extended durations positively influences postural stability.[49]

The present intervention, limited to six weeks with thrice-weekly sessions and without concurrent exercise during treatment, may have been insufficient to elicit measurable improvements in postural control. Therefore, future research should explore longer-duration MSM protocols, include multiple assessment time points, and examine the synergistic effects of MSM combined with exercise interventions to better determine its efficacy in enhancing postural control in children with CP.

In the literature, TENS has often been applied concurrently during the evaluation of postural control. It is suggested that this temporal synchronization may produce cumulative effects by integrating with other sensory inputs, thereby facilitating improvements in postural control.[50,51] In contrast, in our study, post-intervention assessments were conducted after the removal of the Mollii Suit, meaning that the children with CP were deprived of both electrical stimulation and the proprioceptive feedback provided by the garment. This methodological difference may partly explain the discrepancy between our findings and the positive effects of TENS on postural control reported elsewhere.

A meta-analysis of seven randomized controlled trials demonstrates that TENS significantly reduces spasticity and enhances static balance and gait velocity, but does not yield significant improvements in dynamic balance.[52] The postural control assessments employed in our study predominantly measure dynamic balance components, aligning with the meta-analysis results. Furthermore, it is plausible that the effects of TENS dissipate immediately after cessation of stimulation, limiting efficacy to the duration of application. Participant characteristics and the specific stimulation parameters utilized may also influence the impact of TENS on postural control outcomes.

Selective Motor Control

This is defined by the National Institutes of Health Taskforce on Childhood Motor Disorders as the ability to isolate muscle activation in a specific pattern in response to voluntary movement or postural demands.[53] Although the precise etiology of impaired selective motor control remains unclear, it is established that voluntary movements are primarily mediated by the corticospinal tracts.[54] Impairment in selective motor control detrimentally affects motor function in children with CP more profoundly than in other neurological conditions.[55,56]

The underlying mechanisms contributing to the loss of selective motor control are complex and multifactorial. Proposed theories include the release of primitive flexor and extensor movement patterns originating from brainstem regions due to the absence of normal inhibitory control. Alternatively, selective motor control deficits may arise from a loss of descending inhibition of synergistic muscles or a failure of descending excitation to synergists to activate inhibitory spinal interneurons effectively.[57] These varying pathophysiological mechanisms may differentially impact the manifestation and severity of selective motor control impairments.

In the present study, selective motor control of the lower extremities showed significant improvement in the non-ambulatory group, whereas no notable change was observed in the ambulatory group. It is postulated that reductions in spasticity may contribute to enhancements in gross motor function and selective muscle control.[32] Although the decrease in spasticity observed in the non-ambulatory group was not statistically significant, this trend may have facilitated improvements in motor selectivity. Furthermore, previous research suggests that children with more severe impairments tend to exhibit greater gains following intervention,[56] which could explain the more pronounced improvement in lower extremity selective motor control observed in children with CP classified at GMFCS levels IV and V.

Gross motor function is considered a critical determinant of selective motor control,[55] and the loss of selective motor control has been proposed to more substantially hinder progress in gross motor capabilities.[55] Consistent with this, our findings demonstrated greater improvements in gross motor function within the non-ambulatory group compared to their ambulatory children, potentially accounting for the more marked development of selective motor control in this subgroup.

Limitations

Nevertheless, the study has limitations. Perspectives of the children and their caregivers regarding this intervention were not evaluated. Notably, the absence of a control group restricts the ability to definitively attribute observed effects to the intervention. Furthermore, the study design may introduce placebo effects, performance bias, and recall bias, which could potentially influence the outcomes. Future research should focus on assessing the efficacy of MSM in combination with targeted rehabilitation interventions aimed at improving activity performance across different clinical subtypes of spasticity. Larger-scale, longitudinal studies with extended follow-up periods are warranted to establish the true efficacy and optimal application parameters of this method.

CONCLUSION

Technology-assisted rehabilitation represents a valuable opportunity to enhance functional outcomes in children with CP. In this study, MSM delivered as a whole-body form of TENS, demonstrated meaningful improvements in motor function, postural control, and selective motor control in both ambulatory and non-ambulatory children with CP. These findings suggest that MSM can be considered a feasible and effective adjunct to conventional physiotherapy, particularly in populations with severe motor impairment who often have limited treatment options. The high adherence and motivation observed among participants and their families further support the practicality of incorporating MSM into clinical rehabilitation programs. Clinicians may therefore integrate MSM into routine practice to complement existing interventions, while future research should focus on optimizing stimulation protocols and confirming long-term benefits.

ETHICAL DECLARATIONS

Ethics Committee Approval

Ethical approval was obtained from the Gazi University Ethics Committee (Date: 13.06.2024, Decision No: 2024-989).

Informed Consent

Informed consent was obtained from all participants and their legal guardians.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Financial Disclosure

The authors declared that this study has received no financial support.

Author Contributions

All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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