

Reference

Weller, L. J. R.¹, Sherwood, S. M.¹, Ng, S. H.¹, Vellaichamy, M.¹, Noordin, A. A.¹, Tan, L. Y.², Mahadev, A.³, Yeo, T. H.⁴, & Ng, Z. M.⁴

Can External Neuromodulation Garments Improve Gait and Function in Children With Cerebral Palsy? A Prospective Single-Arm Study

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Products

EXOPULSE Mollii Suit

Major Findings

- With the EXOPULSE Mollii Suit after 4 weeks of stimulation:
- **Significant improvement in crawling and kneeling ($p=0.03$) according to Domain C of the Gross Motor Function Measure (GMFM-88)**
 - **Significant improvements ($p=0.04$) were also seen in the *usual activity* domain of the EQ-5D-Y**
 - **Significant improvements in the Gait Profile Score (GPS) as demonstrated in the following variables: GPS Overall ($p<0.01$), GPS Right ($p<0.006$) and GPS Left ($p<0.027$):**

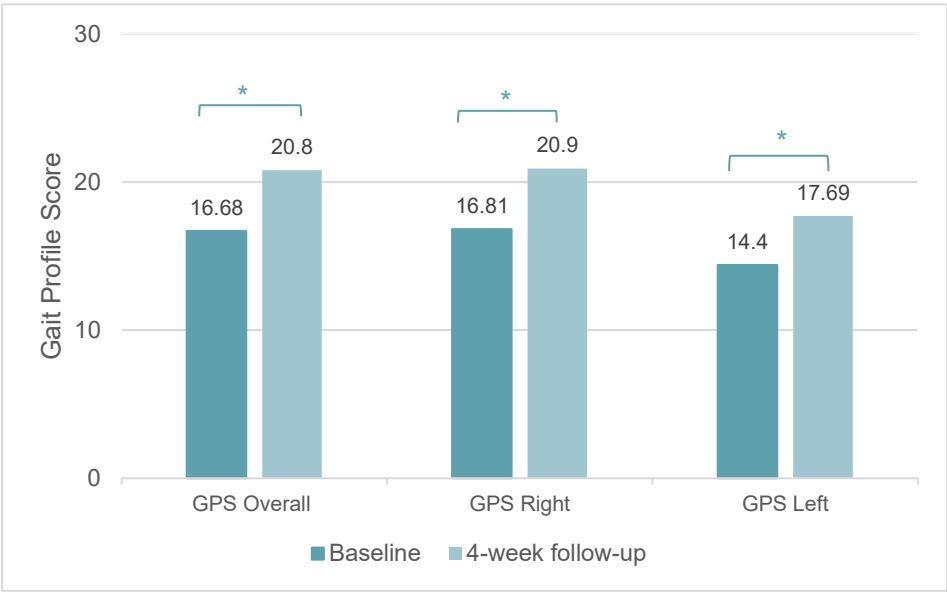


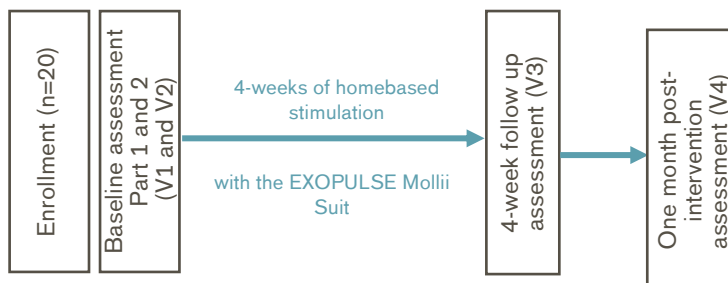
Figure 1. Mean results for the reported GPS variables between baseline and 4 weeks of daily stimulation. * $p<0.05$.

Population

Subjects: n=20 (9 females)
Etiology: Unilateral Spastic CP (n=3)
Bilateral Spastic CP (n=17)
Median age: 7 years (range: 4-16)
2-6 years (preschool) (n=6)
7-16 years (school) (n=14)
GMFCS: I: (n=3)
II: (n=11)
III: (n=6)

Study Design

Prospective single arm study. All participants received daily 60-minute sessions of stimulation during a 4-week intervention period. Clinical assessments were scheduled at baseline, after 4 weeks of homebased stimulation, as well as one month post-intervention:



Results

Body Functions & Structure					Activity			Participation	Environment
Pain	Spasticity	Physiological function	Psychological function	General Health	Activity	Mobility & Safety	ADLs	Preference, Satisfaction, QoL	Health Economics

Category	Outcomes	Results for EXOPULSE Mollii Suit	Sig*
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Spasticity

Tardieu Scale

Muscle	Right lower limb			Left lower limb			0 (except from Right Hamstrings ⁺⁺)
	Pre (difference between R2 ^a and R1 expressed as mean $\pm$ SD)	Post (difference between R2 and R1 expressed as mean $\pm$ SD)	<i>p</i> -value	Pre (difference between R2 and R1 expressed as mean $\pm$ SD)	Post (difference between R2 and R1 expressed as mean $\pm$ SD)	<i>p</i> -value	
Gastrocnemius Right (<i>n</i> =15) Left (<i>n</i> =14)	14.73 $\pm$ 7.81	13.53 $\pm$ 6.90	0.54	10.86 $\pm$ 6.26	14.93 $\pm$ 8.32	0.08	
Hamstrings (<i>n</i> =15)	16.17 $\pm$ 8.82	10.55 $\pm$ 9.25	0.03 ⁺⁺	13.28 $\pm$ 10.02	11.39 $\pm$ 11.14	0.43	
Quadriceps (<i>n</i> =18)	31.94 $\pm$ 36.18	45.94 $\pm$ 50.95	0.31	42.28 $\pm$ 44.09	34.72 $\pm$ 42.65	0.53	

^aR1=the angle of muscle reaction; R2=full passive range of motion. Smaller difference between R2 and R1 demonstrates less spasticity.

Category	Outcomes	Results for EXOPULSE Mollii Suit					Sig*
Physiological function	Gait Profile Score (GPS)	Gait parameter	Baseline (±SD)	Post-Intervention (±SD)	95% CI	p-value	
	Gait Deviation Index (GDI)	GPS Overall	16.68 ± 4.31	20.80 ± 9.40	-7.01 to -1.23	< 0.01	++
	Cadence (step/minute)	GPS Right	16.81 ± 4.74	20.90 ± 8.72	-6.82 to -1.36	0.006	++
	Walking speed (m/s)	GPS Left	14.40 ± 4.34	17.69 ± 9.12	-6.16 to -0.42	0.027	++
		GDI Right	65.93 ± 12.79	64.80 ± 14.21	-3.27 to 5.52	0.60	0
		GDI Left	66.59 ± 12.47	62.36 ± 17.0	-0.3 to 8.77	0.07	0
		Cadence Right	102.93 ± 35.55	108.75 ± 33.81	17.60 to 5.97	0.31	0
		Cadence Left	103.44 ± 38.25	107.35 ± 32.19	-16.22 to 8.39	0.51	0
		Walking Speed Right	0.69 ± 0.36	0.73 ± 0.36	-0.12 to 0.03	0.21	0
		Walking Speed Left	0.70 ± 0.36	0.74 ± 0.36	-0.11 to 0.04	0.29	0
Activity	Gross Motor Function Measure (GMFM-88)	Domain C (crawling and kneeling) improved significantly from 88.47% ± 11.42% to 91.73% ± 9.54% (95% CI: 0.44–6.07, $p=0.026$) after 4 weeks, although the results were no longer significant one month post-intervention.					++
		For the remaining domains, the results were not significant.					0
Preference, Satisfaction, QoL	Patient-reported satisfaction	75% of the participants ($n=15$) perceived excellent or good experience and reported that the suit helped in general functional ability. 75% ($n=15$) reported that the suit was difficult to apply. 73.3% ($n=11$) said that the suit was tight or warm to wear in the local climate.					n.a.
	EQ5D-Y	The <i>usual activity</i> domain of the EQ5D-Y ($n=13$) improved significantly from a mean of 1.46 ± 0.52 to 1.15 ± 0.38 (95% CI: 0.02–0.60, $p=0.040$) after 4 weeks of stimulation, although the results were no longer significant one month post-intervention.					++
	EQ5D (parent reported)	Parent-reported EQ5D ($n=19$) did not improve.					0

* no difference (0), positive trend (+), negative trend (–), significant (++/–), not applicable (n.a.)

Author's Conclusion	"The Mollii Suit made positive changes in gait and function in children with spastic CP immediately after the 4 week intervention period. However, further studies are required to determine its broader impact."
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