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

Health Science Reports, 8(3), e70566. DOI: 10.1002/hsr2.70566 Open Access

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):**

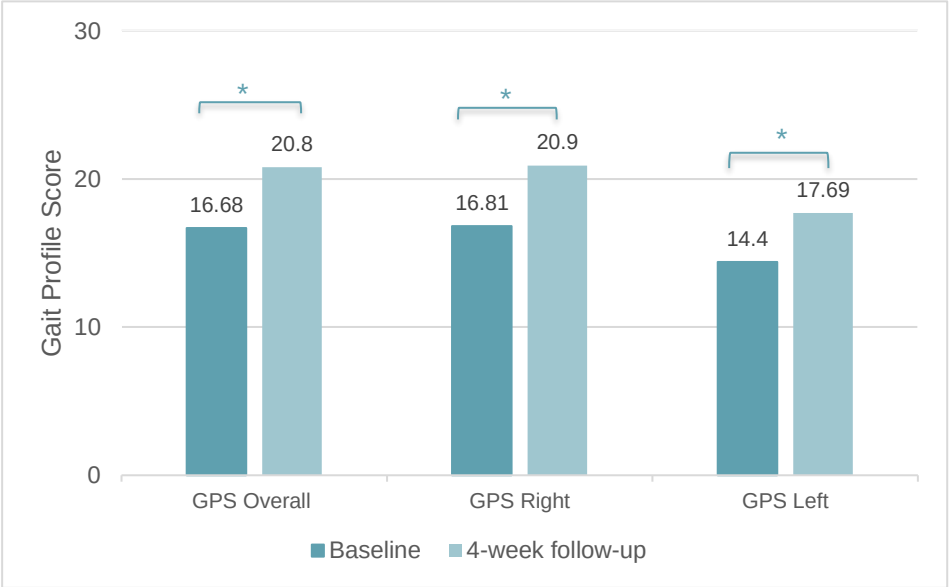


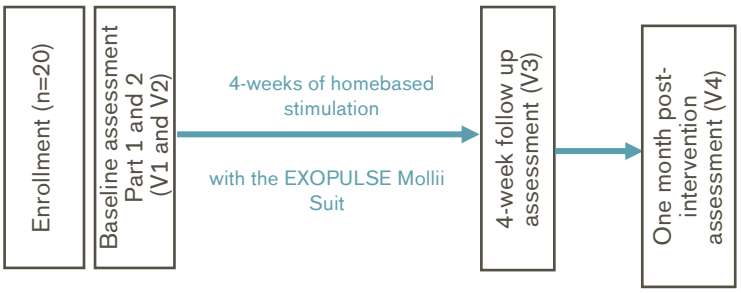
Figure 1. Mean results for the reported GPS variables between baseline and 4 weeks of daily stimulation. *p<0.05.

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***
Spasticity	Tardieu Scale	See table below	0 (except from Right Hamstrings[++])

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

[a]R1=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 Deviation Index (GDI) Cadence (step/minute) Walking speed (m/s)	See table below	
General Health	EQ5D-Y EQ5D (parent reported)	The *usual activity* 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.	++
		Parent-reported EQ5D (n=19) did not improve.	0
Mobility & Safety	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.	n.a.
		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.	

Gait parameter	Baseline (±SD)	Post-Intervention (±SD)	95% CI	*p*-value	Sig*
GPS Overall	16.68 ± 4.31	20.80 ± 9.40	–7.01 to –1.23	< 0.01	++
GPS Right	16.81 ± 4.74	20.90 ± 8.72	–6.82 to –1.36	0.006	++
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

Category	Outcomes	Results for EXOPULSE Mollii Suit	Sig*

* 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."

Author's Affiliation(s)

[1] Physiotherapy Department KKH Women's and Children's Hospital Singapore, Singapore

[2] Division of Nursing KKH Women's and Children's Hospital Singapore, Singapore

[3] Paediatric Orthopaedic Surgery KKH Women's and Children's Hospital Singapore, Singapore.

[4] Neurology Service, Paediatric Medicine KKH Women's and Children's Hospital Singapore, Singapore.