
Reference

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The effect of the EXOPULSE Mollii suit on motor functions in patients with multiple sclerosis – a randomized sham-controlled crossover trial

Multiple Sclerosis Journal – Experimental, Translational and Clinical, 11(2), 20552173251348304. DOI: 10.1177/20552173251348304. [Open Access](#).

Products

EXOPULSE Mollii Suit

Major Findings

With EXOPULSE Mollii Suit after one single 60-min session of active or sham stimulation (Phase 1, RCT; no significant changes for sham condition):

→ Significant improved Balance

- The Berg Balance Scale (BBS) significantly increased by 9.2 points (23.9%) following the active stimulation.
- 68.8% of patients had a BBS score >46 points following the active stimulation, compared to no patient after the sham condition.

→ Significant reduction in spasticity

- A significant reduction in spasticity was observed based on both VAS_{spasticity} (-1.9 points (-34.6%)) and MAS (-2.7 points (-43.9%)) after the active stimulation.

→ A significant Fatigue reduction (-2.0 points / -27.9%) was noted on VAS_{fatigue} following the active stimulation.

→ Improvements in Global Clinical Impression (CGI)

- The active stimulation resulted in a significantly higher frequency of 'much improved' (31.3% vs. 9.4%) and a lower frequency of 'no change' (18.8% vs. 3.8%) compared to the sham condition.

With EXOPULSE Mollii Suit after 4 weeks usage compared to baseline (Phase 2, open-label):

→ Sustained, significant improvements after 4 weeks in balance (+22.9%), spasticity (MAS -2.8 points (-45.4%), and VAS_{spasticity} (-1.6 points (-29.8%)), mobility (FES-I -2.5 points (-6.6%) and MSWS-12 -12.5 points (-17.2%)) and quality of life (MusQoL index score and subscores for activities of daily living, coping and rejection).

→ Reduced Fall Risk

- 60.0% of patients achieved a BBS score >46 following the active stimulation.

→ According to CGI, 80.0% of patients reported improvement after phase 2 (mild in 63.3% and much in 16.7%).

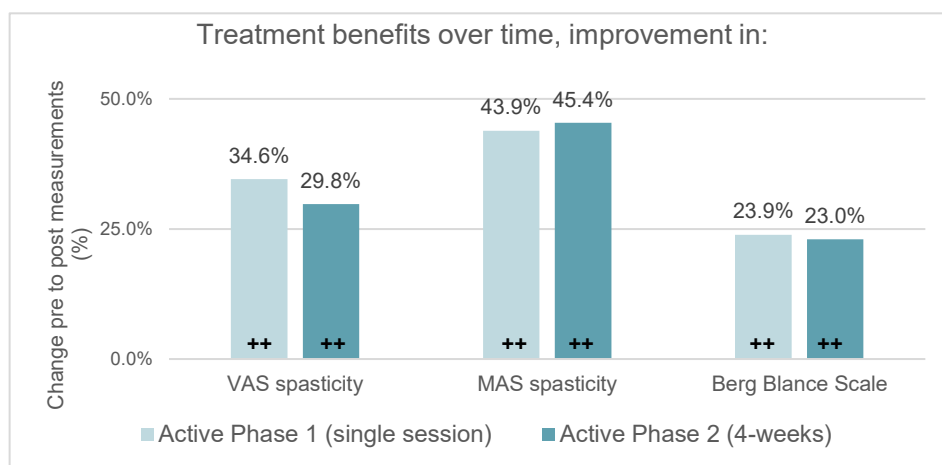


Figure: Progress of study outcomes (selection) within the active condition.
++ = significant change.

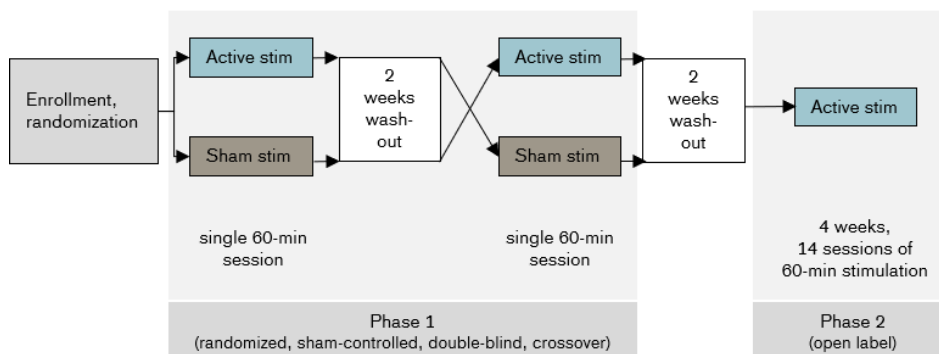
Tolerance:

→ **All the stimulation sessions were well tolerated, and no serious adverse events were reported at any time.**

Population	Subjects:	Phase 1: n = 32 (16 females; all adults) Phase 2: n = 30
	Mean age:	47.81 ± 10.07 years
	Disease:	Multiple Sclerosis (MS)
	Disease type:	n=16 relapsing-remitting, n=8 primary progressive, and n=8 secondary progressive MS
	Mean disease duration:	11.84 ± 9.36 years
	Mean EDSS score:	4.28 ± 1.79
	Comorbidities:	Fatigue (n=15), pain (n=7) [these patients included in the analysis of pain and fatigue]
	Medication:	Dimethyl fumarate (n=2), fingolimod (n=1), natalizumab (n=5), ocrelizumab (n=11), rituximab (n=3), and teriflunomide (n=2).
	Other treatments:	Baclofen (n=8), fampridine (n=10), high-dose biotin (n=1), clonazepam (n=3), dantrolene (n=1), pregabalin (n=3), gabapentin (n=1), amantadine (n=2), vitamins D/B12 (n=12), iron (n=1), alpha-blockers (n=4) and antimuscarinics for urinary symptoms (n=6), statins (n=2), and antihypertensives (n=3)
	Conservative treatments:	Physical therapy (n=19), exercise (n=7), yoga (n=1), and sophrology (n=1)

Study Design

Interventional, randomized, sham-controlled, double-blinded, crossover study (Phase 1); Interventional open-label (Phase 2):



Phase 1: Measurements were performed before (pre-stim) and after (post-stim) each single session of active or sham stimulation.

Phase 2: Measurements were performed before (pre-stim) and after (post-stim) the 4-week active intervention period.

Sham stimulation: the device delivered electric current for 1 minute only and then switched off automatically.

Statistical analysis: Because the quantitative data did not follow a normal distribution (Shapiro-Wilk test), comparisons for Phase 1 were made using Friedman's tests followed by Bonferroni-adjusted post-hoc Dunn's tests. Wilcoxon signed-rank tests were used for Phase 2.

Results

Body Function & 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 pre-stim vs. post-stim (expressed as means ± SD [range])				Sig.*
Pain	Visual Analog Scale (VAS _{pain}) [10 cm] Phase 1: <i>n</i> = 7 Phase 2: <i>n</i> = 6	Phase	stim	pre	post	Sig.
		1	active	5.56 ± 1.03 [4.61 – 6.51]	4.20 ± 2.49 [1.89 – 6.51]	++
		1	sham	6.77 ± 1.45 [5.43 – 8.11]	5.06 ± 2.29 [2.94 – 7.17]	0
		2	active	5.26 ± 2.46 [2.98 – 7.53]	6.62 ± 1.78 [4.75 – 8.49]	0
Spasticity	Modified Ashworth Scale (MAS)	Phase	stim	pre	post	Sig.
		1	active	6.13 ± 5.38 [4.19 – 8.06]	3.44 ± 3.90 [2.03 – 4.84]	++

Category	Outcomes	Results for pre-stim vs. post-stim (expressed as means ± SD [range])					Sig.*	
		1	sham	6.16 ± 5.39 [4.21 – 8.10]	6.16 ± 5.39 [4.21 – 8.10]		0	
		2	active	6.17 ± 5.48 [4.12 – 8.21]	3.37 ± 4.88 [1.54 – 5.19]		++	
	Visual Analog Scale (VAS _{spasticity}) [10 cm]	Phase	stim	pre	post		Sig.	
		1	active	5.49 ± 2.12 [4.72 – 6.25]	3.59 ± 1.87 [2.92 – 4.27]		++	
		1	sham	6.12 ± 2.17 [5.34 – 6.90]	5.45 ± 2.40 [4.59 – 6.32]		0	
		2	active	5.44 ± 2.47 [4.53 – 6.34]	3.82 ± 2.99 [2.71 – 4.94]		++	
	Psychological function	Fatigue on Visual Analog Scale (VAS _{fatigue}) [10 cm] <i>Phase 1: n = 15</i> <i>Phase 1: n = 14</i>	Phase	stim	pre	post		Sig.
			1	active	7.17 ± 1.55 [6.31 – 8.03]	5.17 ± 2.23 [3.94 – 6.41]		++
1			sham	6.25 ± 1.49 [5.43 – 7.08]	5.47 ± 2.82 [3.91 – 7.03]		0	
2			active	5.41 ± 2.31 [4.08 – 6.75]	5.66 ± 2.56 [4.18 – 7.13]		0	
General Health	Global Clinical Impression (GCI)	Phase 1, after stim	very much improved	much improved	minimally improved	no change	Sig.	
		active	9.38 %	31.25 %	40.63 %	18.75 %	++	
		sham	0.00 %	9.38 %	46.88 %	43.75 %	0	
Mobility & Safety	Berg Balance Scale (BBS)	Phase	stim	pre	post		Sig.	
		1	active	38.25 ± 7.68 [35.48 – 41.02]	47.41 ± 7.09 [44.85– 49.96]		++	
		1	sham	37.56 ± 8.09 [34.65 – 40.48]	37.56 ± 8.09 [34.65 – 40.48]		0	
		2	active	37.71 ± 7.28 [35.04 – 40.38]	46.37 ± 9.01 [43.00 – 49.73]		++	
	Timed Up and Go Test (TUG)	Phase	stim	pre	post		Sig.	
		1	active	15.55 ± 9.93 [11.97 – 19.13]	15.33 ± 10.90 [11.40 – 19.26]		++	
		1	sham	16.88 ± 11.13 [12.87 – 20.90]	16.08 ± 11.70 [11.86 – 20.30]		0	
		2	active	15.49 ± 9.24 [12.10 – 18.88]	15.46 ± 10.93 [11.38 – 19.55]		0	
	Falls Efficacy Scale-International (FES-I)	Phase	stim	pre	post		Sig.	
		2	active	37.06 ± 10.17 [33.33 – 40.80]	34.60 ± 9.17 [31.17 – 38.03]		++	

Category	Outcomes	Results for pre-stim vs. post-stim (expressed as means ± SD [range])				Sig.*
	12-item Multiple Sclerosis Walking Scale (MSWS-12)	Phase	stim	pre	post	Sig.
		2	active	72.85 ± 21.15 [64.82 – 80.88]	60.35 ± 24.14 [51.33 – 69.36]	++
Preference, Satisfaction, Quality of Life	MS International Quality of Life Questionnaire (MusiQoL)	Phase 2, after active stim		pre	post	Sig.
		index		62.63 ± 16.32 [56.54 – 68.73]	67.63 ± 14.93 [62.06 – 73.20]	++
		activities of daily living		33.75 ± 19.74 [26.38 – 41.12]	45.84 ± 22.63 [37.39 – 54.29]	++
		psychological well-being		68.96 ± 23.30 [60.26 – 77.66]	72.29 ± 28.56 [61.63 – 82.95]	0
		symptoms		60.83 ± 22.68 [52.36 – 69.30]	66.25 ± 22.68 [57.06 – 75.44]	+
		relationships with friends		62.50 ± 31.39 [50.78 – 74.22]	51.11 ± 35.94 [37.69 – 64.53]	0
		relationships with family		79.45 ± 25.31 [69.99 – 88.90]	77.22 ± 29.52 [66.20 – 88.24]	0
		sentimental and sexual life		61.25 ± 28.31 [50.68 – 71.82]	63.75 ± 33.69 [51.17 – 76.33]	0
		coping		60.42 ± 29.56 [49.38 – 71.45]	77.50 ± 23.53 [68.71 – 86.29]	++
		rejection		70.42 ± 32.74 [58.19 – 82.64]	82.50 ± 26.38 [72.65 – 92.35]	++
		relationships with healthcare system		66.11 ± 30.71 [54.64 – 77.58]	72.22 ± 27.71 [61.87 – 82.57]	0

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

* significance set at p<0.05; trends set at 0.1>p>0.05

Bolded values represent significant p-values (<0.05) for Friedman's test, Chi2 test and post-hoc tests.

Note Phase 1: Some of Friedman's test p values were significant, but post-hoc analysis did not reveal significant differences between pre- and post-active intervention.

Author's Conclusion

"The present results suggest beneficial effects of EXOPULSE Mollii on balance, mobility, spasticity, fatigue and quality of life in PwMS, with further clinical benefits observed when stimulation sessions were repeated. The findings of this intervention appear promising in addressing the debilitating and challenging motor symptoms experienced by PwMS and the associated altered quality of life."

(Ayache et al., 2025)

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