Reference

Ayache, Samar S.[1,2,3,4]; Mattar, Joseph G.[1,2]; Créange, Alain[2,5]; Abdellaoui, Mohamed[5]; Zedet, Mickael[5]; Lefaucheur, Jean-Pascal[2,4]; Megherbi, Hana[6]; Khaled, Hayfa[6]; Lahoud, Georges Naïm Abi[1,7]; Chalah, Moussa A.[1,2,3,8]

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 poins (-6.6%) and MSWS-12 -12.5 points (-17.2%)) and **quality of life** (MusiQoL 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%).

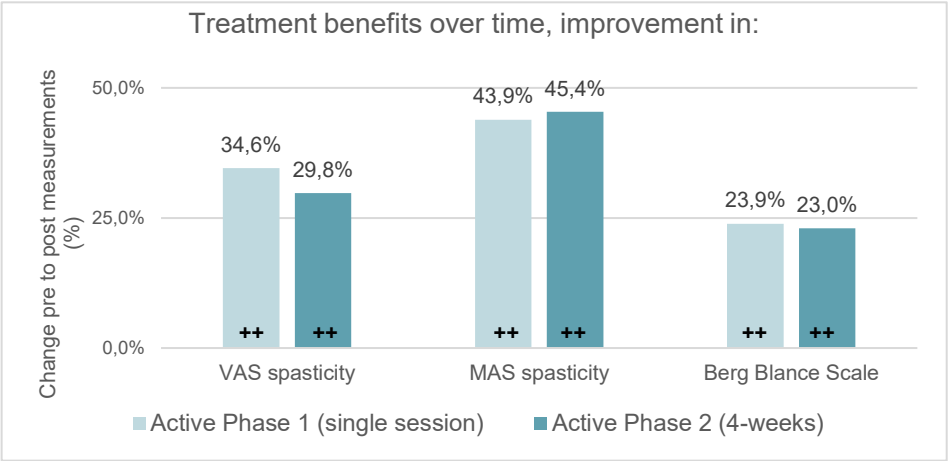


***Figure**: Progress of study outcomes (selection) within the active condition. ++ = significant change.*

Tolerance:

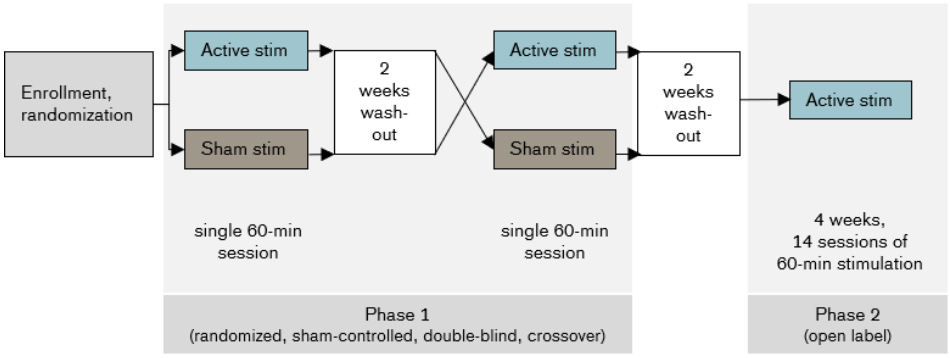
→ **All the stimulation sessions were well tolerated, and no serious adverse events were reported at any time.**

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 the 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.***
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]**	++
		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]*	++

Category	Outcomes	Results for pre-stim vs. post-stim (expressed as means ± SD [range])				Sig.*
	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]*	*++*
Pain	Visual Analog Scale (VAS_{pain}) [10 cm] *Phase 1: n = 7* *Phase 2: n = 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*
Psychological function	Fatigue on Visual Analog Scale ($VAS_{fatigue}$) [10 cm] *Phase 1: n = 15* *Phase 1: n = 14*	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*
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*

Category	Outcomes	Results for pre-stim vs. post-stim (expressed as means ± SD [range])	Sig.*

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]*	*++*

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]*	*++*

Participation, Quality of Life

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

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)

Author's Affiliation

[1] Institut de la Colonne Vertébrale et des Neurosciences (ICVNS), Centre Médico Chirurgical Bizet, Paris, France
[2] Excitabilité Nerveuse et Thérapeutique, Faculté de Santé, Université Paris Est, Créteil, France
[3] Department of Neurology, Gilbert and Rose-Marie Chagoury School of Medicine, Byblos, Lebanon
[4] Service de Physiologie-Explorations Fonctionnelles, DMU FIxIT, Hôpital Henri Mondor, Créteil, France
[5] Service de Neurologie, Hôpital Henri Mondor, Créteil, France
[6] Service de Neurologie, Centre Hospitalier Sud Francilien, Corbeil-Essonnes, France
[7] Department of Neurosurgery, Gilbert and Rose-Marie Chagoury School of Medicine, Byblos, Lebanon
[8] Institut de Neuromodulation, Service Hospitalo-Universitaire, Pôle Hospitalo-Universitaire Psychiatrie Paris 15, GHU Paris Psychiatrie et Neurosciences, Hôpital Sainte-Anne, Paris, France