Reference

Joseph G. Mattar[1,2], Moussa A. Chalah[1,2,3], Naoufel Ouerchefani[4], Marc Sorel[2,5], Johan Le Guilloux[6], Jean-Pascal Lefaucheur[2,7], Georges N. Abi Lahoud[1,8] and Samar S. Ayache[1,2,3]

The effect of the EXOPULSE Mollii Suit on pain and fibromyalgia-related symptoms – A randomized sham-controlled crossover trial

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Products

EXOPULSE Mollii Suit

Major Findings

With EXOPULSE Mollii Suit after 2 weeks of daily usage compared to baseline, active condition (phase 1; no sig. changes for sham condition reported):

- → **PAIN: 14% reduction in VAS pain scale, 17% FIQ pain subscale, 16% in BPI pain interference subscale**
- → **FIBROMYALGIA IMPACT: 18% reduction in total FIQ score, 19% in FIQ physical impairment and 17% in FIQ fatigue subscales**
- → **QUALITY OF LIFE: 47% improvement in SF-36 bodily pain and vitality subscales**
- → **DEPRESSION: 25% decrease in FIQ anxiety score and 13% in HADS anxiety score**
- → **64% improvement in Global Clinical Impression**

With EXOPULSE Mollii Suit after 4 weeks of daily usage compared to baseline, open label phase (phase 2):

- → **PAIN: 25% reduction in VAS & FIQ pain scales, 16% in BPI pain severity and 17% in BPI pain interference subscales**
- → **FIBROMYALGIA IMPACT: reduction in 21% total FIQ score, 20% FIQ fatigue subscale**
- → **QUALITY OF LIFE (SF-36): 20% increase in social functioning, 35% in health change, 54% in vitality, 92% in role emotional and 161% in role physical subscales**
- → **DEPRESSION: 26% reduction in FIQ anxiety, 14% reduction in HADS anxiety and 12% in HADS depression subscales**
- → **79% improvement in Global Clinical Impression**

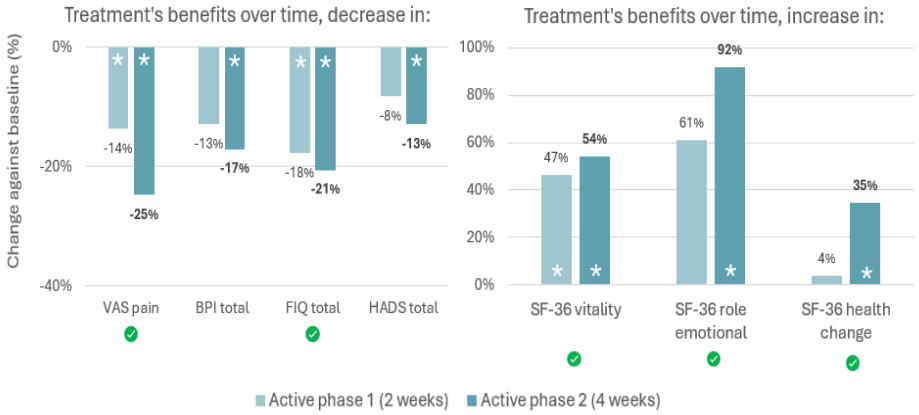

Figure 1. *Progress of study outcomes (selection) within the active condition.*
** = significant (p<0.05) improvement over baseline; green checkmark: above minimal clinically important difference threshold (MCID)*

Population

Subjects:	33 (31 female)
Mean age:	51.33 ± 8.99 years
Disease duration:	8.94 ± 10.74 years
Widespread pain index:	14.15 ± 3.36 points (scale 0-19)
Symptom severity scale:	8.00 ± 2.38 points (scale 0-12)
Comorbidities:	Arterial hypertension (n=8), migraine (8), tension headache (2), diabetes mellitus type 2 (2), thyroid disease (6), asthma (2), polycystic ovary syndrome (2), obstructive sleep apnea (2), glaucoma (1), atopic dermatitis (1), fatty liver disease (1), hepatitis B (1), endometriosis (1)
Medication:	84.85% on treatment: Antiepileptics (n=6), antidepressants (18), anxiolytics (6), opioids analgesics (5), combined opioids and acetaminophen medications (10), anti-inflammatory (9), acetaminophen (13), nefopam (5), baclofen (2), lidocaine transdermal patch (4), cannabinoids (3)
Other therapy:	Physical therapy (n=20), hypnosis (4), physical exercise (4), auriculotherapy (2), yoga/meditation (2), osteopathy (2), acupuncture (1), musical therapy (1)

Study Design

Interventional, randomized, sham-controlled, double blind, cross-over study (Phase 1); interventional open-label (Phase 2):

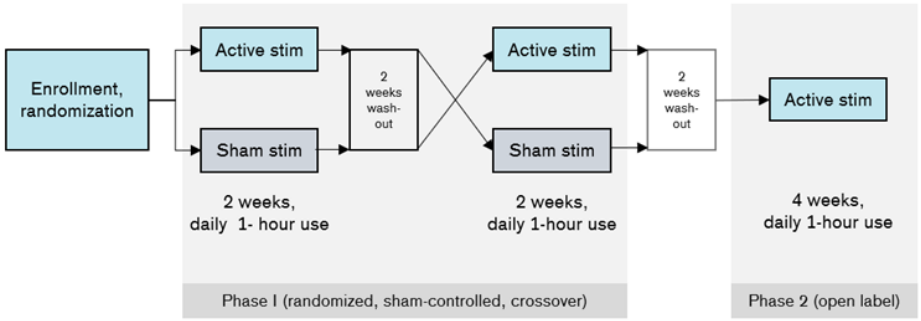

Figure 2. *Study design*

Baseline measurements were performed at the beginning of each phase (pre-stimulation); post-stimulation measurements were performed at 2 (end of phase 1) and 4 weeks (end of phase 2).
Sham stimulation: the device delivered electric current for 1 minute only and then switched off automatically.

Statistical analysis for data: Friedman's test with post-hoc Dunn's and Bonferroni p-value adjustment, Kendall's W for effect size (phase 1); Wilcoxon signed-rank test and $Z/\sqrt{N}$ for effect size (phase 2).

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 Mollii Suit (mean ± SD)	Sig.*
Pain	Visual Analoge Scale (**VAS**) - pain	**Phase 1**	
		Active pre→post score: 6.85 ± 1.36 → 5.91 ± 1.83 (**13.7%,** W=0.11)	++
		Sham pre→post score: 6.80 ± 1.44 → 6.63 ± 1.45 (2.5%)	0
		*First session results (Phase 1 only):	
		Active pre→post score: 6.59 ± 2.13 → 4.91 ± 2.33 (**25.5%** W=0.16)	++
		Sham pre→post score: 6.47 ± 1.77 → 6.47 ± 2.06 (0%)	0
		Phase 2	
		Active pre→post score: 6.73 ± 1.72 → 5.06 ± 2.35 **(24.8%** Z/√N =0.54**)**	++
	Brief Pain Inventory (**BPI**) total	**Phase 1**	
		Active pre→post score: 5.97 ± 1.57 → 5.20 ± 1.99 (**12.9%** W=0.05)	0
		Sham pre→post score: 5.72 ± 1.46 → 5.34 ± 1.83 (6.6%)	0
		Phase 2	
		Active pre→post score: 5.78 ± 1.98 → 4.79 ± 2.15 (**17.1%** Z/√N =0.36)	++
	BPI pain severity	**Phase 1**	
		Active pre→post score: 5.84 ± 1.54 → 5.33 ± 1.94 (**8.7%** W=0.03)	0
		Sham pre→post score: 5.91 ± 1.17 → 5.75 ± 1.61 (2.7%)	0
		Phase 2	
		Active pre→post score: 5.84 ± 1.84 → 4.88 ± 2.27 (**16.4%** Z/√N =0.31)	++
	BPI pain interference	**Phase 1**	
		Active pre→post score: 6.11 ± 1.83 → 5.12 ± 2.38 (**16.2%** W=0.13)	++**
		Sham pre→post score: 5.58 ± 2.05 → 5.75 ± 1.61 (3.0%)	0
		Phase 2	
		Active pre→post score: 5.74 ± 2.31 → 4.74 ± 2.36 (**17.4%** Z/√N =0.38)	++
	Fibromyalgia Impact Questionnaire (**FIQ**) - pain	**Phase 1**	
		Active pre→post score: 7.46 ± 1.82 → 6.18 ± 2.42 (**17.2%** W=0.09)	++
		Sham pre→post score: 7.30 ± 1.86 → 6.61 ± 1.92 (9.4%)	0
		Phase 2	
		Active pre→post score: 6.87 ± 2.17 → 5.15 ± 2.55 (**25.0%** Z/√N =0.46)	++
	Pain Catastrophizing Scale (**PCS**) total	**Phase 1**	
		Active pre→post score: 29.61 ± 12.56 → 23.82 ± 13.69 (**19.6%** W=0.05)	0
		Sham pre→post score: 29.72 ± 11.58 → 27.06 ± 12.90 (8.95%)	0
		Phase 2	
		Active pre→post score: 24.67 ± 14.98 → 20.36 ± 14.02 (**17.5%** Z/√N=0.35)	++
	PCS rumination	**Phase 1**	
		Active pre→post score: 10.09 ± 4.52 → 8.24 ± 4.64 (**18.3%** W=0.02)	0
		Sham pre→post score: 10.12 ± 4.00 → 9.12 ± 4.86 (9.9%)	0
		Phase 2	
		Active pre→post score: 8.27 ± 5.17 → 6.85 ± 4.66 (**17.2%** Z/√N =0.32)	++
	PCS magnification	**Phase 1**	
		Active pre→post score: 5.18 ± 3.14 → 4.55 ± 3.34 (**12.2%** W=0.02)	0
		Sham pre→post score: 5.52 ± 3.39 → 4.94 ± 3.40 (10.5%)	0
		Phase 2	
		Active pre→post score: 4.91 ± 3.68 → 3.67 ± 3.28 (**25.3%** Z/√N =0.35)	++

Category	Outcomes	Results for Mollii Suit (mean ± SD)	Sig.*
	PCS	**Phase 1**	
	helplessness	Active pre→post score: 14.33 ± 6.15 → 11.03 ± 6.67 (**23.0%** W=0.08)	0
		Sham pre→post score: 14.09 ± 5.72 → 13.00 ± 5.92 (7.7%)	0
		Phase 2	
		Active pre→post score: 11.48 ± 7.07 → 9.85 ± 6.89 (**14.2%** Z/√N =0.25)	**++**
Physiological Function	**VAS**	**Phase 1**	
	fatigue	Active pre→post score: 6.87 ± 1.89 → 6.50 ± 1.81 (**5.4%** W=0.06)	0
		Sham pre→post score: 6.89 ± 1.65 → 6.62 ± 1.80 (3.9%)	0
		Phase 2	
		Active pre→post score: 6.87 ± 1.90 → 5.60 ± 2.34 (**18.5%** Z/√N =0.45)	**++**
	FIQ	**Phase 1**	
	physical impairment	Active pre→post score: 5.45 ± 2.03 → 4.39 ± 2.23 (**19.4%** W=0.14)	**++**
		Sham pre→post score: 5.00 ± 1.96 → 5.09 ± 2.55 (1.8%)	0
		Phase 2	
		Active pre→post score: 5.22 ± 2.27 → 4.62 ± 2.22 (**11.5%** Z/√N =0.29)	**++**
	FIQ	**Phase 1**	
	fatigue	Active pre→post score: 7.59 ± 1.98 → 6.33 ± 2.32 (**16.6%** W=0.08)	**++**
		Sham pre→post score: 7.47 ± 2.00 → 6.73 ± 2.26 (9.9%)	0
		Phase 2	
		Active pre→post score: 7.19 ± 2.14 → 5.76 ± 2.46 (**19.9%** Z/√N =0.47)	**++**
	FIQ	**Phase 1**	
	rested	Active pre→post score: 7.12 ± 2.39 → 5.52 ± 2.83 (**22.5%** W=0.17)	**++**
		Sham pre→post score: 7.42 ± 2.27 → 5.85 ± 2.53 (21.1%)	0
		Phase 2	
		Active pre→post score: 6.54 ± 2.54 → 5.36 ± 2.68 (**18.0%** Z/√N =0.38)	**++**
	FIQ	**Phase 1**	
	stiffness	Active pre→post score: 6.60 ± 2.64 → 5.53 ± 2.84 (**16.2%** W=0.10)	**++**
		Sham pre→post score: 6.75 ± 2.70 → 5.93 ± 2.38 (12.2%)	0
		Phase 2	
		Active pre→post score: 6.45 ± 2.55 → 5.27 ± 2.76 (**18.3%** Z/√N =0.38)	**++**
Psychological Function	**FIQ**	**Phase 1**	
	feel good	Active pre→post score: 7.28 ± 3.08 → 6.62 ± 3.15 (**9.1%** W=0.06)	0
		Sham pre→post score: 7.62 ± 2.13 → 6.66 ± 2.64 (12.6%)	0
		Phase 2	
		Active pre→post score: 7.14 ± 2.28 → 5.37 ± 3.29 (**24.8%** Z/√N =0.33)	**++**
	FIQ	**Phase 1**	
	depression	Active pre→post score: 4.68 ± 2.91 → 3.78 ± 2.99 (**19.2%** W=0.04)	0
		Sham pre→post score: 4.40 ± 3.02 → 3.91 ± 2.92 (11.1%)	0
		Phase 2	
		Active pre→post score: 4.31 ± 3.25 → 3.50 ± 3.04 (**18.8%** Z/√N =0.21)	+
	FIQ	**Phase 1**	
	anxiety	Active pre→post score: 5.95 ± 2.66 → 4.48 ± 2.95 (**24.7%** W=0.15)	**++**
		Sham pre→post score: 5.55 ± 2.86 → 4.47 ± 2.60 (19.5%)	0
		Phase 2	
		Active pre→post score: 5.10 ± 2.78 → 3.75 ± 2.84 (**26.5%** Z/√N =0.31)	**++**
	Hospital Anxiety and Depression Scale (**HADS**) depression	**Phase 1**	
		Active pre→post score: 9.76 ± 4.60 → 9.45 ± 5.15 (**3.2%** W=0.03)	0
		Sham pre→post score: 10.36 ± 4.26 → 10.06 ± 4.96 (2.9%)	0
		Phase 2	
		Active pre→post score: 10.09 ± 5.60 → 8.91 ± 5.37 (**11.7%** Z/√N =0.26)	**++**

Category	Outcomes	Results for Mollii Suit (mean ± SD)	Sig.*
	HADS anxiety	**Phase 1** Active pre→post score: 10.73 ± 4.38 → 9.33 ± 4.83 (**13.0%** W=0.07) Sham pre→post score: 10.24 ± 4.17 → 9.42 ± 4.62 (8.0%) **Phase 2** Active pre→post score: 9.94 ± 4.44 → 8.54 ± 4.50 (**14.1%** Z/√N =0.34)	+ 0 **++**
	HADS total	**Phase 1** Active pre→post score: 20.48 ± 7.69 → 18.79 ± 9.00 (**8.2%** W=0.03) Sham pre→post score: 20.61 ± 7.52 → 19.48 ± 8.57 (5.5%) **Phase 2** Active pre→post score: 20.03 ± 9.14 → 17.45 ± 9.20 (**12.9%** Z/√N=0.37)	0 0 **++**
Preference, Satisfaction, Quality of Life	Short form 36 health survey (**SF-36**) bodily pain	**Phase 1** Active pre→post score: 27.27 ± 22.56 → 40.14 ± 25.58 (**47.2%** W=0.23) Sham pre→post score: 23.48 ± 17.45 → 30.30 ± 18.77 (29.0%) **Phase 2** Active pre→post score: 32.35 ± 21.47 → 41.27 ± 22.44 (**27.6%** Z/√N=0.25)	**++** 0 **++**
	SF-36 physical functioning	**Phase 1** Active pre→post score: 39.09 ± 21.23 → 43.48 ± 24.57 (**11.2%** W=0.03) Sham pre→post score: 42.42 ± 19.61 → 42.12 ± 23.25 (0.7%) **Phase 2** Active pre→post score: 41.51 ± 21.60 → 47.73 ± 22.64 (**15.0%** Z/√N=0.28)	0 0 **++**
	SF-36 social functioning	**Phase 1** Active pre→post score: 42.67 ± 24.89 → 49.24 ± 26.87 (**15.4%** W=0.05) Sham pre→post score: 41.29 ± 26.05 → 46.59 ± 28.17 (12.8%) **Phase 2** Active pre→post score: 46.21 ± 28.04 → 55.68 ± 30.47 (**20.5%** Z/√N=0.36)	0 0 **++**
	SF-36 role physical	**Phase 1** Active pre→post score: 29.55 ± 35.61 → 33.33 ± 34.04 (**12.8%** W=0.11) Sham pre→post score: 16.67 ± 29.76 → 18.18 ± 28.83 (9.1%) **Phase 2** Active pre→post score: 17.42 ± 26.13 → 45.45 ± 39.75 (**160.9%** Z/√N=0.46)	0 0 **++**
	SF-36 role emotional	**Phase 1** Active pre→post score: 31.31 ± 39.91 → 50.41 ± 40.98 (**61.0%** W=0.10) Sham pre→post score: 32.32 ± 41.24 → 42.42 ± 41.90 (31.2%) **Phase 2** Active pre→post score: 25.25 ± 38.22 → 48.48 ± 40.05 (**92%** Z/√N=0.31)	0 0 **++**
	SF-36 vitality	**Phase 1** Active pre→post score: 21.52 ± 16.61 → 31.53 ± 32.24 (**46.5%** W=0.14) Sham pre→post score: 21.23 ± 13.38 → 26.41 ± 20.79 (24.4%) **Phase 2** Active pre→post score: 24.85 ± 18.56 → 38.33 ± 23.14 (**54.2%** Z/√N=0.44)	**++** 0 **++**
	SF-36 mental health	**Phase 1** Active pre→post score: 45.39 ± 18.95 → 51.21 ± 22.63 (**12.8%** W=0.04) Sham pre→post score: 44.64 ± 21.77 → 50.97 ± 23.04 (14.2%) **Phase 2** Active pre→post score: 47.34 ± 22.99 → 54.30 ± 23.83 (**14.7%** Z/√N =0.29)	0 0 **++**
	SF-36 general health	**Phase 1** Active pre→post score: 35.38 ± 15.03 → 38.03 ± 20.11 (**7.49%** W=0.06) Sham pre→post score: 31.85 ± 16.33 → 33.73 ± 16.71 (5.9%) **Phase 2** Active pre→post score: 34.73 ± 18.26 → 36.18 ± 19.99 (**4.2%** Z/√N =0.19)	0 0 0

Category	Outcomes	Results for Mollii Suit (mean ± SD)	Sig.*
	SF-36	**Phase 1**	
	health change	Active pre→post score: 38.64 ± 28.01 → 40.15 ± 32.44 (**3.9%** W=0.10)	0
		Sham pre→post score: 31.33 ± 27.50 → 33.33 ± 27.00 (6.4%)	0
		Phase 2	
		Active pre→post score: 37.12 ± 29.40 → 50.00 ± 34.80 (**34.7%** Z/√N =0.38)	**++**
	FIQ	**Phase 1**	
	total	Active pre→post score: 52.11 ± 13.84 → 42.85 ± 17.78 (**17.8%** W=0.20)	**++**
		Sham pre→post score: 51.52 ± 13.15 → 45.26 ± 14.90 (12.2%)	0
		Phase 2	
		Active pre→post score: 48.83 ± 15.05 → 38.78 ± 18.16 (**20.6%** Z/√N=0.48)	**++**

* no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)
** p value after post-hoc Bonferroni correction did not reach significance (p=0.052)
Significance set at $p<0.05$; trends set at $0.1>p>0.05$
Effect sizes classified by the authors as small (<0.3), moderate (>0.3 and <0.5) or large (>0.5).

Author's Conclusion

"In conclusion, we observed the benefit of daily one-hour sessions of EXOPULSE Mollii Suit to alleviate pain and related symptoms, in adult patients with fibromyalgia, after 2 weeks of intervention. This strategy appears promising, in the context of debilitating and difficult-to-manage diseases, such as fibromyalgia. Its potential utility in the management of fibromyalgia symptoms merits further exploration." (Mattar et al. 2024)

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