
Reference

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The effects of EXOPULSE Mollii Suit in patients with fibromyalgia: A double-blind randomized sham-controlled trial (EXOFIB2)

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Products

EXOPULSE Mollii Suit

Major Findings

With EXOPULSE Mollii Suit:

→ **Overall, significantly reduced fibromyalgia disease impact and significantly reduced pain was shown after two weeks of active stimulation (phase 1), which were even further enhanced after 4 weeks of use (phase 2).**

With EXOPULSE Mollii Suit after two weeks usage with daily 60-min session of active or sham stimulation (Phase 1, RCT; no significant changes for sham condition):

→ **Significantly decreased Fibromyalgia disease impact (FIQ) score**

- Significant, clinically relevant decrease in FIQ total score by 24.01% after active treatment (pre-active 66.06 ± 13.46 vs. 50.81 ± 23.22; p = 0.01)

→ **Significantly decreased pain following active stimulation as per Pain Catastrophizing Scale (PCS)**

- PCS Total Score decreased significantly by 32.9% (pre-active 26.77 ± 10.96 vs. post-active 17.64 ± 11.4; p = 0.002)
- PCS subscores (helplessness, rumination and magnification) decreased significantly by up to 33.4 (p < 0.05)

→ **Significant increase in quality of life in one subscale of the Short Form 36 Health Survey (SF-36)**

- SF-36 social functioning score improved significantly by 34.1% (p = 0.003)

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

→ **Significantly decreased Fibromyalgia disease impact (FIQ) score**

- Significant, clinically relevant decrease in FIQ total score by 27.9% after active treatment (pre-active 59.30 ± 14.82 vs. 42.77 ± 27.04; p = 0.004)

→ **Significantly decreased pain**

- Visual Analog scale (VAS) pain score decreased by 45.16% (pre-active 5.58 ± 2.41 vs. post-active 3.06 ± 3.3; p < 0.001)
- Brief Pain Inventory (BPI) Total score as well as the subscore for pain severity decreased significantly (p < 0.05)
- PCS Total score significantly decreased by 22.4% (p = 0.008), PCS helplessness by 24.0% (p = 0.037) and PCS magnification by 30.4% (p = 0.023)

→ **Significant improvements in depression, anxiety and emotional wellbeing**

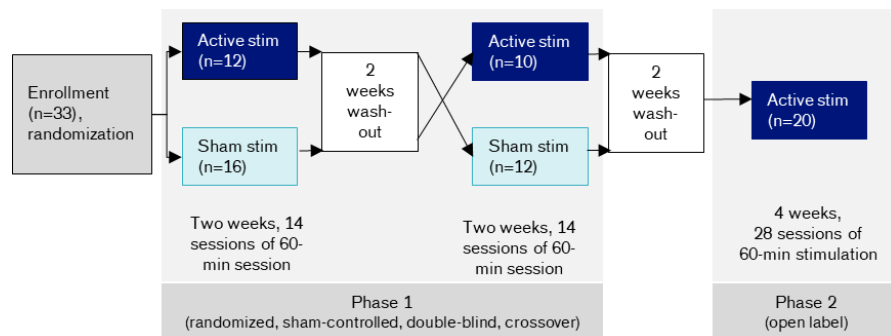
- HADS depression score significantly improved by 30.9% (p = 0.012) and HADS anxiety by 10.8% (p = 0.037)
- SF-36 subscore emotional wellbeing improved by 17.5% (P = 0.014)

→ **Significantly improved quality of life**

- SF-36 subscores improved significantly in 8 out of 9 subscores, including social functioning (p = 0.015), general health (p = 0.004), health change (p = 0.002), role limitation due to physical health (p = 0.007) due to emotional health (p = 0.031), energy/vitality (p = 0.002), emotional wellbeing and pain (p = 0.002)

Population	Subjects:	n = 33 enrolled, n = 22 completed phase 1, n = 20 completed phase 2
	Disease	Fibromyalgia (confirmed per ACR 2010 criteria (American College of Rheumatology))
	Pain level:	Pain intensity ≥4 on Visual Analogue Scale (VAS)
	Gender:	20 females, 2 males
	Mean age:	40.59 ± 10.59 years
	Mean disease duration:	1.64 ± 1.29 years
	Mean BMI:	27.34 ± 4.38 kg/m ²

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



Measurements were performed before first (pre-stim) and after last (post-stim) stimulation after each block (sham and active) in phase 1 and phase 2 - not on every evaluation assessment all outcomes were required. Each block was separated with an at least 2 weeks wash out period.

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 pain (VAS _{pain})	Significant differences for VAS _{pain} only after open-label phase 2				
		Phase	stim	pre	post	
		1	active	6.12 ± 2.45	4.35 ± 3.12	+
		1	sham	6.4 ± 2.4	5.53 ± 2.47	0
2	active	5.58 ± 2.41	3.06 ± 3.30	++		
No difference after sham stimulation in phase 1				0		

Category	Outcomes	Results for pre-stim vs. post-stim (expressed as means ± SD [range])	Sig.*																									
	Visual Analog scale (VAS _{fatigue})	No difference for VAS _{fatigue} after active or sham stimulation in phase 1	0																									
		Significantly reduced VAS _{fatigue} score after 4 weeks of open-label active stimulation (phase 2) – pre-active 5.73 ± 2.37 vs. post-active 3.71 ± 3.25	++																									
	Brief Pain Inventory (BPI)	No difference after sham stimulation in phase 1	0																									
		Significantly decreased BPI _{total} score, pain severity score after 4 weeks of open-label use (phase 2)																										
		<table border="1"> <thead> <tr> <th>phase 2</th> <th>stim</th> <th>pre</th> <th>post</th> <th></th> </tr> </thead> <tbody> <tr> <td>BPI Total score</td> <td>active</td> <td>4.88 ± 3.32</td> <td>3.32 ± 2.70</td> <td>++</td> </tr> <tr> <td>BPI Pain severity</td> <td>active</td> <td>5.44 ± 1.88</td> <td>3.66 ± 2.69</td> <td>++</td> </tr> <tr> <td>BPI Pain interference</td> <td>active</td> <td>4.67 ± 2.54</td> <td>2.98 ± 2.86</td> <td>++</td> </tr> </tbody> </table>	phase 2	stim	pre	post		BPI Total score	active	4.88 ± 3.32	3.32 ± 2.70	++	BPI Pain severity	active	5.44 ± 1.88	3.66 ± 2.69	++	BPI Pain interference	active	4.67 ± 2.54	2.98 ± 2.86	++						
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	Pain Catastrophizing Scale (PCS)	Significantly decreased pain following active stimulation (phase 1) as per PCS for total score and subscores																										
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Physiological function	Clinical global Impression (CGI)	During phase 1 no differences were found between the conditions <ul style="list-style-type: none"> No change from pre- to post- was reported by 54.55% of the patients for active stimulation and by 81.82% for sham stimulation Improvement from pre- to post was reported by 40.91% of patients for active stimulation and by 13.64% for sham stimulation Worsening from pre- to post- was reported by 4.55% of patients for each condition 	0																									
		After 4 weeks of use Exopulse Mollii Suit (phase 2) CGI showed improvement in 75% of patients (25% reported no change and none reported worsening from pre to post).	n.a.																									

Category	Outcomes	Results for pre-stim vs. post-stim (expressed as means ± SD [range])	Sig.*																
	Fibromyalgia Impact Questionnaire (FIQ)	Significantly decreased Fibromyalgia Disease Impact measured by FIQ _{total} score after active stimulation.																	
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		Clinically relevant mean improvement after two weeks of active stimulation (pre-active to post-active in phase 1) was 24% (MCID = 14%).	++																
		Clinically relevant mean improvement after four weeks of active stimulation (pre-active to post-active in phase 2) was 30.96% (MCID = 14%).	++																
Psychological function	Hospital Anxiety and Depression Scale (HADS)	Significant difference in HADS depression and HADS anxiety scores in phase 2 after active stimulation																	
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Preference, Satisfaction, QoL	Short Form 36 Health Survey (SF-36)	After phase 1, only 1 of 9 SF-36 subscales showed significant improvements after active stimulation: <ul style="list-style-type: none"> SF-36 social functioning (pre-active 50.0 ± 21.48 vs. post-active 67.05 ± 26.03) 	++																
		After 4 weeks of active stimulation (phase 2), significant improvements in quality of life were shown in 8 out of 9 subscales: <ul style="list-style-type: none"> SF-36 role limitations due to physical health SF-36 role limitations due to emotional health SF-36 energy/vitality SF-36 emotional well being SF-36 social functioning SF-36 pain SF-36 general health SF-36 health change 	++ ++ ++ ++ ++ ++ ++ ++																
*no difference (0), positive trend (+), negative trend (-), significant (++/--), not applicable (n.a.) Significance is set at p < 0.05 and trends for 0.05 < p < 0.1																			

Author's Conclusion

"The findings of the present study indicate that the utilization of the EXOPULSE Mollii Suit for a duration of 1 h daily over a period of 2 weeks is associated with a reduction in disease impact, pain, and related outcomes in adults diagnosed with fibromyalgia, with additional effects observed following a period of 4 weeks of daily stimulation. This approach holds promise in fibromyalgia, and its potential role in the therapeutic management of this debilitating condition warrants further investigation." (Riachi et al., 2026)

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