Reference

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

Pain Medicine, 2026, **00**, 1–11. doi: 10.1093/pm/pnag010. Open Access

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

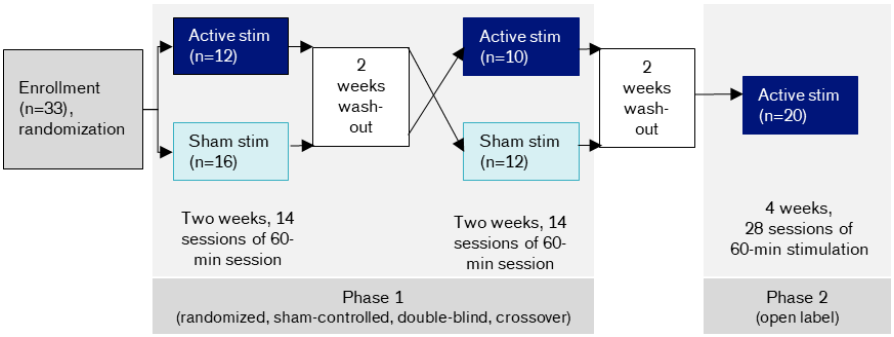
- SF-36 subscores improved significantly in 8 out of 9 subscores, including social functioning (p = 0.015), general health (p = 0.004), health change (p = 0.002), role limitation due to physical health (p = 0.007) due to emotional health (p = 0.031), energy/vitality (p = 0.002), emotional wellbeing and 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/m²

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

<table>
<tr><th>Category</th><th>Outcomes</th><th>Results for pre-stim vs. post-stim
(expressed as means ± SD [range])</th><th>Sig.*</th></tr>
<tr><td></td><td>Visual Analog scale ($VAS_{fatigue}$)</td><td>No difference for $VAS_{fatigue}$ after active or sham stimulation in phase 1</td><td>0</td></tr>
<tr><td></td><td></td><td>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</td><td>++</td></tr>
<tr><td></td><td>Brief Pain Inventory (BPI)</td><td>No difference after sham stimulation in phase 1</td><td>0</td></tr>
<tr><td></td><td></td><td>Significantly decreased BPI_{total} score, pain severity score after 4 weeks of open-label use (phase 2)
<table><tr><th>phase 2</th><th>stim</th><th>pre</th><th>post</th></tr><tr><td>BPI Total score</td><td>active</td><td>4.88 ± 3.32</td><td>3.32 ± 2.70</td></tr><tr><td>BPI Pain severity</td><td>active</td><td>5.44 ± 1.88</td><td>3.66 ± 2.69</td></tr><tr><td>BPI Pain interference</td><td>active</td><td>4.67 ± 2.54</td><td>2.98 ± 2.86</td></tr></table></td><td>++
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<tr><td></td><td>Pain Catastrophizing Scale (PCS)</td><td>Significantly decreased pain following active stimulation (phase 1) as per PCS for total score and subscores
<table><tr><th>phase 1</th><th>stim</th><th>pre</th><th>post</th></tr><tr><td>PCS Total score</td><td>active</td><td>26.27 ± 10.98</td><td>17.64 ± 11.4</td></tr><tr><td>PCS helplessness</td><td>active</td><td>11.82 ± 5.89</td><td>7.36 ± 5.64</td></tr><tr><td>PCS magnification</td><td>active</td><td>5.05 ± 2.89</td><td>3.09 ± 2.52</td></tr><tr><td>PCS rumination</td><td>active</td><td>9.41 ± 3.69</td><td>7.18 ± 4.29</td></tr></table></td><td>++
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<tr><td></td><td></td><td>No difference after sham stimulation in phase 1</td><td>0</td></tr>
<tr><td></td><td></td><td>Significantly decreased PCS_{total} score, helplessness, magnification subscores after 4 weeks of open-label use (phase 2)
<table><tr><th>phase 2</th><th>stim</th><th>pre</th><th>post</th></tr><tr><td>PCS Total score</td><td>active</td><td>19.90 ± 12.75</td><td>15.45 ± 11.73</td></tr><tr><td>PCS helplessness</td><td>active</td><td>8.55 ± 6.41</td><td>6.50 ± 6.12</td></tr><tr><td>PCS magnification</td><td>active</td><td>3.45 ± 2.91</td><td>2.40 ± 2.41</td></tr><tr><td>PCS rumination</td><td>active</td><td>7.90 ± 4.56</td><td>6.55 ± 4.30</td></tr></table></td><td>+
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0</td></tr>
<tr><td>Psychological function</td><td>Hospital Anxiety and Depression Scale (HADs)</td><td>Significant difference in HADS depression and HADS anxiety scores in phase 2 after active stimulation
<table><tr><th>Phase 2</th><th>stim</th><th>pre</th><th>post</th></tr><tr><td>HADs depression</td><td>active</td><td>6.8 ± 4.29</td><td>4.70 ± 4.43</td></tr><tr><td>HADs anxiety</td><td>active</td><td>9.25 ± 2.53</td><td>8.25 ± 2.49</td></tr></table></td><td>++
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<tr><td>General Health</td><td>Clinical global Impression (CGI)</td><td>During phase 1 no differences were found between the conditions
• No change from pre- to post- was reported by 54.55% of the patients for active stimulation and by 81.82% for sham stimulation</td><td>0</td></tr>
</table>

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<tr><th>Category</th><th>Outcomes</th><th>Results for pre-stim vs. post-stim
(expressed as means ± SD [range])</th><th>Sig.*</th></tr>
<tr><td></td><td></td><td>• 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</td><td></td></tr>
<tr><td></td><td></td><td>After 4 weeks of use Exopulse Molllii Suit (phase 2) CGI showed improvement in 75% of patients (25% reported no change and none reported worsening from pre to post).</td><td>n.a.</td></tr>
<tr><td>Preference, Satisfaction, QoL</td><td>Short Form 36 Health Survey (SF-36)</td><td>After phase 1, only 1 of 9 SF-36 subscales showed significant improvements after active stimulation:
• SF-36 social functioning (pre-active 50.0 ± 21.48 vs. post-active 67.05 ± 26.03)</td><td>++</td></tr>
<tr><td></td><td></td><td>After 4 weeks of active stimulation (phase 2), significant improvements in quality of life were shown in 8 out of 9 subscales:
• SF-36 role limitations due to physical health
• SF-36 role limitations dure 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</td><td>
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<tr><td></td><td>Fibromyalgia Impact Questionnaire (FIQ)</td><td>Significantly decreased Fibromyalgia Disease Impact measured by FIQ_{total} score after active stimulation.
<table><tr><th>phase</th><th>stim</th><th>pre</th><th>post</th></tr><tr><td>1</td><td>active</td><td>66.06 ± 13.46</td><td>50.81 ± 23.22</td></tr><tr><td>1</td><td>sham</td><td>63.83 ± 17.61</td><td>62.52 ± 14.38</td></tr><tr><td>2</td><td>active</td><td>59.30 ± 14.82</td><td>42.77 ± 27.04</td></tr></table></td><td>
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0
++</td></tr>
<tr><td></td><td></td><td>Clinically relevant mean improvement after two weeks of active stimulation (pre-active to post-active in phase 1) was 24% (MCID = 14%).</td><td>++</td></tr>
<tr><td></td><td></td><td>Clinically relevant mean improvement after four weeks of active stimulation (pre-active to post-active in phase 2) was 30.96% (MCID = 14%).</td><td>++</td></tr>
</table>

*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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