Reference

Rubio-Zarapuz, Alejandro[1]; Apolo-Arenas, María Dolores[2,3]; Tornero-Aguilera, José Francisco[1]; Parraca, Jose A.[4,5]*; Clemente-Suárez, Vicente Javier[1,6]

Comparative efficacy of neuromodulation and structured exercise program on pain and muscle oxygenation in fibromyalgia patients: a randomized crossover study

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Products

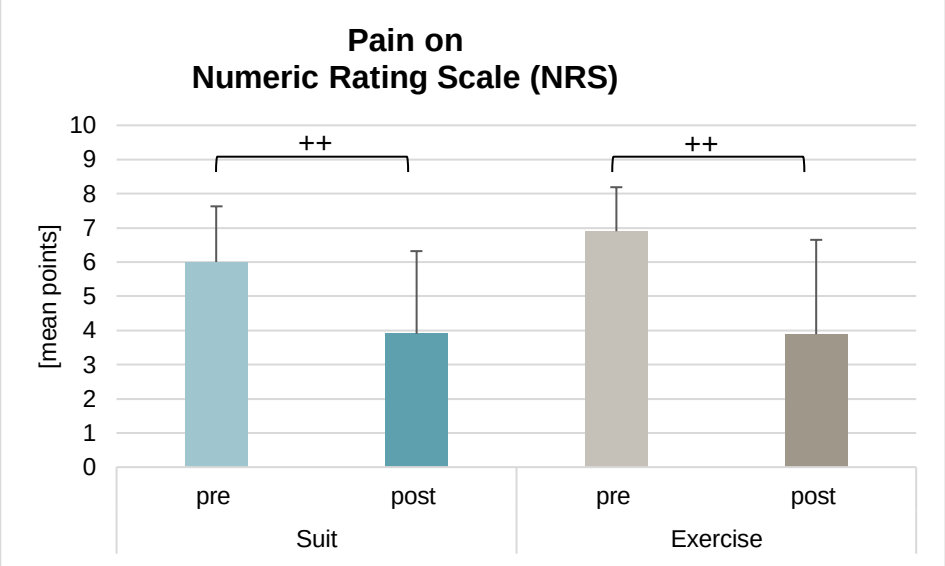
EXOPULSE Mollii Suit vs. Exercise

Major Findings

With EXOPULSE Mollii Suit compared to Exercise after 8 weeks of each intervention:

→ Significant improved subjective Pain Rating with both interventions

- **Suit**: reduced by 2.10 points (-35%)$^{++}$
- **Exercise**: reduced by 3.01 points (-44%)$^{++}$



Pain on NRS ranging from 0= "no pain" to 10= "the worst pain imaginable" before the 1st session (pre), and after the 16th session (post) of intervention. ++ Significant change (p< 0.05).

→ Improved pain tolerance with both interventions

- **Suit**: increase of 0.87 kg (48%)$^{++}$ at the epicondyle and of 0.83 kg (41%) at the knee
- **Exercise**: increase of 0.38 kg (41%) at the epicondyle and of 0.72 kg (30%)$^{++}$ at the knee

→ Significant improvement in all muscle oxygenation variables with interventions

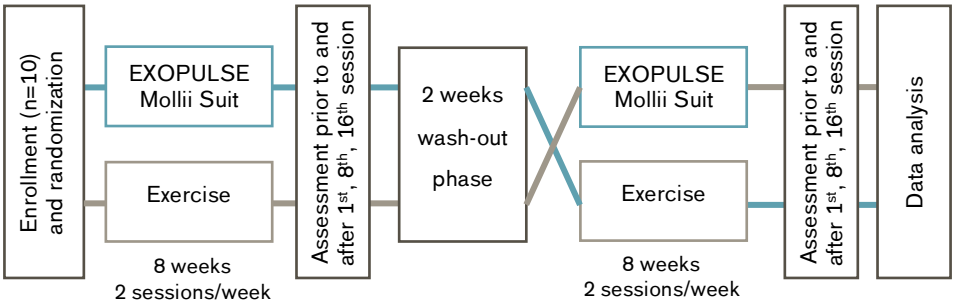
- **Exercise**: exercise program yielded more pronounced basal adaptations in muscle oxygenation

Population

Subjects:	n = 10 (all female)
Etiology:	Fibromyalgia (at least three months); no pharmacological therapies in the past month
Mean age:	51.6 ±7.2 years
Mobility:	Able to walk independently, devoid of reliance on assistive devices

Study Design

Randomized, crossover, longitudinal pilot study:



The intervention phases consisted of 2 sessions per week for 8 weeks with EXOPULSE Mollii Suit or Exercise, respectively.

EXOPULSE Mollii Suit: 60 min session with the Suit with all 58 electrodes active, participants lay on a massage table facing upwards.

Exercise: 60 min training consisting of warm up, strength training, and High-Intensity Interval Training (HIIT).

Results

Body Functions & Structure					Activity			Participation	Environment
Pain	**Spasticity**	**Physiological Function**	**Psychological Function**	**General Health**	**Activity**	**Mobility & Safety**	**ADLs**	**Preference, Satisfaction, QoL**	**Health Economics**

Results Table 1: Results for comparison of both interventions (over all sessions)

Category	Outcomes	Results for comparison of interventions → Suit vs. Exercise	Sig.*
Pain	Numeric Analog Scale (NAS) [0-10 points]	No significant differences between interventions	0
	Pressure Pain Threshold (PPT) [kg]	- *PPT epicondyle*: No significant differences between interventions	0
		- *PPT knee*: No significant differences between interventions	0
General Health - Muscle Oxygen Variables	Muscle oxygen saturation (SmO_2) [%]	Significant differences between interventions. More profound impact with exercise therapy.	--
	Total hemoglobin (THb) [g/dL]	Significant differences between interventions. More profound impact with exercise therapy.	--

Category	Outcomes	Results for comparison of interventions → Suit vs. Exercise	Sig.*
	Deoxygenated hemoglobin (HHb) [g/dL]	Significant differences between interventions. More profound impact with exercise therapy.	--
	Oxygenated hemoglobin (O_2Hb) [g/dL]	Significant differences between interventions. More profound impact with exercise therapy.	--

* no difference (0), positive/negative trend (+/- with p<0.05), significant (**++/−−** with p<0.01), not applicable (n.a.)
* Analysis comparing both treatments for each measurement

Results Table 2: Results for pre- and post-intervention variables for Suit and Exercise intervention

Category	Outcomes	Results for pre-intervention vs. post-intervention *(expressed as means ± SD for quantitative variables)*		Sig.*
Pain	Numeric Analog Scale (NAS) [0-10 points]	**Suit**	Significant change between 1st pre vs. 16th post session	+

session	pre	post	*Sig.*
1st	**6.00 ± 1.63**	4.80 ± 1.69	*+*
8th	6.80 ± 1.99	4.85 ± 1.49	*++*
16th	5.30 ± 2.87	**3.90 ± 2.42**	*+*

		Exercise	Significant change between 1st pre vs. 16th post session	+

session	pre	post	
1st	**6.90 ± 1.29**	5.30 ± 1.77	*+*
8th	6.50 ± 1.65	5.70 ± 1.83	*0*
16th	6.33 ± 2.12	**3.89 ± 2.76**	*+*

	Pressure Pain Threshold (PPT) [kg] - PPT epicondyle	**Suit**	Significant change between 1st pre vs. 16th post session	+

session	pre	post	
1st	**1.80 ± 0.65**	2.17 ± 0.49	*+*
8th	1.86 ± 0.63	2.00 ± 1.02	*0*
16th	1.81 ± 0.94	**2.67 ± 1.98**	*+*

		Exercise	No significant change but enhanced pain tolerance between 1st pre vs. 16th post session	0

session	pre	post	
1st	2.09 ± 0.83	2.34 ± 1.25	*0*
8th	2.21 ± 0.94	2.21 ± 0.86	*0*
16th	2.19 ± 1.03	2.47 ± 0.96	*0*

Category	Outcomes	Results for pre-intervention vs. post-intervention *(expressed as means ± SD for quantitative variables)*		Sig.*
	- PPT knee	**Suit**	No significant change but enhanced pain tolerance between 1st pre vs. 16th post session	0
			session: 1st — pre: 2.01 ± 0.69 — post: 2.47 ± 0.91 — *+* session: 8th — pre: 2.23 ± 1.55 — post: 2.26 ± 0.81 — *0* session: 16th — pre: 2.38 ± 1.44 — post: 2.84 ± 1.38 — *0*	
		Exercise	Significant change between 1st pre vs. 16th post session	**+**
			session: 1st — pre: **2.41 ± 1.31** — post: 2.79 ± 1.26 — *0* session: 8th — pre: 2.06 ± 0.74 — post: 2.28 ± 1.16 — *0* session: 16th — pre: 2.14 ± 1.23 — post: **3.13 ± 1.49** — *+*	
General Health - Muscle Oxygen Variables	Muscle oxygen saturation (SmO_2) [%]	**Suit**	Significant change between 1st pre vs. 16th post session	**++**
			session: 1st — pre: **59.44 ± 14.97** — post: 62.04 ± 16.31 — *++* session: 8th — pre: 55.49 ± 19.76 — post: 57.01 ± 15.59 — *++* session: 16th — pre: 55.27 ± 11.64 — post: **59.56 ± 15.36** — *++*	
		Exercise	Significant change between 1st pre vs. 16th post session	**++**
			session: 1st — pre: **49.59 ± 12.74** — post: 62.22 ± 12.16 — *++* session: 8th — pre: 48.05 ± 16.17 — post: 63.72 ± 14.49 — *++* session: 16th — pre: 65.48 ± 15.06 — post: **69.16 ± 14.05** — *++*	
	Total hemoglobin (THb) [g/dL]	**Suit**	Significant change between 1st pre vs. 16th post session	**++**
			session: 1st — pre: **11.77 ± 0.36** — post: 11.84 ± 0.40 — *++* session: 8th — pre: 11.81 ± 0.38 — post: 11.85 ± 0.33 — *0* session: 16th — pre: 11.89 ± 0.44 — post: **11.78 ± 0.48** — *++*	
		Exercise	Significant change between 1st pre vs. 16th post session	**++**
			session: 1st — pre: **11.84 ± 0.37** — post: 11.69 ± 0.34 — *++* session: 8th — pre: 11.76 ± 0.41 — post: 11.64 ± 0.39 — *++* session: 16th — pre: 11.74 ± 0.41 — post: **11.69 ± 0.43** — *++*	
		Suit	Significant change between 1st pre vs. 16th post session	**++**

Category	Outcomes	Results for pre-intervention vs. post-intervention *(expressed as means ± SD for quantitative variables)*	Sig.*
	Deoxygenated hemoglobin (HHb) [g/dL]		

session	pre	post	
1st	**4.8 ± 1.85**	4.54 ± 2.08	*++*
8th	5.3 ± 2.41	5.12 ± 1.90	*++*
16th	5.35 ± 1.50	**4.81 ± 1.94**	*++*

Exercise	Significant change between 1st pre vs. 16th post session	**++**

session	pre	post	
1st	**5.98 ± 1.54**	4.43 ± 1.48	*+*
8th	6.11 ± 1.87	4.22 ± 1.67	*0*
16th	4.09 ± 1.86	**3.64 ± 1.72**	*0*

	Oxygenated hemoglobin (O_2Hb) [g/dL]		
	Suit	Significant change between 1st pre vs. 16th post session	**++**

session	pre	post	
1st	**6.96 ± 1.66**	7.3 ± 1.80	*++*
8th	6.51 ± 2.20	6.73 ± 1.74	*++*
16th	6.55 ± 1.29	**6.97 ± 1.67**	*++*

Exercise	Significant change between 1st pre vs. 16th post session	**++**

session	pre	post	
1st	**5.86 ± 1.48**	7.25 ± 1.34	*++*
8th	5.65 ± 1.89	7.42 ± 1.68	*++*
16th	7.65 ± 1.63	**8.05 ± 1.48**	*++*

* no difference (0), positive/negative trend (+/- with $p<0.05$), significant (++/−− with $p<0.001$), not applicable (n.a.)
* Analysis comparing all pre- and post-session measurements withing suit or exercise intervention, respectively.
Analysis comparing baseline and post-session measurement for each session and intervention.

Author's Conclusion

"In conclusion, this study demonstrates that both neuromodulation therapy, specifically utilizing the EXOPULSE Mollii Suit, and a structured exercise program are efficacious in modulating pain and enhancing muscle oxygenation in Fibromyalgia patients. Despite the absence of a significant difference in pain modulation efficacy between the two treatments, the exercise intervention exhibits a more profound impact on muscle oxygenation, facilitating long-term basal adaptations. This finding underscores the potential of exercise as a critical component in the holistic management of conditions involving altered muscle oxygenation and pain perception, such as Fibromyalgia. Future studies should consider larger sample sizes to confirm these findings and explore the underlying mechanisms driving the differential effects of exercise and neuromodulation therapy on muscle oxygenation. Additionally, longitudinal studies examining the long-term benefits and potential synergistic effects of combining both treatment modalities could provide valuable insights into optimizing therapeutic strategies for Fibromyalgia management." (Rubio-Zarapuz *et al.*, 2024).

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